Lessons on "pay-for-delay" agreements: the EU Court of Justice ruling in the GSK generics paroxetine case

11 February 2020

In a major judgment handed down on 30 January 2020 in *Generics (UK) and Others*,[i] the EU Court of Justice (the Court) – the EU's highest court – clarified for the first time the analytical framework for assessing when patent settlement agreements that restrict a generic pharmaceutical company's ability to enter the market infringe the EU antitrust rules. While the ruling addresses specific questions raised by a UK court in the context of an individual antitrust case relating to the anti-depressant drug paroxetine, manufactured by GlaxoSmithKline (GSK), the ruling also carries wider significance. The judgment provides detailed guidance that will assist pharmaceutical companies in self-assessing whether any patent settlement agreements they contemplate are in line with EU antitrust rules. It will also serve as an important reference point for other on-going and future cases, including the upcoming judgments in *Lundbeck* and *Servier*.

In 2016, the UK antitrust authority, the Competition and Markets Authority (CMA), imposed a fine of approximately GBP 45 million on an originator company, GSK, and several generic companies for entering into certain patent settlement agreements in relation to paroxetine. At the time of the conclusion of the agreements, GSK held certain patents in relation to paroxetine, namely secondary patents which covered a number of processes for the manufacture of the active ingredient. As part of the agreements, the generic companies agreed to discontinue patent challenges and refrain, for a specific period, from entering the market with their own generic medicines. In return they would receive payments from GSK as well as other rights, such as the right to distribute a limited quantity of generic paroxetine manufactured by GSK. GSK and the generic companies, including Generics (UK), challenged the CMA's decision before the UK Competition Appeal Tribunal (CAT), which referred a number of questions to the Court.

Overall, the ruling confirms that patent settlement agreements that delay a generic company's market entry in return for a payment, or other value transfer from the originator to the generic company, are exposed to high EU antitrust risks under both Article 101 of the Treaty on the Functioning of the European Union (TFEU), which prohibits anticompetitive agreements, and Article 102 TFEU, which prohibits abusive unilateral conduct by dominant firms. While the judgment acknowledges that such agreements are not, by definition, anticompetitive, it makes clear that the scope for a successful defense is very limited where the settlement involves a value transfer from the originator to the generic company that is sufficiently large to act as an incentive to the generic company to refrain from entering the market, and which does not have a proven legitimate objective.

Key takeaways from the judgment

The ruling clarifies that certain patent settlement agreements may be characterized as a restriction by object, i.e. attract EU antitrust liability due to their nature. At the same time, it limits EU antitrust authorities' discretion to treat such agreements as a restriction by object and offers guidance to pharmaceutical companies wishing to steer away from such a classification.

- Originator and generic companies can be regarded as potential competitors for the purposes of application of Article 101 TFEU to settlement agreements, despite the former holding a manufacturing process patent. However, according to the Court, a generic company is only regarded as a potential competitor where it has a firm intention and inherent ability to enter the market and in the absence of insurmountable entry barriers.

- A patent settlement agreement is likely to constitute a restriction by object (i.e. is deemed harmful to competition by its nature) if the net value transferred to the generic company cannot be explained by legitimate objectives and is sufficiently large to incentivize it to stay out of the market. Any proven pro-competitive effects specifically related to the agreement should be taken into account in that assessment, but they must be sufficiently significant for the agreement to escape characterization as a restriction by object.

- If the patent settlement agreement escapes the classification as a restriction by object, it may still amount to a restriction of competition by effect. The existence of anticompetitive effects depends on the counterfactual, which focuses on the realistic possibilities that the generic company would have had to enter the market in the absence of the agreement at issue. The counterfactual does not, however, require any definitive finding on the chances of success of the generic company in patent proceedings or the probability of the conclusion of a less restrictive agreement.

- Where an originator company pursues a strategy that leads it to enter into a set of patent settlement agreements, it may simultaneously infringe (i) Article 101 TFEU, by reason of each agreement taken individually that is found to restrict competition by object or effect; and (ii) Article 102 TFEU, where the originator holds a dominant position and the strategy causes additional harm to the competitive structure of the market. Such additional harm may result from the fact that the strategy has a significant foreclosure effect on the market which deprives consumers of the benefits of the market entry of potential competitors and, therefore, reserves that market to the originator company.

- Patent rights cannot, in and of themselves, shield patent settlement agreements from EU antitrust law. The Court dismissed a number of arguments based on patent rights and patent law principles.

Open Questions Remain

The ruling constitutes a significant EU precedent on the issue of "pay-for-delay" agreements. It sets out some detailed guidance on the criteria to be considered for the antitrust analysis under Articles 101 and 102 TFEU. Pharmaceutical companies should take this analytical framework into account when they contemplate patent settlement agreements. In particular, when entering into patent settlement agreements that restrict the market entry of generic companies and involve a value transfer from originator companies to generic companies, it is advisable to conduct a comprehensive assessment of all types of value transfer, pecuniary and non-pecuniary, and to ensure that the net benefit can be justified by legitimate objectives, such as compensation for litigation costs and remuneration for the supply of goods or services.

Despite the helpful guidance provided by the Court's judgment, a number of open questions remain. For example:

- Patent rights and patent litigation will not shield patent settlement agreements from EU antitrust law but can and have to be taken into account as part of the overall analysis. It remains to be seen how antitrust authorities and courts will in practice navigate this intersection between antitrust and intellectual property and which concrete impact, if any, patent rights will have on the assessment.

- In many cases, the analysis will likely center around the notion of the value transfer to the generic company. However, while any value transfer that materially exceeds arm's length transaction value and legitimate litigation costs, can be expected to raise concerns, the calculation of the transferred value may be particularly complex in cases involving co-promotion agreements, preferential supply contracts, multiple settlements and acceleration clauses.

- How will antitrust authorities and courts apply in practice the legal test for assessing whether a generic company is a potential competitor? There may be cases where the generic company's intention and/or its ability to enter the market is not sufficiently strong for it to be considered as a potential competitor. Also, the question arises whether there are any circumstances at all under which patents represent an "insurmountable" barrier to market entry and, if so, how those cases can reliably be identified.

- The judgment makes clear that even where the net gain arising from a value transfer indicates that a patent settlement agreement constitutes, in principle, a restriction by object, pharmaceutical companies may still argue that the agreement should escape such a classification on account of its pro-competitive effects. However, this possibility is subject to strict conditions, i.e. the pro-competitive effects must be proven, be agreement-specific and sufficiently significant. Future cases may show how receptive competition authorities will be in taking such claimed effects on board.

Catriona Hatton
Partner
T: +32.2.891.7310
catriona.hatton@bakerbotts.com

Paul Lugard
Senior Associate
T: +32.2.891.7320
paul.lugard@bakerbotts.com

Daniel Vasbeck
Senior Associate
T: +32.2.891.7314
daniel.vasbeck@bakerbotts.com

[i] EU Court of Justice, judgment of 30 January 2020, Case C-307/18, *Generics (UK) Ltd and Others v Competition and Markets Authority*, ECLI:EU:C:2020:52.