PAY-FOR-DELAY AGREEMENTS IN RULINGS OF THE CJEU

On January 30, 2020 the Court of Justice of the European Union announced its judgment in the case: Generics (UK) and others (C-307/18). It is worth to take a closer look at its decision, since it is the first time when the Court has taken position on *pay-for-delay* agreements which are quite commonly made between subjects that are present in pharmaceutical markets.

What is the goal of *pay-for-delay* agreements

First of all, it is necessary to remark that when it comes to a *pay-for-delay* agreement, its parties are: a holder of a pharmaceutical patent, as well as a producer of generic drugs. Under such an agreement, the patent holder commits to pay a compensation in a specified amount to a producer of generics, while the latter refrains — temporarily or permanently — from entering the market.

The agreements made by the pharmaceutical group GlaxoSmithKline

Such an agreement — actually, to be more precise: three agreements — were signed in the case that has been reviewed by the CJEU. The pharmaceutical group GlaxoSmithKline (GSK) was a holder of a patent for an active pharmaceutical ingredient of the anti-depressant medication paroxetine, as well as of secondary

patents that protected some processes for manufacturing of this ingredient. The patent for a main ingredient expired in 1999. GSK however, not willing to relinquish its special position in the market that it was able to enjoy thanks to the patent protection, challenged the actions of producers of generics who were preparing themselves to enter the market — what resulted in reaching the aforementioned agreements in years 2001-2003. The agreements contained mostly provisions regarding distribution: GSK was supposed to pay a compensation to producers, while they were obliged under those deals to cease manufacturing, importing and selling paroxetine in Great Britain, since then they were allowed to sell exclusively the substance produced by GSK.

The agreements signed by GSK attracted the attention of the British Competition and Markets Authority. Upon its evaluation of agreements, the Competition and Markets Authority determined that in fact they were detrimental to competition and GSK abused its dominant position, which led it to impose on parties of those deals fines amounting to 44,99 million pounds. The case reached the second instance where it fell under the competence of the Competition Appeal Tribunal (the British appellate court in the field of competition law). The Tribunal has decided to refer the case to the CJEU for a preliminary ruling, thus initiating proceedings before the Court in Luxembourg. The CJEU provided an elaborate and very thorough analysis of a legal status of such agreements in the light of prohibitions of Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU).

Legal grounds

The CJEU, in order to ascertain the conformity of the *pay-for-delay* agreements with the European law, relied on two provisions that can be found in the TFEU: Article 101 and Article 102. According to the first one of those provisions, incompatible with the internal market are all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market. The Treaty further lists examples of agreements that the prohibition shall apply to: particularly, agreements directly or indirectly fixing purchase or selling prices or any other trading conditions; limiting or controlling production, markets, technical

development, or investment; sharing markets or sources of supply; applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage; as well as making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts. Furthermore, the provision of Article 101 resolves unequivocally that such agreements and decisions shall be automatically void.

The subsequent provision, Article 102, pertains to an abuse of a dominant position: it states that any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States. Specifying what a prohibited practice could entail, Article 102 indicates that in particular, an abuse may exist in such cases as: directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions; limiting production, markets or technical development to the prejudice of consumers; applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage; and finally making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.

The CJEU declared, that even though Article 101 and Article 102 of TFEU serve different objects, one cannot rule out a situation wherein a given conduct of a subject present in a market violates those two prohibitions simultaneously. In the Generics (UK) and others case the CJEU examined the practice of GSK in the context of both of those distinct legal grounds. Below we are presenting the most important theses derived from the argumentation presented by the CJEU.

The prohibition of Article 101 TFEU shall be relevant whenever an existence of agreements between undertakings that produce a negative, appreciable impact on a competition within the internal market can be demonstrated.

This thesis implies that the undertakings that are parties to a given agreement, have to be bound by the relationship of competition. This was underlined subsequently by the CJEU when it explained that “with respect to horizontal cooperation agreements entered into by undertakings that operate at the

same level of the production or distribution chain, that the coordination involves undertakings who are in competition with each other, if not in reality, then at least potentially". Therefore in the Generics (UK) and others case it was necessary to determine what was actually the relationship between GSK and producers of generics. As rightly noticed the CJEU, at the moment of conclusion of the agreements only one of the parties (GSK) was a participant of the market; the producers of generics were barely planning to enter it.

Determining whether an undertaking that does not participate in the market, can potentially compete with another undertaking, requires to examine whether real and concrete possibilities for the former to enter the market exist.

As the CJEU explained, especially when a given subject postpones its decision to enter a market due to an agreement it has reached with another undertaking that is already present in the market, it is crucial to examine whether in the lack of such an agreement real and concrete possibilities of entry would in fact exist. All purely hypothetical scenarios are irrelevant in this case; the assessment shall take into account a complex structure of the market, as well as its economic and legal conditions. The CJEU referred in this context to some particular features of the pharmaceutical sector (special requirements in terms of marketing authorization of products; issues related to protection of intellectual property, etc.). Next, it declared that in order to identify a nature of a mutual relationship between GSK and the producers of generics, it is essential to consider in particular if at the moment of making of an agreement, a producer of generics took sufficient steps in preparation to enter the market in a foreseeable, not distant future (which would exert pressure on GSK). The relationship of competition would occur whenever a producer of generics has "a firm intention and an inherent ability to enter the market, and (…) market entry does not meet barriers to entry that are insurmountable" — the existence of such insurmountable barriers is however for a referring court to determine.

The prohibition under Article 101 TFEU shall apply to all measures taken by undertakings that have as their object or effect the prevention, restriction or distortion of a competition within the internal market.

The CJEU made specific efforts to determine whether influencing a competition within the internal market, could have been "an object" or "an effect" of

the agreements in question — as it demonstrated in the grounds for the judgment, the distinction between those two categories is very clear and it entails different requirements in the field of evidence. The premise of an object shall be interpreted strictly — it shall be met, whenever an assessment of concerted practices between the undertakings, considering the text of applicable contractual provisions, their economic and legal context, reveals "a sufficient degree of harm to competition" (those practices are of such nature that they distort competition *ipso facto*).

When in the light of available information it can be determined that a net gain from transfers of value between a patent holder and a producer of generics has no other explanation than a commercial interest of the parties not to engage in the competition on the merits, such an agreement would violate prohibition of Article 101 due to its object.

The CJEU presented a very detailed, nuanced analysis of the character of the agreements and it came to a conclusion that they were made in the circumstances of an actual dispute concerning the patent rights — therefore they did not serve only to resolve a fictitious dispute, neither did they aim only to divide the market between themselves, nor to exclude any of the other subjects. Examining the transfer of value, the CJEU acknowledged that hypothetically it might have been justifiable — for example if its purpose would have been to compensate for litigation expenses. The CJEU noticed as well that an infringement would not have occurred, if the agreements had been accompanied by application of procompetitive measures capable of raising some reasonable doubt as to the presence of "a sufficient degree of harm to competition". The Court found the impact of such measures in that case to be minimal and dubious: even though a slight reduction in the price of paroxetine did occur, it observed that "the supply of paroxetine by GSK to the manufacturers of generic medicines provided for by those agreements did not give rise to meaningful competitive pressure on GSK".

While determining the existence of an agreement prohibited under Article 101 of TFEU due to its effects, it is imperative to analyze a whole context of a given practice (especially its economic and legal background), the nature of goods or services that are involved, as well as actual conditions of functioning and a structure of a relevant market or markets.

The analysis shall have for its object both real, as well as potential effects (if they can be estimated). It is necessary to envision what the competition in the market would have looked like if the agreements had not been reached. In order to establish that an agreement was illegal because of its effects, a referring court does not have to prove with absolute certitude that a producer of generics as a party of an agreement would have been successful in the proceedings before the patent office, or that it would been capable to negotiate an agreement that would have been more favorable for him or her.

The point of departure in an assessment of whether the prohibition of Article 102 TFEU has been violated, i.e. an undertaking has abused its dominant position, a relevant market must be identified — when certain conditions are fulfilled, it might also comprehend generic medicines that are not present in the market.

The CJEU, confronted with the factual situation in the Generics (UK) and others case, had to consider the relevant product market (as opposed to relevant geographic market and relevant temporal market). Evoking its judgement of January 23, 2018 in a case C-179/16 F. Hoffmann-La Roche and others, the Court pointed out that a notion of a relevant market is based on an interchangeability of goods and services with regards to their specific functions — yet interchangeability of products is not exclusively determined, as the CJEU clarified, by the objective features of goods and services, but also by the conditions of competition and the structure of supply and demand on the market. While the interchangeability of the generics was not a controversial issue, what the CJEU had to establish was whether products that have not actually entered the market, can be considered as belonging to the relevant market. It stated unambiguously that “the generic versions of an originator medicine containing an active ingredient which is in the public domain, but the process of manufacturing which is protected by a patent, the validity of which remains uncertain, must be taken into account for the purposes of definition of the relevant market”.

Article 102 TFEU prohibits strategies of concluding agreements that temporarily prevent potential competitors that produce generics from entering the market, as long as such strategies can hinder the competition and their exclusionary impact surpasses the concrete results of specific agreements.

The CJEU underlines that an abuse of a dominant position within the meaning of Article 102 TFEU is a conduct of a given undertaking present in the market where the level of competition is already weakened because of its very existence, that resorts to methods that impede the maintenance of that degree of competition or prevent it from developing. The hypothesis of Article 102 is completely objective — it does not require to identify the subjective intents of a dominating undertaking. This provision does not obviously prohibit an undertaking from taking necessary measures to defend its own interests (for example when pursuing its rights in the field of intellectual property), nevertheless such "defense" cannot actually serve only to reinforce the position of domination and to extend its sphere of influence. GSK could have exculpated itself, had it demonstrated that its conduct had actually resulted in an improvement in effectivity, and the consumers had been able to benefit from it. In a given state of affairs, the CJEU declared the opposite: GSK, by abusing it dominant position and not allowing competition in the market, hurt the interests of consumers and public health services.

Summary

As it has been mentioned in the introduction, the CJEU's judgment in Generics (UK) and others case marks the first time when the Court in Luxembourg took a position with regards to *pay-for-delay* agreements which are quite common in the pharmaceutical market. The grounds for its decision offer a very insightful analysis of the application of the European competition law in this specific sector and clarify some issues of great significance. Right now we can only speculate what impact this decision may actually produce when it comes to functioning of the market. It would not be that surprising though, if it could provide a stimulus for relevant national supervisory authorities to start monitoring closely the agreements that pharmaceutical firms and concerns conclude, and evaluate them through the use of new criteria put forward by the CJEU.

