GIBSON DUNN

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EUROPEAN COURT OF JUSTICE ADOPTS STRICT STANDARD FOR REVERSE PAYMENT SETTLEMENTS

To Our Clients and Friends:

ECJ Case C-307/18, Generics (UK) Ltd and others v. CMA

In its judgment of 30 January, 2020, the European Court of Justice ("ECJ") adopted a very strict standard for the assessment of settlement agreements entered into between originator and generic pharmaceutical suppliers. The ruling, which has been welcomed by the European Commission ("EC") and the UK Competition and Markets Authority ("CMA"), threatens to limit the ability of the settling parties to defend such settlements by relying on the strength of the underlying patents and illustrates a very sceptical attitude towards reverse-payment settlements.

Key Facts

The judgment is a preliminary ruling sought by the UK's Competition Appeal Tribunal ("CAT") in relation to proceedings concerning settlement agreements covering an anti-depressant pharmaceutical. The underlying disputes between the originator and the generic suppliers took place after the expiry of the patents covering the active ingredient itself but at a period where the originator still held a process patent that it contended covered the pharmaceutical product at issue.

Following what the ECJ recognised was a "genuine" patent dispute (and not simply a cover for a market sharing arrangement), the parties entered into a series of settlement agreements. The key characteristics of these agreements were that the generic company would become a limited distributor of the originator's medicine, would receive some compensation, and would refrain from challenging the patent and entering the market with a generic drug for a certain period.

The CMA found those settlements to be an infringement of European competition rules and also found the originator's overall conduct of the parallel settlement agreements to constitute an abuse of a dominant position.

When are Generic Suppliers Potential Competitors?

The ECJ first explains that the gating item for the application of Article 101 TFEU is if the originator and generics suppliers are potential competitors. The ECJ frames the question as being if "*there are real and concrete possibilities of the* [generics supplier] *joining the market*". In order to determine this, the authorities/courts must look at the "*structure of the market and the economic and legal context*". Market entry need not be demonstrated "*with certainty*" but must be more than "*purely hypothetical*".

The ECJ expresses the test as being if the generics supplier "*has in fact a firm intention and an inherent ability to enter the market, and that market entry does not meet barriers to entry that are insurmountable*". In relation to the former, it will be relevant to analyze the generics supplier's actions to seek the required administrative authorisations and its ability to produce or source the generic medicine. In relation to the latter, the potential for insurmountable barriers to entry, the ECJ appears to largely dismiss the relevance of patent rights. It holds that even where the originator has obtained an injunction, which was the case here, this "*in no way prejudge*[s] *the merits of an infringement*" and therefore is not enough to demonstrate that the IP represented an insurmountable barrier to entry. Further, the ECJ refers to such patent disputes being common in pharmaceutical markets and finds that the existence of the IP dispute in fact "*constitutes evidence of the existence of a potential competitive relationship*" between the generics supplier and the originator.

It should be noted that the patents in the relevant case were process patents and that the active ingredient was already in the public domain. However, the judgment does not appear to make any distinction between the different types of patents.

As a result of the test set out by the ECJ, even strong patent rights may not constitute an adequate defence to a patent settlement with a reverse payment, and the test for a finding that the generics supplier is a potential competitor appears to have a very low threshold.

Does the Settlement Amount to a Restriction of Competition by Object or Effect?

The ECJ recognises that, as a result of the patent dispute, a generics supplier may decide to abandon the market entry and in that context may enter into a settlement. Furthermore, the fact that the settlement involves transfers of value from the originator to the generics supplier "*is not sufficient to classify it as a 'restriction by object'*". This may be the case where the value transfer corresponds to "*compensation for the costs of or disruption caused by the litigation*", "*to remuneration for the actual supply* […] *of goods or services*" to the originator, or when the generics supplier "*discharges undertakings, particularly financial, given by the patent holder to him, such as cross-undertaking in damages*".

According to the judgment, the critical test is whether the transfer of value is "*sufficiently beneficial to encourage the manufacturer of generic medicines to refrain from entering the market concerned and not to compete on the merits*". The ECJ clarified that the uncertainty as to the outcome of the patent dispute is not sufficient to justify the transfer of value as it "*is precisely the uncertainty as to the outcome of the court proceedings in relation to whether the patent held by the manufacturer of the originator medicine is valid and whether the generic version of that medicine infringes that patent which contributes, for as long as it lasts, to the existence of at least potential competition*". The focus is therefore on the value transferred to the generics supplier and the settlement will be regarded a 'restriction by object' where the transfer of value "*can have no other explanation that the commercial interest of the parties to the agreement not to engage in competition on the merits*" unless there are "*proven pro-competitive effects capable of giving rise to a reasonable doubt that it causes a sufficient degree of harm to competition*".

Consequently, where a patent settlement includes a transfer of value to the generics supplier, it will be critical for the settling parties to demonstrate that this transfer of value is compensation for something other than the absence from the market and challenge of the patent.

In a similarly restrictive finding, the ECJ also held that a settlement agreement can be classified as a "*restriction by effect*", without having to demonstrate that the generics supplier "*would probably have been successful in the proceedings*" or "*would probably have concluded a less restrictive agreement*". In line with earlier case-law, "*potential*" effects are sufficient provided that they are "*sufficiently appreciable*".

Abuse of Dominance

While likely of less practical importance, the ECJ also confirmed that an originator's strategy, in a market where it is dominant, to enter into a series of settlements to temporarily keep generic medicines out of the market may also amount to an abuse of that dominant position.

Implications

As evidenced by the EC's and the CMA's eagerness to welcome and comment on the judgment, the ECJ's judgment sets out a very stringent test for settlements in which there is some transfer of value to the generics supplier. Focus will need to be on the justifications for making any such transfer of value. The risks and litigation costs involved in patent litigation are, however, given no clear relevance in this test. The judgment may therefore make it harder to reach settlements in this type of patent disputes and have the unfortunate consequence of leading to more drawn out patent litigation in the pharmaceutical sector. On the other hand, the limited prospects of achieving a quick and lucrative settlement may reduce the number of attempts by generic suppliers to enter markets early on.

There is hope that the application of this judgment is limited to cases involving process patents, but the reasoning does not suggest that this was the intention.

Finally, the ECJ's reluctance to consider the merits of the underlying patent litigation raises a question as to whether the court's reasoning would extend to private litigation. Presumably, for a private claimant to demonstrate damages, some showing that the generics supplier was likely to succeed in the underlying IP case would be necessary in order to show harm to the claimant. The ECJ had no occasion to reach that question at this time.

The following Gibson Dunn lawyers assisted in the preparation of this client update: Christian Riis-Madsen and Eric Stock.

Gibson Dunn's lawyers are available to assist in addressing any questions you may have regarding these developments. To learn more about these issues, please contact the Gibson Dunn attorney with whom you work or any member of the Antitrust & Competition practice group:

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