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The EU Court of Justice clarifies the conditions under which 'pay-for-delay' agreements preventing generic versions of a patented medicine from entering the market or delaying such entry may constitute a restriction of competition 'by object' or 'by effect" as well as an abuse of dominant position *(Generics - UK)*

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On 30 January 2020, the Court of Justice of the EU ('CJEU') ruled on the applicability of competition law to settlement agreements between a holder of a pharmaceutical patent and manufacturers of generic medicines. In a judgment issued only a week after Advocate General Kokott delivered her Opinion [***1***], the CJEU clarifies the conditions under which 'pay-for-delay' agreements preventing generic versions of a patented medicine from entering the market or delaying such entry may constitute a restriction of competition 'by object' or 'by effect" as well as an abuse of dominant position.

I. The parties

GlaxoSmithKline plc ('GSK') is one of the world's largest multinational pharmaceutical companies. The other parties to the dispute are pharmaceutical companies producing generic drugs ('generic manufacturers') namely Generics UK ('GUK'), currently trading as Mylan, and Alpharma, composed of Alpharma LLC, Xellia ApS and Actavis UK.

II. The facts

GSK is the holder of a patent for the active pharmaceutical ingredient of the anti-depressant medicine paroxetine, a prescription-only drug marketed in the UK by GSK under the brand name 'Seroxat'. Following the expiry of GSK's principal patent in 1999, several generic manufacturers such as IVAX, GUK and Alpharma tried to enter the UK market for generic paroxetine. Consequently, GSK brought infringement proceedings against these generic manufacturers while the latter challenged the validity of one of GSK's secondary patents protecting the process to produce the medicine. GSK and the generic manufacturers thereafter entered into settlement agreements whereby the generic manufacturers essentially agreed to abstain from entering the market with the generic version of paroxetine for a certain period in exchange of financial compensation from GSK.

On 12 February 2016, the British Competition and Markets Authority ('CMA') imposed fines of £44.99 million on GSK and the generic manufacturers for entering into anticompetitive agreements (Art. 101 TFEU). The CMA also found that GSK had abused its dominant position on the market for paroxetine by entering into patent settlement agreements (Art. 102 TFEU).

In March 2016, GSK and the generic manufacturers appealed the CMA's decision to the Competition Appeal Tribunal ('referring court'), which decided to refer questions for a preliminary ruling to the CJEU.

In substance, the referring court asked the CJEU whether 'pay for delay' agreements between a patent holder and generic manufacturers amount to a restriction of competition 'by object' or 'by effect' pursuant to Art. 101 TFEU. Guidance was also sought on whether such agreement may constitute a simultaneous infringement of Art. 102 TFEU.

III. The judgment

Are patent holder and generic manufacturers potential competitors? The CJEU first recalled that Art. 101 TFEU only applies to agreements between parties which are in competition with each other (if not in reality, then at least potentially). The CJEU therefore assessed whether a patent holder and generic manufacturers not yet in the market may be regarded as potential competitors.

According to the Court, such assessment must be carried out having regard to the structure of the market and the economic and legal context within which it operates. With respect to the pharmaceutical sector, the CJEU identifies several factors to be considered when evaluating the existence of a relationship of potential competition. It should first be determined whether, at the time of the conclusion of the agreement, the generic manufacturers had taken '*sufficient preparatory steps to enable it to enter the market concerned within such a period of time as would impose competitive pressure on the manufacturer of originator medicines*' (§43). Sufficient preparatory steps include measures taken by the generic manufacturer to enter the market with the generic medicine, such as, *inter alia* obtaining the required market authorizations ('MA'), ensuring adequate stock or legally challenging process patents.

Second, the referring court must determine whether the market entry of the generic manufacturer '*does not meet barriers to entry that are insurmountable*' (§45). The CJEU holds that the mere existence of a (process-)patent cannot as such be seen as an insurmountable barrier, since their validity can be challenged. In the CJEU's opinion, the existence of a dispute between a patent holder and generic manufacturers could even constitute evidence of the existence of a potential competitive relationship between them (§52). Even a granted interim injunction prohibiting the generic manufacturer to enter the market would not prejudge the merits of an infringement action and therefore does not hinder potential competition (§53).

The CJEU further identifies additional factors to be considered as a firm intention and an inherent ability to enter the market. In line with previous case law [*2*], the conclusion of an agreement between undertakings operating at the same level in the production chain constitutes a strong indication that a competitive relationship existed (§55). The intention of the patent holder to make a transfer of value to the generic manufacturer to delay its entry into the market should also be taken into consideration (§56). In the case at hand, the CJEU holds that patent holder and generic manufacturers are deemed to be potential competitors.

Restriction of competition 'by object'? It follows from the CJEU's settled case-law that the concept of restriction of competition 'by object' is only applicable to forms of coordination which reveal a sufficient degree of harm for competition, such that there is no need to examine their effects. This judgment clarifies however the conditions under which a 'pay-for-delay' agreement may be regarded as a restriction 'by object'. To this end, the CJEU stresses the importance of the agreements' background. In that regard, agreements bringing to an end entirely fictious disputes, or designed with the sole aim of disguising a market-sharing agreement or a market-exclusion agreement must be characterized as restrictions of competition 'by object' (§76). However, the CJEU states that the fact that a settlement agreement involves a transfer or value (pecuniary or not) from the manufacturer of the originator medicine to the generic manufacturer is not sufficient to classify the agreement as a restriction of competition 'by object'. A transfer of value may be justified and even appropriate and necessary to pursue the legitimate purpose of both parties (e.g. a compensation for the costs of the litigation between them or a remuneration for the actual supply of goods and services (§§85,86)). Settlement agreements have a sufficient degree of harm to be characterized as a restriction of competition 'by object' when the transfer of value '*cannot have any explanation other than the commercial interest of both the holder of the patent and the party allegedly infringing the patent not to engage in competition on the merits*' (§87). What matters therefore is that the net gain arising from the transfers 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 with the manufacturer of originator medicines concerned'* (§§93, 94).

In the CJEU's opinion, if these conditions are met, settlement agreements may be regarded as a restriction of competition 'by object' unless they are *'accompanied by proven pro-competitive effects capable of giving rise to a reasonable doubt that it causes a sufficient degree of harm to competition*' (§111). Such pro-competitive effects must be demonstrated, relevant and specifically related to the agreement at issue, but should also be significant enough to justify a reasonable doubt on the anticompetitive object of the agreement (§§105, 107).

…or restriction of competition 'by effect'? If the agreements such as those at issue do not reveal a sufficient harm to competition to amount to a restriction 'by object', it is still necessary to assess the existence of potential or real effects on competition. Rather than identifying elements which demonstrate the existence of a restriction 'by effect', the CJEU stresses two elements that *cannot* presuppose such finding: (i) the probability of the generic manufacturers concerned being successful in the patent proceedings or (ii) the finding that the parties to the agreement could probably have concluded a less restrictive settlement agreement. The referring court should not take those elements into consideration when establishing whether the settlement agreements have appreciable or real effects on competition (§121).

Abuse of dominant position. Addressing the questions in relation to an infringement of Art. 102 TFEU, the CJEU first states that generic drugs (of a patent-protected medicine) not yet in the market should be taken into consideration for the purpose of defining the relevant product market. This inclusion is however subject to the generic manufacturers being in a position to enter the market within a short period of time and with sufficient

strength, thereby constituting a serious counterbalance to the patent holder that is already active on that market (§133). This is the case if generic manufacturers have put in place prior effective strategies and taken legal steps to achieve the market entry, such as obtaining a MA for the generic product (§134).

With regards to the existence of an abusive conduct, the CJEU observes that the dominant position held by an undertaking does not prevent it from taking reasonable steps to protect its own commercial interests (e.g. the exercise of intellectual property rights) (§149). In the case at hand, the CJEU recognizes that patent holders could put an end to a dispute by concluding settlement agreements, without infringing Art. 102 TFEU. However, the use of such agreement can constitute an abuse of dominant position if the party engaging in it does so to strengthen and abuse its dominant position, as it would deprive potential competitors of effective access to the market (§151). More specifically, in order to be characterized as abusive, settlement agreements have *'a capacity to restrict competition and, in particular, to have exclusionary effects, going beyond the specific anticompetitive effects of each of the settlement agreements that are part of that strategy'* (§172). According to the CJEU, such strategy has a significant foreclosure effect as it deprives consumers of the benefits of generic medicines and reserves the market to the manufacturer of the originator medicine. Anti-competitive effects may nonetheless be counterbalanced by efficiency gains claimed by the dominant undertaking. The CJEU concludes in this regards that those pro-competitive effects should be taken into account regardless of the objectives pursued by the dominant undertaking (§168).

IV. Comment

Aside from being the first ruling on patent settlement agreements, this judgment is particularly interesting because it clarifies several key aspects of competition law, such as the notion of potential competitors, the market definition for generic medicines and more importantly, the way to assess settlement agreements under competition law rules (both Art. 101 and 102 TFEU).

Yet, with respect to the definition of potential competitor, the CJEU's approach appears too broad, as there may be cases where the generic manufacturer complies with all the criteria set out by the CJEU without however having a real incentive to enter the market. As the MA is an indicator of a firm intention to enter the market, the undertakings may not be able to demonstrate such intention through other means.

In addition, the CJEU gives little guidance on the assessment of pro-competitive effects that are capable of calling into question the existence of a sufficient degree of harm. It is for instance not clear under which circumstances pro-competitive effects can give rise to a 'reasonable doubt' on the anticompetitive object of the agreement. Pharmaceutical companies might therefore face greater difficulties in providing justification for their anticompetitive behavior.

The ruling also highlights the interplay of competition and intellectual property law. When protecting their intellectual property right, patent holders should pay due attention to competition law. The conclusion of settlement agreement may be seen as a means to put an end to long and costly proceedings, but competition law rules still apply. As a result, the undertakings concerned may decide to steer clear of settlement agreements to avoid the risk of running into a breach of competition law rules and decide instead to challenge the validity of the patents.

The CJEU will hopefully give more guidance regarding the above issues in its upcoming judgments in the *Lundbeck* ***[3]*** and *Servier* ***[4]*** cases, which are also dealing with patent settlement agreements.

[1] Opinion delivered on 22.01.2020; EU:C:2020:28, *http://curia.europa.eu/juris/document/document.jsf?text=&docid=222521&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=2441121* ↗.

[2] {} *Toshiba Corporation,* C-373/14 P, EU:C:2016:26, para. 33-34.

[3] *Lundbeck*, C-591/16 P (4th plea of appeal pending of the judgement of the General Court T-472/13).

[4] *Servier*, C-176/19 P and C-201/19 P (2nd plea of the latter appeal pending of the judgement of the General Court T-691/14).