

## ANTITRUST KEEPS PATENT SETTLEMENT AGREEMENTS IN CHECK

The judgment handed down by the European Court of Justice in the *Paroxetine* case (C-307/18) provides some guidance on when patent settlement agreements, which include "pay-for-delay" clauses from the patent holder to the potential infringer, may constitute a restriction "by object" or "by effect" and/or an abuse of a dominant position

### THE *PAROXETINE* CASE AND REFERRAL TO THE EUROPEAN COURT OF JUSTICE

#### Seek for guidance on the antitrust assessment of patent settlement agreements and, in particular, of "pay-for-delay" clauses that may be agreed in them

By means of its decision dated 12 February 2016, the Competition and Markets Authority in the United Kingdom ("CMA") sanctioned GlaxoSmithKline plc ("GSK") and several manufacturers of generic medicines. The CMA found that the patent settlement agreements entered into by GSK and the generics companies were contrary to antitrust rules as they included "pay-for-delay" clauses that resulted in a delay of the generics' entry onto the paroxetine market. Moreover, the CMA also found that GSK abused its dominant position by entering into these agreements.

The CMA's decision was appealed before the UK's Competition Appeal Tribunal ("CAT"), which decided to stay the proceedings and to refer several questions to the European Court of Justice ("ECJ") in order to obtain guidance on how to analyse these patent settlement agreements and, in particular, the "pay-for-delay" clauses contained therein, under competition rules, basically Arts. 101 and 102 of the Treaty on the Functioning of the European Union ("TFEU"), which prohibit the conclusion of restrictive agreements and abuses of a dominant position, respectively.

In its judgment, the ECJ provides some guidance on how to assess, under competition rules, patent settlement agreements which include "pay-for-delay" clauses established by the patent holder and innovator company against the generics company and potential patent infringer.

#### Key issues

- Patent settlement agreements do not violate antitrust law *per se*, but they may be considered a restriction "by object" in specific circumstances.
- If the generics company has taken sufficient preparatory steps to enter the market, it will be considered a "potential competitor" from an antitrust perspective, even if there are patents still in force.
- Be careful with any transfer of value agreed in the patent settlement agreement in favour of the generics company and potential patent infringer.
- Entering into patent settlement agreements could constitute an abuse of dominant position, if it is part of an overall strategy of a dominant company to maintain its monopoly in the market.

## **GENERICS COMPANIES CAN BE "POTENTIAL COMPETITORS" OF THE PATENT HOLDER AND MANUFACTURER OF THE ORIGINATOR MEDICINE**

The first question posed by the CMA referred to whether a generics company could be considered a potential competitor of the patent holder and manufacturer of the originator medicine, a pre-requisite for the application of Article 101 TFEU. The ECJ confirmed that the potential competition condition could not be considered in abstract, as a mere wish to enter by a generic company, nor could it possible to request certainty of said entrance. Market structure and economic and legal context needs to be analysed.

The Court states that it is necessary to assess whether the generics company has a firm intention and an inherent ability to enter the market. It would be necessary to check if, at the time of entering into the patent settlement agreement, the generics company has already taken sufficient preparatory steps to be able to enter into the market within a period of time that would put competitive pressure on the patent holder. These steps could consist of, for example: obtaining the corresponding marketing authorisation for the generic product, entering into supply agreements with third parties or bringing nullity proceedings (i.e. a revocation action) challenging the patent's validity.

Moreover, in order for a generics company to be considered a potential competitor, its market entry should not meet a barrier to entry that is insurmountable. Interestingly, the ECJ declares that the existence of a patent which protects a manufacturing process to obtain an active ingredient that is already in the public domain does not constitute an insurmountable barrier, despite the presumption of validity from which the patent benefits and the uncertain outcome of the nullity proceedings when the generics company has taken the steps above.

According to the ECJ, transfers of value from the manufacturer of originator medicines to the generics manufacturer can be used as an indication of the firm intention of the former to enter the market. The greater the transfer of value, the stronger the indication of potential competition.

## **PATENT SETTLEMENT AGREEMENTS WITH REVERSE PAYMENTS CAN CONSTITUTE A RESTRICTION "BY OBJECT" OF COMPETITION**

### **Special focus on "pay-for-delay" clauses**

By the referral to the ECJ, the CAT sought guidance on whether a patent settlement agreement can constitute a restriction "by object" for the purpose of Art. 101.1 TFEU. This question is relevant because restrictions "by object" relieve competition authorities of demonstrating the existence of restrictive effects. In line with recent judgements in *Cartes Bancaires* (C-67/13 P) and *Maxima Latvija* (C-345/14), the ECJ confirms that this notion must be interpreted strictly.

The ECJ's initial assumption is that a patent settlement agreement bringing to an end a genuine dispute regarding the validity and infringement of a process patent has not been designed with the sole aim of disguising a market-sharing agreement or a market-exclusion agreement and thus, it cannot be considered, *per se*, a restriction "by object".

However, depending on the specific circumstances, the ECJ opens the door to the possibility of considering these agreements as a restriction "by object".

## **Be careful with any transfer of value agreed in favour of the generics company and potential patent infringer**

In this respect, the ECJ first focuses on transfers of value from the manufacturer of the originator product to the manufacturer of the generic product that may have been agreed as a counterpart to the generics manufacturer's agreement to not enter the market while the patent is still in force and not challenge its validity.

The ECJ clarifies that the mere existence of such transfers of value is not sufficient to classify the patent settlement agreement as a restriction "by object", as these transfers may be justified and be deemed appropriate, taking into account the legitimate objectives of the parties thereto. In this respect, it gives the following examples:

- when the transfer of value corresponds to compensation for the costs of, or disruption caused by, the litigation between the parties;
- when the transfer of value corresponds to remuneration for the actual supply, whether immediate or subsequent, of goods or services to the manufacturer of the originator medicines; or
- when the manufacturer of the generic medicines discharges undertakings made by the patent holder to the generics company, such as a cross-undertaking in damages.

However, the patent settlement agreement may be characterised as a restriction "by object" when it is clear from an analysis thereof that the transfers of value agreed cannot have any plausible explanation other than the commercial interest of both the patent holder and the generics company infringing the patent, not to engage in competition on the merits. This would be the case, for instance, when it is verified that the net gain from the transfers of value in favour of the generics company is sufficiently beneficial to encourage it to refrain from entering the market and challenging the patent. When making this assessment, any transfer of value will be considered, whether direct or indirect, pecuniary or non-pecuniary.

## **The respect of the patent's scope and the uncertainty of the proceedings are not relevant factors**

The ECJ furthermore states that the characterisation of a patent settlement agreement as a restriction "by object" cannot be ruled out on the basis that the outcome of the proceedings is uncertain. As for the fact that the restriction agreed by the generics company does not go beyond the scope of the patent in dispute, the ECJ does not consider this a relevant factor for ruling out such a characterisation.

## **Pro-competitive effects are only relevant if sufficiently significant**

In addition, the ECJ sets a novel principle: procompetitive effects can also be balanced in the framework of Article 101.1 TFEU to exclude a finding of restriction "by object". The ECJ warns that these allegations should not be read as the admission of a "*rule of reason*" in EU competition law. Procompetitive effects cannot exclude the existence of a restriction of competition, just the characterisation of a restriction as a restriction "by object".

Regarding the pro-competitive effects that may derive from the patent settlement agreement, the ECJ states that they must be demonstrated, relevant, specifically related to the settlement agreement and sufficiently significant to raise reasonable doubts as to whether the settlement agreement causes a sufficient degree of harm to competition. Slight price reductions of paroxetine were not considered sufficient in the case at hand by the Court.

## **PATENT SETTLEMENT AGREEMENTS WITH REVERSE PAYMENTS CAN CONSTITUTE A RESTRICTION "BY EFFECT" OF COMPETITION**

### **Specificities of the "counter-factual" analysis to be conducted**

In the event that the patent settlement agreement is not to be characterised as a restriction "by object" the existence of appreciable potential or real effects on competition are to be proved by the antitrust authority. To that effect, the ECJ refers to its former case law, according to which, in order to assess the effects of a concerted practice with regard to Article 101 TFEU, competition should be assessed within the actual context in which it would occur in the absence of the agreement in dispute (i.e. the so-called "*counter-factual*" scenario).

However, the ECJ expressly clarifies that when establishing this "*counter-factual*" scenario in the case of patent settlement agreements, it is not necessary for the Court to first find that, in the absence of that agreement, either the generics company would probably have succeeded in the patent proceedings or, alternatively, that the parties would have entered into a less restrictive agreement.

## **IN THE DEFINITION OF THE PRODUCT'S RELEVANT MARKET IN THE FRAMEWORK OF ARTICLE 102 TFEU, GENERIC PRODUCTS MAY BE RELEVANT**

The ECJ judgment also develops case law in the field of market definition in the pharmaceutical market. In the *Hoffman La-Roche* case (C-179/16) the ECJ excluded from the relevant product market pharmaceutical products that were sold or manufactured illegally. However, in the present case, the ECJ confirms that this case law is not applicable in the case at hand and that generic versions of a medicine containing an active ingredient which is already in the public domain, but for which the manufacturing process is protected by a patent, must be taken into account when defining the product's relevant market, even if they are not yet in the market. The ECJ clarifies that this would be the case if there is a sufficient degree of interchangeability between the originator medicine and the generic medicines, i.e. if the generics company is in a position to be on the market within a short period of time and with sufficient strength to constitute a serious counterbalance to the originator company or if, before the patent expires, the generics company has taken the necessary steps to enter the market upon the patent's expiry. The ECJ thus confirms the dynamic interchangeability of products in this area.

## **ENTERING INTO PATENT SETTLEMENT AGREEMENTS CAN CONSTITUTE AN ABUSE OF DOMINANT POSITION**

The ECJ bases its judgment on the premise that a patent settlement agreement entered into by and between the patent holder and the parties allegedly infringing its patent in order to end litigation is one of the patent

holder's rights and, consequently, even if done by a dominant undertaking, it cannot in itself constitute an abuse of dominant position.

However, the ECJ clarifies that if entering into different patent settlement agreements is part of an overall strategy aiming to maintain a monopoly within the paroxetine market, having exclusionary effects that go beyond the specific anticompetitive effects of each settlement agreements that are part of that strategy, then such action may constitute an abuse of this dominant position in the sense of Art. 102 TFEU. The dominant undertaking can provide an objective justification for this conduct, i.e. prove that any exclusionary effect produced by such settlement agreement could be counterbalanced or outweighed by advantages in terms of efficiency that also benefit consumers.

## **PATENT SETTLEMENT AGREEMENTS ARE KEPT IN CHECK BY THE ANTITRUST AUTHORITIES**

The ECJ judgment in the *Paroxetine* case clarifies that patent settlement agreements do not constitute *per se* a restriction "by object" or "by effect" of competition, nor do they constitute *per se* an abuse of dominant position. However, these agreements are kept in check by the antitrust authorities, which keep an eye on them to ensure that they do not imply a restriction of the competition.

By means of this judgment, the ECJ has provided some guidance to both the antitrust authorities and also the companies interested in settling a patent litigation, as to whether a patent settlement agreement is in line with antitrust law. We expect that this guidance will be confirmed and, most likely, also complemented in the forthcoming judgements in the Citalopram (C-591/16) and Perindopril (C-176 and 201/19) cases, which are currently pending before the ECJ.

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