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CJEU on the assessment in terms of antitrust law of pay-for-delay agreements between the holder of pharmaceutical patents and the manufacturers of generic medicines – Generics (GB), GSK et al. vs. Competition and Markets Authority (CJEU, judgment dated Jan. 30, 2020 – Case C-307/18)
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According to the CJEU, pay-for-delay agreements between the holder of pharmaceutical patents and manufacturers of generic medicines have the object of restricting competition and, thus, violate Art. 101 TFEU if the assets transferred to the manufacturers of generic medicines do not have any explanation other than omitted competition and the agreement is not proven to promote competition. In spite of an existing patent protection, a relationship of potential competition may exist between the parties.

Furthermore, the conclusion of several pay-for-delay agreements may constitute an abuse of a dominant market position pursuant to Art. 102 TFEU if the effects restricting competition that result from such agreements exceed those of the individual agreements. In addition to the originator medicine, generic medicines are also part of the relevant product market, even if they could not legally enter the market before the patents expire, as long as it is possible for the manufacturers of generic medicines to quickly enter the market with sufficient strength to be a serious counterbalance.

Facts of the case

The British Competition and Markets Authority considered settlement agreements which the pharma company and manufacturer of originator medicines GlaxoSmithKline (GSK) had concluded with several manufacturers of generic medicines to violate competition law. GSK held a patent for an ingredient of the antidepressant Paroxetin and several secondary patents which protect processes for the manufacture of that ingredient. After GSK's main patent and document protection had expired, several manufacturers of generic medicines obtained a marketing authorization for a generic version of Paroxetin in various EU member states. GSK proceeded against these companies based on secondary patents still valid at that time; in response, corresponding nullity complaints were filed. These disputes were settled by the following three settlement agreements:

1) An agreement with IVAX, a manufacturer of generic medicines, under which IVAX received the exclusive right of distributing a maximum volume of authorized generic medicines in Great Britain and an annual remuneration.

2) Two separate settlements with GUK and Alpharma, under which GSK undertook, inter alia, to buy the entire stock of generic medicines intended for Great Britain and pay for half of the legal cost

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incurred by GUK/Alpharma as well as an annual/monthly remuneration. In exchange, GUK and Alpharma undertook to sign a sub-distribution agreement with IVAX, including an indexed price and undertook to not distribute any generic medicines in Great Britain as long as the supply agreement between IVAX and GUK is valid.

Referrals to the Court of Justice of the European Union

The British appellate instance for decisions by antitrust authorities[1] referred the following questions to the CJEU for a preliminary ruling (abridged):

1) Does a **relationship of potential competition** exist between the holder of a pharma patent and manufacturers of generic medicines intending to enter the market?

2) Is the **restriction on competition** within the meaning of Art. 101(1) **an object** of a settlement agreement between the patent holder and a manufacturer of generic medicines if the agreement terminates ongoing infringement and nullity proceedings and the manufacturer of generic medicines undertakes to not enter the market, to discontinue challenging the patent's validity and receives a considerable amount from the patent holder for which there is no other performance in return?

3) Does item 2 **effect** a **restriction on competition** within the meaning of Art. 101(1)?

4) Do generic medicines need to be taken into consideration when **defining the relevant market** within the meaning of Art. 102 TFEU if they are able to substitute for the patented pharmaceutical product in treatment, but the patent holder prevents their entry into the market and, thus, they are not legally available on the market if the patents turn out to be valid and infringed?

5) Does a patent holder **abuse** its **dominant market position** within the meaning of Art. 102 TFEU by concluding agreements according to item 2?

The decision of the Court of Justice of the EU

Regarding item 1: The question regarding a **potential competition** between the holder of a pharma patent and manufacturers of generic medicines that intend to enter the market was answered in the **affirmative** by the CJEU subject to the proviso that the manufacturers of generic medicines have the firm intention and the inherent ability to enter the market and that there is no insurmountable obstacle to their market entry.

In this context, the Court took into account the question of whether the manufacturers of generic medicines had taken sufficient steps to enter the market soon enough to already put competitive pressure on the manufacturer of originator medicines (e.g. applied for a marketing authorization, provided sufficient stock of the generic medicines, developed marketing activities, challenged validity of existing patents). **Patents** held by the manufacturer of originator medicines which, per se, are an

1 Competition Appeal Tribunal.

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obstacle to the market entry of a generic medicinal product **were not deemed an insurmountable barrier**, even if a preliminary injunction in favor of the patent holder had already been issued. This is because, otherwise, all and any meaning would be removed from Art. 101 TFEU in this context, and European antitrust law would be frustrated. In particular, the Court states that the competition authorities do not need to assess the prospects of success of existing patent infringement and nullity proceedings but, instead, assess the extent to which the existing patents are suitable for preventing the actual entry into the market by the company manufacturing generic medicines. The Court says that, in case of pay-for-delay agreements which prevent market entry temporarily, the question whether a real and specific possibility of a market entry exists without the corresponding agreement is decisive. It continues that one clear indication of a relationship of potential competition is a situation in which companies on the same level of the chain of production, not all of which are on the market, conclude agreements with each other. What also is a clear indication, according to the Court, is the payment of considerable sums by the manufacturer of originator medicines to the manufacturers of generic medicines for a delay of the latters' market entry. The perception of the manufacturers of generic medicines by the manufacturer of originator medicines - as a competitor or not - also needs to be taken into consideration, the Court holds. This is because this subjective perception may result in competitive pressure even before the patent protection expires.

Regarding item 2: The CJEU also answered the question of whether such pay-for-delay agreements constitute a **restriction on competition "by object"** within the meaning of Art. 101 TFEU in the **affirmative**, provided that it is clear in the individual case that the transfer of value from the originator company to the company manufacturing generic medicines does not have any explanation other than the parties' economic interest in not competing against each other. However, the Court states, this does not apply if the settlement agreement is proven to have positive effects in terms of competition law which justify reasonable doubts that the agreement establishes sufficient damage to competition.

The CJEU reiterates the high requirements for restrictions on competition by object. Regarding these requirements, experience has already shown that the conduct in question leads to a decrease in production and increase in prices, and causes poor allocation of resources, particularly to the disadvantage of consumers. The proof of the actual occurrence of negative effects on competition is not required here, as opposed to a restriction on competition by effect. According to the CJEU, the fact that it was not possible that the payments made to the manufacturers of generic medicines by the patent holder have any explanation other than the economic interest of both parties in avoiding competition against each other in the present case suggests a restriction on competition by object. Additionally, the Court states, due to the significant barriers to market access (the administrative requirements, in particular) and its pricing mechanisms (regulated by law and influenced by the market entry of a manufacturer of generic medicines to a very high

degree), the medical field reacts particularly sensitively to a delay in market entry of generic medicines.

Regarding item 3, the question of whether the agreements also **"effected"** restrictions of competition, the CJEU clarified that this does not necessarily require the finding that (i) the manufacturer of generic medicines is expected to win patent litigation proceedings or (ii) the parties would probably have concluded a less restrictive agreement if it was not for the agreement in question. The Court stated that these aspects are to be taken into consideration, but only constitute some of many relevant aspects.

Regarding item 4, the CJEU confirms that generic medicinal products need to be taken into consideration when **defining the relevant market within the meaning of Art. 102 TFEU**, provided that a sufficient degree of interchangeability exists. It states that this requires, inter alia, that the manufacturers of generic medicines are able to position themselves on the market in a short period of time and with sufficient strength to be a serious counterbalance to the manufacturer of originator medicines already on the market. What needs to be taken into account in this context, according to the Court, is whether the manufacturers of the generic medicines have already developed an effective strategy for entering the market, taken care of the marketing authorization or concluded supply contracts with third-party distributors. Here, the Court says, the perception of the manufacturers of generic medicines by the manufacturer of originator medicines, particularly whether the risk of the market entry is imminent, also plays a role. The CJEU emphasized that the assessment of what is interchangeable is subject to change. It continues that the therapeutic agent of the patent holder belongs to a group of therapeutic agents, which means that, prior to the development of the generic medicines, the "relevant market" might comprise all therapeutic agents of that group - whereas, after the development of one or more generic medicinal products, only those products are to be considered to be the relevant market.

Regarding item 5, the CJEU stated that a manufacturer of originator medicines **potentially abuses its dominant position** by concluding a number of settlement agreements if they serve the purpose of pursuing a strategy of - at least temporarily - keeping potential competitor from entering the market. As a precondition, the strategy does not only have to be suitable for restricting competition, but also have effects of excluding the other party from competition and exceeding the special anti-competitive effects of each settlement agreement individually (in this case, the general delay of generic medicines entering the market and the considerable decrease in the prices of the originator preparation). Whether this is the case has to be assessed by the referring court.

This means that a complex of conduct can violate both Art. 101 TFEU (by the individual agreements) and Art. 102 TFEU (by the overall strategy). However, a company that has a powerful position on the market, the conduct of which is subject to Art. 102 TFEU per se, can exculpate itself by submitting that its conduct restricting competition is counterbalanced by efficiency gains which benefit consumers, in particular.

Comments

Many aspects of this judgment of the CJEU aim to strike an appropriate balance between considerations under antitrust law on the one hand and patent law on the other: An existing patent alone does not suffice to rule out a relationship of potential competition, since patent law would invalidate antitrust law from the outset otherwise. Vice versa, the prospects of success of patent litigation proceedings may be one of many aspects taken into consideration, for example when assessing the issue of effects restricting competition. In trying to strike a balance, parts of the guidelines of the CJEU have become slightly vague. Regarding the issue of a relationship of potential competition between the patent holder and manufacturers of generic medicines striving to enter the market, for example, the guidelines state that the competition authorities do not have to assess the certainty of the validity of a patent, or the prospects of success of infringement proceedings, on the one hand, but demand that the authorities have to evaluate the extent to which the manufacturers of generic medicines have real and specific possibilities of entering the market in spite of the existence of the patent on the other hand. Since these two assessments are inevitably interconnected, this can only mean that the competition authorities will indeed have to make assessments with respect to patent law, even if these assessments will be made conservatively, and that other aspects, such as purely factual preparations for a market entry are of similar importance.

With respect to a potential violation of competition law by pay-for-delay agreements, they may, but do not automatically, violate competition law (and be subject to severe fines). In particular, the CJEU decisively bases such a distinction on the purpose for which the manufacturer of originator medicines transferred value to the manufacturer of generic medicines. If there was a real performance in the form of goods or services in return or it is a compensation for procedural costs already paid for, a corresponding agreement might comply with antitrust law. However, the CJEU has not explained in more detail which cases it had in mind in this context; probably, an entirely different type of agreement which pursues a new strategy of dealing with manufacturers of generic medicines and generates real added value for competition and consumers. Even if pay-for-delay agreements are subjected to a makeover, the hurdles for wording them in compliance with antitrust law in the pharma industry seem very high in view of the sensitive market and the considerable effect such agreements have on prices. The question to be answered by manufacturers of originator medicines is: For which reasons in compliance with competition law should a manufacturer of generic medicines accept a pay-for-delay agreement, thus refraining from entering a lucrative market, if no transfer of value takes place in return?