On 30 January 2020 the European Court of Justice ("ECJ") clarified for the first time the criteria governing whether so-called “pay-for-delay” agreements entered into between originator and generic pharmaceutical companies fall foul of EU competition law rules. Such agreements are a form of patent dispute settlement, whereby in return for a value transfer, a generic manufacturer acknowledges the patent of the originator pharmaceutical company, and agrees to refrain from marketing its generic version of the drug in question for a specified period of time. Pay-for-delay agreements have been in the spotlight of the European Commission ("EC") and national competition authorities for over a decade.

In line with the non-binding Opinion delivered by Advocate-General Kokott on 22 January 2020, the ECJ held that such agreements may constitute “by object” infringements of the prohibition on anti-competitive agreements (such that a competition regulator is not required to prove effects on the market) or “by effect” infringements, and may also amount to an abuse of a dominant position.

The ECJ had been asked to provide guidance on this issue by the UK Competition Appeal Tribunal ("CAT"), by way of a reference for a preliminary ruling in the UK Paroxetine case. That case involves an appeal by GlaxoSmithKline ("GSK") and five generics against a 2016 decision of the UK Competition and Markets Authority ("CMA") imposing fines totalling £45 million on the basis that such pay-for-delay agreements infringed competition law.

WHY IS THE ECJ’S JUDGMENT IMPORTANT?
The ECJ’s judgment is expected to have significant implications for both ongoing and future cases in the pharmaceutical sector:

- The ECJ has sent a clear message to both originator and generic companies that once a generic has demonstrated a clear intention to market a rival version of an originator drug, it is likely to be considered a “potential competitor” of the originator (and thus any patent settlement between the originator and that generic involving a value transfer is likely to attract antitrust scrutiny).

- The ECJ held that patent settlement agreements can be lawful. In particular, the existence of a value transfer (pecuniary or not) is not, by itself, sufficient to classify the agreement as a restriction of competition by object. This is because such value transfer may be justified taking into account the parties' legitimate objectives (e.g. if it constitutes compensation for the generic's litigation costs). However, the ECJ considered that where the value transfer by the originator to the generic cannot have any explanation other than the commercial interest of both parties not to compete on the merits, the agreement at issue will constitute a restriction of competition “by object” (i.e. it will be anticompetitive by its very nature). Therefore, although patent settlement agreements between originators and generics are not automatically anti-competitive, it appears that agreements with large value transfers from the originator to the generic(s) in exchange for a delay in market entry are highly likely to be deemed to be an “object” infringement in most cases. Pharmaceutical companies wishing to argue otherwise are likely to face an uphill struggle (although the ECJ has left the door open in very limited circumstances).

- Further, the judgment indicates the approach the ECJ is likely to take in pending appeals against EC infringement decisions in two other pay-for-delay cases: Lundbeck (citalopram) and Servier (perindopril).

- It also seems likely to encourage both the EC and national competition authorities to aggressively pursue more pay-for-delay cases in the future. Indeed, Commissioner Vestager commented to journalists that the judgment “looks very promising on first reading, and in that of course we feel very much encouraged because we find these cases important”. Similarly, the CMA has welcomed the judgment, noting that it “has clarified a number of important questions and will help competition authorities, including the CMA, in their work to tackle this harmful behaviour by pharmaceutical companies”.

**BACKGROUND**
As noted above, the appeal to the CAT which generated the reference for a preliminary ruling relates to the CMA’s February 2016 decision imposing fines totalling £45 million on GSK and five generics. GSK had concluded agreements with various generics to settle disputes relating to the anti-depressant medication paroxetine. The disputes related to GSK’s secondary patents for the drug and arose after GSK’s main patent expired and the generics planned to enter the UK market. Under the settlement agreements, the generics essentially agreed to abstain from entering the market for a certain period in exchange for payments by GSK.

The CMA concluded that the settlement agreements constituted (i) anti-competitive agreements; and (ii) an abuse by GSK of its dominant position on the relevant market. GSK and the five generics appealed the infringement decision to the CAT. In March 2018, the CAT decided to seek guidance from the ECJ by way of a reference for a preliminary ruling on how to apply EU competition law rules in the context of pay-for-delay agreements.

**GENERIC MANUFACTURERS AS “POTENTIAL COMPETITORS”**

In order for an agreement to be capable of having a negative and appreciable effect on competition (such that it is subject to the Article 101 TFEU prohibition on anti-competitive agreements), the parties entering into the agreement must be at least “potential competitors”.

The ECJ held that in order to assess whether an undertaking that is not present in a market is a potential competitor of one or more other undertakings that are already present in that market, it must be determined whether there are “real and concrete possibilities” of access to the market (paras 36-38). In this regard, the ECJ considered that it is necessary to assess for each generic whether it 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” (para. 58). It suggested that such an intention could be demonstrated by, for example, seeking the required administrative authorisations for marketing a generic version of the drug in question, or undertaking the legal steps to challenge the patent in court (para. 44).

According to the ECJ, any patent rights do not constitute by themselves “insurmountable barriers” given that their validity can be contested (paras 50-51). The ECJ further held that “[t]he greater the transfer of value [by the originator to the generic pursuant to the agreement], the stronger the indication” that the parties are potential competitors (para. 56).

**RESTRICTION OF COMPETITION “BY OBJECT”**
The characterisation of an infringement as an “object” infringement makes an infringement finding much more straightforward for a competition regulator, as in such cases there is no need to undertake a detailed assessment and prove actual effects on the market. Referring to previous case law on the distinction between “by object” and “by effect” infringements, the ECJ reiterated that “the concept of restriction by object must be interpreted strictly”. It confirmed that an agreement will only restrict competition by object if, having regard to the content of its provisions, its objectives and economic and legal context, it reveals in itself “a sufficient degree of harm to competition for the view to be taken that it is not necessary to assess their effects, since some forms of coordination between undertakings can be regarded, by their very nature, as being harmful to the proper functioning of normal competition” (para. 67).

The ECJ held that the existence of a value transfer (pecuniary or not) is not, by itself, sufficient to classify the agreement as a restriction of competition by object. This is because such value transfer “may prove to be justified, that is, appropriate and strictly necessary having regard to the legitimate objectives of the parties” (para. 85). This may be in particular the case where, for example, the value transfer constitutes compensation for the generic's litigation costs or where the generic discharges financial undertakings provided to it by the originator, such as a cross-undertaking in damages (para. 86).

However, the ECJ considered that the characterisation of a restriction of competition by object must be adopted when it is plain from the analysis of the agreement that the value transfers by the originator “cannot have any explanation other than the commercial interest [of both parties] not to engage in competition on the merits” (para. 87). In this regard, it is necessary to assess inter alia whether the net gain arising from the value transfer may be justified and, if not, whether the net gain is “sufficiently large” to act as an incentive for the generic to stay out of the market (paras 92-93).

For the purposes of the characterisation as a restriction by object, the ECJ also stated that any pro-competitive effects must be taken into consideration, provided that those effects are demonstrated. However, this is merely a part of the analysis of whether the agreement at issue causes a “sufficient degree of harm” (para. 103). The ECJ concluded that it is for the national court to assess whether the demonstrated pro-competitive effects are sufficient to permit “a reasonable doubt” as to whether the agreement causes a sufficient degree of harm to competition (paras 107, 110).

**RESTRICTION OF COMPETITION "BY EFFECT"**

With regard to the characterisation of an agreement as a restriction of competition “by effect”, the ECJ stated 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 agreement” (the “counterfactual”) (para. 118).

However, it is not necessary in this regard to establish the probability of the generic being successful in the patent proceedings or of a less restrictive agreement being concluded (para. 119).
ABUSE OF DOMINANCE

The ECJ was also asked to provide guidance on whether entering into a pay-for-delay agreement could also amount to an abuse of a dominant position, in breach of Article 102 TFEU. In this regard, the ECJ noted first that the relevant 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 the generics are in a position to enter the market with “sufficient strength to constitute a serious counterbalance” to the originator (para. 140).

On the issue of abuse, the ECJ stated that the finding of an abuse presupposes an adverse effect on the competitive structure of the market that exceeds the specific effects of each of the agreements with respect to which penalties were imposed under Article 101 TFEU. The ECJ noted that, taking into account 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 (paras 156-157).

The ECJ recalled that it is open for a dominant company to provide justification for its conduct if it proves that its anti-competitive effects may be counterbalanced (or outweighed) by advantages in terms of efficiency that also benefit consumers (see in this regard Case C-209/10 Post Danmark) (para. 165). For the purposes of that weighing of effects, the favourable effects on competition must be taken into consideration irrespective of the objectives pursued by the dominant company (para. 168).

WHAT HAPPENS NEXT?

The case will now go back to the UK CAT for a final judgment on the appeal, based on the guidance provided by the ECJ.

KEY CONTACTS

If you have any questions, or would like to know how this might affect your business, phone, or email these key contacts.

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