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ECJ Ruling on *Paroxetine*

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On January 30, 2020 (just sneaking in before Brexit), the European Court of Justice ruled in *Paroxetine*, confirming the narrow interpretation of restrictions by object. It also clarified certain issues relating to patent settlement agreements, while leaving a number of questions to be decided in other cases. The Court of Justice's ruling confirms that the analysis of each patent settlement is highly fact-specific, according to the individual context of the agreement.

Background

1. The 2016 CMA Fine

In February 2016, the Competition and Markets Authority ("CMA") imposed fines totaling £44.99 million on GlaxoSmithKline ("GSK"), Alpharma Limited and Generics (UK) Limited (the "generic manufacturers") for entering into patent settlement agreements with respect to the drug paroxetine (the "CMA Decision").[2] Paroxetine, which GSK sells under the brand name Seroxat, is a prescription-only medicine used to treat depressive and anxiety-related disorders.

The agreements concerned the pausing of court proceedings between GSK and Alpharma, and GSK and Generics (UK), relating to a GSK patent for a process of producing a form of paroxetine. Under those agreements, the generic manufacturers agreed not to market their generic versions of paroxetine for the term of the agreement, and in return GSK (i) made payments to the generic manufacturers, and (ii) sold the generic manufacturers quantities of paroxetine that they would then distribute. Thus, the agreements caused the arrival of generic paroxetine on the market to be delayed in return for payments made by GSK (which is why the agreements are sometimes known as "pay for delay"). They were not complete settlements of the litigation, as the Advocate General noted, they only "*deferred resolution of the disagreement … until after the expiry of the agreements.*"[3]

The CMA found that these agreements breached Article 101 of the Treaty on the Functioning of the European Union ("TFEU") and the equivalent prohibition under Chapter I of the Competition Act 1998 ("CA98").[4] The CMA also found that GSK held a dominant position in the market for paroxetine, and abused that position (contrary to the prohibition in Chapter II of the CA98), by entering into agreements with the generic manufacturers (and a third company, IVAX, which had also intended to launch a generic version of paroxetine).[5]

2. CAT Appeal and Referral to the ECJ

In April 2016, GSK and the generic manufacturers all appealed the CMA Decision to the Competition Appeal Tribunal ("CAT"). In March 2018, it handed down a preliminary judgment but decided that in order to make a final ruling it would refer a number of questions to the European Court of Justice ("ECJ") for a preliminary ruling.[6] We focus below on five of the issues considered by the ECJ:

(a) Whether the generic manufacturers could be considered potential competitors of GSK for the manufacture of paroxetine in the period concerned;

(b) Whether the agreements constituted a restriction of competition "by object";

(c) The approach to be taken when considering whether the agreements constituted a restriction of competition "by effect";

(d) The appropriate approach to product market definition for paroxetine for the purposes of assessing whether GSK has abused a dominant position; and

(e) Whether a strategy consisting of the conclusion of series of settlement agreements in cases such as these could constitute abuse of a dominant position.

Advocate General Kokott delivered her 80-page opinion analyzing the case on January 22, 2020. No doubt with Brexit in mind, the ECJ issued its ruling only 8 days later – which must be record timing for a complicated case like this.[7]

The ECJ Ruling

3. Are Generic Manufacturers Competitors?

The settlement agreements had the effect of temporarily preventing the generic manufacturers from launching generic versions of paroxetine. The CAT's question to the ECJ was whether the generic manufacturers could still be considered potential competitors to GSK for the supply of paroxetine, despite the fact that their ability to enter the market for paroxetine was subject to the outcome of the court proceedings relating to the validity of the patent. The case was argued on the basis that the result of the patent proceedings was impossible to predict (as noted by the referral court) and accordingly that the generic manufacturers could not be characterized as potential competitors as it was impossible to know whether the generic manufacturers had real concrete possibilities to enter the market.[8]

The ECJ held that the relevant test is whether there were a real and concrete possibility of the generic manufacturers entering the market and competing with undertakings on that market if the relevant settlement agreement had not been concluded, thus confirming the position set out in classic case law such as *Delimitis*.[9]

The Court noted that this test meant that potential competition could not be inferred merely from the purely hypothetical possibility of such entry nor from the mere wish or desire of the generic manufacturer to enter the market.[10] Conversely, there was no need to show that it was certain that the generic manufacturers would in fact enter.[11] The Court ruled out both extremes, while indicating that the assessment of potential competition had to be carried out having regard to the structure of the market, including the specific features of the pharmaceutical sector, the relevant economic and legal context, and the facts of the specific case.[12]

The ECJ noted the existence of regulatory constraints in the pharmaceutical sector, notably the need for a marketing authorization, as well as the existence of patents, which the Court said should be accorded a high level of protection.[13]

The first point to consider when analyzing potential competition was whether a generic manufacturer 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.[14] Such steps could include measures taken to gain marketing authorizations, assembling adequate stocks of the generic, and taking legal steps — including steps to challenge the process patents held by the patent-holder.

Ultimately what needs to be shown is that the generic manufacturer had a firm intention and an inherent ability to enter the market.[15]

The second element to consider was whether the existence of a process patent could be considered an insurmountable barrier to entry. Here, the Court disagreed with the argument that, since the patent dispute had not been decided, the patent had to be presumed valid, and thus constituted an absolute bar to the generic manufacturers entering the market.[16] Whilst the ECJ held that the existence of patent rights is part of the relevant legal and economic context, it ruled that competition authorities are not obliged to conduct a review of the strength of the patent rights and to make an assessment of the probability of who would have won the patent dispute absent the settlement.[17]

The appropriate approach was whether the generic manufacturer, notwithstanding the existence of the patent, had real and concrete possibilities of entering the market at the relevant time,[18] and listed a number of relevant factors that should be taken into account in this assessment.[19] These included: that there is no presumption of infringement; the fact that challenges to patent validity and entry "at risk" by generic manufacturers are common in the sector; the absence of patent linkage (i.e. the grant of a marketing authorization to a generic manufacturer does not take account of patent infringement); and the fact that potential competition may exist before the expiry of a compound patent, as generic manufacturers want to be ready to enter the market as soon as the patent expires.[20]

The ECJ also noted that the genuineness of the patent litigation could be taken as evidence that there is a potential competitive relationship.[21] In addition, the existence of a value transfer to the generic manufacturers could be an indication of potential competition. The greater the size of the value transfer, the stronger the indication that there is potential competition.[22]

Overall, the Court's judgment reconfirms that the test to determine whether a potential entrant is an incumbent's competitor is whether the potential entrant had "*real and concrete possibilities*" of entering the market. While an authority need not conduct a mini patent trial itself, the existence of patents is part of the legal and factual context in which the real and concrete possibilities need to be analyzed.[23]

4. Restrictions "By Object" or "By Effect"?

A. What Are the Limits for a "By Object" Classification?

The Court was also asked to consider whether the settlement agreements constituted agreements that had as their object the prevention, restriction or distortion of competition, contrary to Article 101(1) TFEU.

The classification of an agreement as a restriction of competition "by object," rather than "by effect," means that a competition authority does not need to demonstrate any actual or potential negative effects on the market due to the agreement. Rather, the mere existence of such an agreement constitutes a restriction of competition that contravenes Article 101(1) TFEU.

The Court's judgment is important for the broad principles that it sets out about the difference between restriction by object and by effect, which follow the modern case law, including *Cartes Bancaires* and *Maxima Latvija*.[24] The Court also accepted (following

Advocate General Kokott) that the pro-competitive effects of an agreement could prevent it being a restriction by object where they were such as to give rise to a reasonable doubt as to whether the agreement caused a sufficient degree of harm to competition to constitute a by-object restriction.[25] This is also in line with the Opinion of Advocate General Wahl in *Cartes Bancaires*, who said that agreements having ambivalent effects on competition should not be qualified as restrictions by object.[26]

The concept of a restriction by object must be interpreted strictly. It only applies to conduct which is by its very nature harmful to competition. Experience is one relevant factor here. As is the content of the relevant provisions and their objectives, judged in the light of the economic and legal context of which they form part. When examining context, the real conditions of the functioning and structure of the market in question must be taken into account.[27]

Having discussed the context of the specific agreements and the characteristics of the sector as a whole, the ECJ noted that an agreement to settle patent infringement proceedings could not automatically be considered a restriction by object, even where the agreement entailed a value transfer from the originator to the generic.[28] The ECJ noted that such value transfers could be justified, appropriate, or necessary in light of legitimate objectives of the agreement.[29] This could be the case where the value transfer corresponded to costs incurred because of the litigation or the value of goods or services supplied by the generic manufacturer to the originator.[30]

However, where it was plain from the analysis of the agreement that the value transfers could not have any explanation other than as a reflection of the commercial interests of the parties not to engage in competition, the agreement would restrict competition "by object."[31] In light of the principle that a by-object restriction must be interpreted narrowly, the Court was careful to limit this to clear cases, where there is no other explanation.[32] The Court gave an example where the sole consideration for a settlement was a substantial payment, with no other plausible explanation for the settlement – notably not the perception of the patent strength or other factors inducing the generic manufacturer to settle, then that settlement agreement would be a restriction by object.[33] This apparent attempt to limit the qualification of restriction by object may reflect the fact that there is no prior experience showing that any settlement agreement with a value transfer displays a sufficient degree of harm to competition, unless the value transfer to the generic has no other explanation than buying off competition. In this context, the value transfer must have acted as a clear inducement – in other words, it had to cause the generic manufacturer to refrain from entering the market.[34]

The Court rejected the "scope of the patent" test as being the limit of by object restrictions.[35] Nor did the fact that there was uncertainty as to the validity of the patent prevent a settlement from being a by object restriction.[36]

B. Were the Settlement Agreements Restrictions "By Effect"?

Discussion of by effect restrictions is brief, due to the very narrow question asked by the referring court. The CAT had asked the ECJ for guidance on whether, in order to find a restriction "by effect," it needed to be shown that there was more than a 50 percent chance that, in the counterfactual scenario, the generic would have prevailed in the patent dispute or that there would have been a less restrictive form of settlement.[37]

The ECJ answered that the referring court did not need to make a finding as to the precise mathematical probability of one side or another winning a patent case, or that a less restrictive form of a settlement could have been found.[38]

While the counterfactual analysis could take into account the chances of the generic manufacturer winning the patent case, this was just one of the factors to be taken into account in order to determine the likely structure of competition, if the agreement were not concluded. When assessing effects, competition should be assessed within the actual context in which it would occur absent the agreement – in other words, a realistic counterfactual, not a hypothetical or abstract scenario. [39]

The ECJ added (thus confirming a point made by Advocate General Kokott) that the effects also need to be sufficiently appreciable.[40] While the judgment does not provide much guidance on this aspect, it can be inferred from the opinion of Advocate General Kokott that attempts by other generic firms to enter the market, the existence of other litigation, as well as the existence of other settlements (and their cumulative effects on competition or lack thereof) are all relevant when assessing whether the effects of a given settlement agreement on competition are appreciable. Indeed, the General Court in the *Servier* case examined the effect of one settlement agreement *inter alia* in light of other on-going litigations and attempts by other generic firms to enter the market. In essence, the General Court concluded that the Commission had not shown that the agreement in question had had any appreciable effect on competition when analyzed in its proper context.

5. Defining the Market

The CAT had asked whether, for the purposes of defining the market for paroxetine, the generic products should be taken into account even though they could not lawfully enter the market before the expiry of the patent (on the uncertain assumption that the patent was valid and infringed by the generic products). The narrowness of the question meant that the ECJ was not asked to consider a broader question of how pharmaceutical markets should be defined. The ECJ thus considered only whether, in circumstances where an originator drug no longer had the protection of a molecule patent but had a process patent of uncertain validity, generic versions of the drug should be taken into account when defining the relevant market. The Court's answer was thus rather short.

The ECJ found that the existence of a process patent did not preclude generic products being part of the relevant market, because a process patent (unlike a molecule patent) could not offer certainty that a generic version of the originator's product could not enter the market.[41]

The ECJ said that the key was to apply the traditional criteria on market definition, namely whether there was a sufficient degree of interchangeability between the originator and the generic medicines.[42] In the pharmaceutical sector, the views of healthcare professionals clearly play an important role, something the ECJ confirmed when it said the test was whether the products were considered interchangeable "*in the professional circles concerned.*"[43]

The ECJ also noted that the generic manufacturers had to be in a position to put their products on the market within a short period and "*with sufficient strength to constitute a serious counterbalance*" to the originator medicine.[44] The Court highlighted certain

factors that might point to a generic being in such a position, such as having applied for a marketing authorization and concluded supply contracts with distributors.[45]

6. Are Settlement Agreements Considered an Abuse of a Dominant Position?

Lastly, as regards the notion of abuse, the ECJ was asked to rule on whether a strategy consisting of the conclusion of a series of patent settlements, including some agreements which had not been found in breach of Article 101 TFEU (here, the GSK/Ivax agreement), could constitute an abuse of a dominant position.

The ECJ found that this could be the case, where the overall strategy was capable of restricting competition and of producing exclusionary effects going beyond the specific anticompetitive effects of the individual agreements.[46]

The ECJ's conclusions rest largely on the CAT's finding of the existence of a strategy that had, if not as its object, at least the effect of delaying generic entry. According to the CAT, the effect of the strategy as a whole was liable to exceed the effects of the individual agreements.[47] This finding appears to justify, in the ECJ's eyes, that the concept of abuse of a dominant position could encompass agreements that, although they did not breach Article 101 TFEU, contributed to the cumulative anti-competitive effects of the other agreements.[48]

Final Thoughts

The judgment is probably most important for what it says about the broad principles involved in assessing whether an agreement is an infringement by object under Article 101 TFEU. The Court has followed recent cases like *Cartes Bancaires* and *Maxima Latvija* and said that restrictions by object must be interpreted restrictively and limited to situations where experience or the context shows that the agreement will cause a sufficient degree of harm competition. The Court also follows Advocate General Bobek in *Budapest Banks* and Advocate General Kokott in this case, in finding that if an agreement may give rise to pro-competitive effects then this may prevent it being designated as a restriction by object.

The ECJ also gave some clarification on how the concepts of restriction by object and potential competition apply in the pharma sector. In a preliminary ruling, the ECJ does not make any assessment of the underlying facts but rather responds to the questions of law posed to it in the context of the dispute before the national court. Therefore, the findings are necessarily limited by the facts of the case as found by the national court (e.g. that these were not settlements, but just a deferred resolution of the dispute) and the specific questions posed (e.g. the focus on whether a competition authority had to decide what the chances were of one side winning a hypothetical patent dispute).

The judgment is especially limited in scope in its discussion of market definition and restrictions by effect due to the narrowness of the referring court's questions. Thus, the judgment offers limited insights on these topics. The upcoming judgment in the *Servier* case will hopefully provide more clarity.

[1] The authors are lawyers in the Brussels and London offices of White & Case LLP. The views expressed in this article are personal and do not necessarily represent those of the firm or any of its clients.

[2] Case CE-9531/11 – *Paroxetine*, Decision of the Competition and Markets Authority, February 12, 2016; no fine was imposed on IVAX Pharmaceuticals UK Limited as the GSK / IVAX agreement was found to constitute a vertical agreement, which was excluded from the remit of Chapter I of the CA98 at the time of the behavior complained of.

[3] Case C-3017/18 *Generics (UK) Ltd and Others v.* CMA, Opinion of Advocate General Kokott ("AG Opinion"), §135.

[4] CMA Decision, §1.14.

[5] CMA Decision, §§1.20, 4.100 and 8.36.

[6] *Paroxetine GSK v. CMA* [2018] CAT 4 ("CAT Decision").

[7] Case C-307/18 *Generics (UK) and others v CMA (Paroxetine)* (the "ECJ Decision").

[8] See, e.g. AG Opinion, §§64-65.

[9] ECJ Judgment, §36; Case C-234/89 *Delimitis*, EU:C:1991:91.

[10] ECJ Judgment, §38.

[11] *Ibid.*

[12] ECJ Judgment, §§39-40.

[13] ECJ Judgment, §41.

[14] ECJ Judgment, §43.

[15] ECJ Judgment, §44.

[16] ECJ Judgment, §49.

[17] ECJ Judgment, §50.

[18] *Ibid.*

[19] ECJ Judgment, §51.

[20] *Ibid.*

[21] ECJ Judgment, §52.

[22] ECJ Judgment, §56.

[23] ECJ Judgment, §50.

[24] Case C-67/13 P *Groupement des Cartes Bancaires v Commission*, EU:C:2014:2204 (*"Cartes Bancaires"*) and Case C-345/14 *Maxima Latvija,* EU:C:2015;784.

[25] ECJ Judgment, §§103-107.

[26] Case C-67/13 Opinion of AG Wahl in *Cartes Bancaires*, §56.

[27] ECJ Judgment, §§66-67.

[28] ECJ Judgment, §§84-85.

[29] ECJ Judgment, §85.

[30] ECJ Judgment, §86.

[31] ECJ Judgment, §87.

[32] *Ibid.*

[33] ECJ Judgment, §89.

[34] ECJ Judgment, §§93-94.

[35] ECJ Judgment, §97.

[36] ECJ Judgment, §§98-100.

[37] ECJ Judgment, §113.

[38] ECJ Judgment, §119.

[39] ECJ Judgment, §§115-116, 118 and 120.

[40] ECJ Judgment, §117. See also AG Kokott at §203 *et seq*.

[41] ECJ Judgment, §§137-9.

[42] ECJ Judgment, §132.

[43] ECJ Judgment, §131.

[44] ECJ Judgment, §133.

[45] ECJ Judgment, §134.

[46] ECJ Judgment, §172.

[47] ECJ Judgment, §157.

[48] ECJ Judgment, §§155-160.