



CPI EU News Presents:

Paroxetine – The EU Court of Justice Rules on Pay-For-Delay Settlements for the First Time

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Introduction

While we are still awaiting the judgments in the pending appeals on pay-for-delay settlements in *Lundbeck*² and *Servier*,³ the Court of Justice of the European Union was faster in answering the preliminary reference by the UK Competition Appeal Tribunal (“CAT”) in Case C-307/18 *Paroxetine*. The judgment came out on January 30, 2020. A just-on-time delivery before Brexit.

A pay-for-delay settlement refers to an agreement in which a transfer of value (e.g. a large sum of money) takes place from a patent owner (the manufacturer of the originator medicine) to a generics manufacturer for which the generics manufacturer delays market entry in return. Pay-for-delay settlements can give rise to antitrust concerns and have been investigated by competition authorities on both sides of the Atlantic.⁴ Antitrust scrutiny has focused in particular on pay-for-delay settlements in the pharmaceutical sector.⁵

National Proceedings

The *Paroxetine* case concerns a range of settlements entered into by GlaxoSmithKline (“GSK”) with several generics producers in regard of the antidepressant paroxetine. When GSK entered into the settlements in question, the patent in the active ingredient of paroxetine had expired, but GSK continued to hold process patents for manufacturing the drug. Entry into the market for paroxetine was thus possible for generics companies, as long as they did not infringe GSK’s process patents. In addition, proceedings were pending which challenged the validity of GSK’s process patents.

Generics UK (“GUK”) and Alpharma, two generics companies, had both undertaken steps to enter the market for paroxetine. Those efforts were interrupted by GSK, by suing them for infringing its process patents. In response, the generics manufacturers claimed that GSK’s patents were invalid. Before the patent proceedings were concluded, GSK offered payments to both generics companies for not further pursuing their invalidity claims and for not making, importing, or supplying generic versions of Paroxetine in the UK. In addition, GSK arranged agreements between the generics companies and its sole distributor of Paroxetine for the UK, IVAX. Under these agreements, IVAX would supply GUK and Alpharma with a certain amount of paroxetine, which the generics companies could sell in the UK, and which came with a profit guarantee. The generics companies had the option to terminate these agreements in the event of the formation of a generic market. The agreements thus covered two aspects: the settlement of the patent disputes together with the delay of generic entry.

The UK Competition and Markets Authority adopted a decision in 2016 which found that GSK had abused its dominant position in the market for paroxetine by entering into the above-mentioned agreements in contravention of national competition rules. In addition, the CMA found that the agreements between GSK and the generics companies infringed Article 101 TFEU and its national equivalent. The CMA went on to impose GBP 44.99 million in fines against the companies involved, which led to an appeal to the CAT.

In order to hand down the judgment in the appeal proceedings, the CAT referred 10 questions to the Court of Justice in order to clarify the interpretation of EU competition law and the parallel national competition provisions in the Competition Act 1998.⁶ The questions revolved around five issues: (i) the concept of potential competition, the interpretation of restriction of competition (ii) by object and (iii) by effect, (iv) market definition, and (v) the concept of abuse.

The Judgment

As this was a preliminary reference procedure, the Court of Justice only gave interpretative guidance (in contrast to appeal proceedings from the General Court in which the Court of Justice decides the case) and left the final assessment to the CAT. The Court followed the Opinion of Advocate General Kokott delivered on January 22, 2020.

(I) Potential Competition

In order to find an infringement of Article 101(1) TFEU, coordination must take place between undertakings which are, at least potentially, in competition with each other.⁷ The question in this case was whether the generics companies could be considered as potential competitors to GSK without having entered into the market (due to the settlements), in particular given that there was genuine uncertainty as to the validity of GSK's process patents, and patents in the active ingredient had expired.

The Court found that this question had to be answered with regard to the structure of the market in question and its legal and economic context,⁸ in this case the pharmaceutical sector and its regulatory constraints (including the need for market authorization before placing a medicine on the market).⁹ Full account also had to be taken of the IP rights in question, in this case GSK's process patents.¹⁰ The Court held that in the circumstances, the generic companies could be considered potential competitors of the originator company where it was established that they had "the firm intention and an inherent ability to enter the market."¹¹ Such intention and ability could be deduced from a variety of factors, including that the generic companies had undertaken sufficient preparatory steps to enter the market in the form of requesting market authorization, challenging the process patents in question, or engaging in marketing initiatives.¹² In addition, there should be no "barriers to entry that are insurmountable" for the generic companies.¹³ A process patent protecting the manufacturing process of an active ingredient that was in the public domain could not be considered to be an insurmountable barrier to entry as such,¹⁴ irrespective of the likelihood of it being declared invalid in ongoing patent proceedings.¹⁵ Lastly, the originator company's willingness to transfer value in exchange for delayed entry could be an additional indication that there was potential competition from the generic companies.¹⁶

(II) By-object Restriction of Competition

The longest part of the judgment is dedicated to the question whether the settlements in question fell into the “by object” category of restrictions of competition under Article 101 (1) TFEU. The Court reiterated that the category of by object restrictions of competition is to be interpreted strictly and in the context of the actual conditions of the market in question.¹⁷ In respect of the pharmaceutical sector, the Court noticed that pricing of pharmaceuticals in the UK is strictly controlled by legislation and heavily influenced by generic entry, which usually leads to a radical fall in sales prices for medicines.¹⁸

The Court held that the part of the settlements bringing the patent disputes in questions to and end could not be considered a disguised market-sharing or market-exclusion agreement, which would clearly be considered a restriction of competition by object, because the patent disputes were genuine.¹⁹ Neither did the fact that there was a transfer of value from the originator company to the generic company lead to an automatic classification of the agreement as restriction of competition by object.²⁰ Such settlements could only be considered a restriction of competition by object if they had no “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.”²¹ In order to assess whether this was the case, all transfers of value made between the parties had to be analyzed individually to determine whether overall transfer of value incentivized the generics company to refrain from entering the market and not to compete on the merits.²² The fact that the settlement did not go beyond the scope of patent was not relevant to the assessment of whether there was a restriction of competition by object.²³

Lastly, the Court held that pro-competitive effects can be taken into account to establish whether there is restriction of competition by object.²⁴ Positive effects must be demonstrated, relevant and specifically related to the agreement in order to preclude the finding of a by-object restriction.²⁵ In this case, the Court deemed this unlikely, since the pro-competitive effects from the settlements in question seemed minimal and uncertain.²⁶

(III) By-effect Restriction of Competition

The Court went on to analyze whether the settlements in questions could restrict competition by effect, should they be considered not sufficiently harmful as to amount to restrictions of competition by object. The question in this respect was about constructing the counter-factual, i.e. the competitive situation that would have existed in the absence of the settlements. Were the likelihood of success in the invalidity proceedings against the process patents or the possibility of concluding a less restrictive settlement between the parties determinative in the establishment of the counter-factual? The Court answered this question in the negative. These possible scenarios were only some factors among many to be taken into account when establishing the counter-factual in order to determine the existence of appreciable effects on competition by the settlements.²⁷

(IV) Definition of the Relevant Market

As the case also concerned the allegation that GSK had abused its dominant position by concluding the settlement agreements, the CAT also referred a question relating to the definition of the relevant market in order to determine whether GSK was dominant. In particular, the CAT inquired whether generic medicines should be included in the relevant product market of the patented medicine, given that the patent in the active ingredient had expired, but the process patents continued to be valid. Unsurprisingly, the Court's analysis ran in parallel to its analysis on potential competition. According to the Court, the generic and originator versions of the medicine could be considered to be substitutes, and thus be included in the product market definition, if the generic manufacturers could enter the market immediately or within a short period.²⁸ The Court mentioned the same factors as those determining whether there was potential competition to decide whether the generic versions should be included in the scope of the relevant product market.²⁹

(V) Abuse

Lastly, the Court was asked whether GSK's overall strategy to conclude agreements with the generics manufacturers and its sole UK distributor, which had the effect to keep generics companies temporarily outside the market, could amount to an abuse of dominance.³⁰ The Court clarified, first, that the exercise of an exclusive right linked to an intellectual property right, such as the conclusion of a settlement in a patent litigation, could not in itself constitute an abuse.³¹ By reference to the special responsibility of dominant undertakings not to impair genuine competition under EU competition law, however, such conduct could be an abuse if it deprived potential competitors of effective access to a market.³² For such an abuse to be established, it was necessary to show that the conduct was capable of producing exclusionary effects.³³ Based on the information provided by the CAT that GSK's settlements and agreements had delayed the generic entry, and thus impeded the fall of prices for paroxetine on the UK market to the detriment of the National Health Service and final consumers, the Court found that GSK's contract-oriented strategy had anticompetitive effects. In addition, the Court found that the intent of the dominant undertaking, while not determinative, could be taken into account to determine whether there was an abuse.³⁴

Lastly, the Court mentioned that it was open to GSK to provide an objective justification of its behavior. By reference to its *Intel* judgment,³⁵ the Court found that to assess whether the conduct was justified entailed the balancing of pro- and anticompetitive effects of the practice in question.³⁶ The efficiency gains, for example, from the exclusive distribution agreement between IVAX and GSK, even if accidental, could positively factor into such balancing.³⁷ In this case, however, those were unlikely to counterweigh the negative effects from delaying generic entry.³⁸

Comment

The *Paroxetine* judgment is a dense read. While it provides important guidance for the assessment of pay-for-delay agreements in EU competition law, it also addresses fundamental issues in EU competition law that might have an impact beyond pay-for-delay settlements.³⁹

In respect of pay-for-delay settlements, the judgment is tailored to the specific situation that generic entry was possible as long as GSK's process patents were not infringed. This made the Court's argument that the generics companies were potential competitors more plausible, which is a precondition for finding that patent settlements or payments for delayed entry are contrary to Article 101 TFEU. Whether the same logic applies to a situation in which the active ingredient is still covered by patent is unclear. While the reasoning in *Paroxetine* in relation to by object restrictions of competition could be transferred to a situation in which the product patent for a medicine has not expired yet, it would be less likely that generics manufacturers are considered potential competitors to the originator.

A second conclusion to be drawn from the judgment is that questions regarding the strength or validity of the patent inhibiting generic entry are of no concern to the assessment of the pay-for-delay agreements under Article 101 and 102 TFEU. In this regard, the Court seems to stick to its old case law according to which EU competition law leaves the core of the IP right (its specific subject matter) untouched, while it can limit the exercise of IP rights.⁴⁰ There is thus a clear split between questions of patent validity, which remain in the sphere of patent law, and restrictions of competition arising from the exercise of a patent, which are assessed under competition law.

The judgment also addresses issues that have been part of fundamental debates within EU competition law, especially when it comes to the use of effects-based analysis. Regarding restrictions of competition by object, for example, the Court held that pro-competitive effects could be taken into account under Article 101 (1) TFEU (while the Court was very careful to state that this was not opening the door to US antitrust-style rule of reason analysis).⁴¹ This will be unwelcome news to those that have defended that that pro-competitive effects are only to be analyzed under Article 101 (3) TFEU and are irrelevant for the classification of an anticompetitive practice as restriction of competition by object. Effects were also relevant for the assessment of an objective justification for a conduct that would otherwise be contrary to Article 102 TFEU. In this respect, the Court found that pro- and anticompetitive effects from the conduct needed to be balanced against each other. The more economic approach to EU competition law thus continues to gain ground after *Post Danmark*,⁴² *Cartes Bancaires*,⁴³ and *Intel*,⁴⁴ and *Paroxetine* can be considered a further step in this direction.

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² Appeal Case C-591/16 P *Lundbeck v. Commission*; Judgment by the General Court in T-472/13 *Lundbeck v. Commission* ECLI:EU:T:2016:449.

³ Appeal Cases C-176/19 P *Commission v. Servier and Others* and C-201/19 P *Servier and Others v. Commission*; Judgment by the General Court in T-691/14 *Servier and Others v. Commission* ECLI:EU:T:2018:922.

⁴ In the final results of its Sector Inquiry into the Pharmaceuticals Sector in 2009, the EU Commission found that delays in generic market entry were of particular concern, which could be attributed to instruments used by originator companies, including pay-for-delay settlements. It subsequently started monitoring patent settlements, and initiated several proceedings, including *Lundbeck* (Case AT.39226) Commission Decision of 19 June 2013, *Fentanyl* (Case AT.39685) Commission Decision of 10 December 2013, and *Perindopril* (Servier) (Case AT.39612) Commission Decision of July 9, 2014.

⁵ As Justice Breyer noted in *Actavis*, “[a]pparently most if not all reverse payment settlement agreements arise in the context of pharmaceutical drug regulation.” See *FTC v. Actavis, Inc.*, 133 S. Ct. 2223, 2229 (2013), at 2227.

⁶ The Court of Justice found that, in line with its earlier case law, it had no jurisdiction to interpret national law but that it had “jurisdiction to give a ruling on a request for a preliminary ruling concerning the provisions of EU law in situations where, although the facts in the main proceedings do not fall directly within the scope of that law, the provisions of that law have been made applicable under national law by means of a reference made in national law to their content.” See Case C-307/18 *Generics (UK) and Others (Paroxetine)* ECLI:EU:C:2020:52 at 26.

⁷ Case C-307/18 *Generics (UK) and Others (Paroxetine)* ECLI:EU:C:2020:52 at 37.

⁸ *Id.* at 39.

⁹ *Id.* at 40.

¹⁰ *Id.* at 41.

¹¹ *Id.* at 58.

¹² *Id.* at 44.

¹³ *Id.* at 58.

¹⁴ *Id.* at 46.

¹⁵ The Court made clear that “the assessment of the rights conferred by a patent, to be carried out by the competition authority, must not consist of a review of the strength of the patent or of the probability of a dispute between the patent holder and a manufacturer of generic medicines being brought to an end with a finding that the patent is valid and has been infringed. That assessment must rather concern the question whether, notwithstanding the existence of that patent, the manufacturer of generic medicines has real and concrete possibilities of entering the market at the relevant time.” *Id.* At 50.

¹⁶ *Id.* at 56.

¹⁷ *Id.* at 67-68.

¹⁸ *Id.* at 69.

¹⁹ *Id.* at 76.

²⁰ *Id.* at 85.

²¹ *Id.* at 87.

²² *Id.* at 94.

²³ *Id.* at 97.

²⁴ *Id.* at 103.

²⁵ *Id.* at 107.

²⁶ *Id.* at 108-109.

²⁷ *Id.* at 120.

²⁸ *Id.* at 134.

²⁹ The Court follows the exact reasoning of its part on potential competition in paragraphs 134-136.

³⁰ The Court referred to its previous case law noting that the same practice may give rise to an infringement of both Articles 101 and 102 TFEU. Case C-307/18 *Generics (UK) and Others (Paroxetine)* ECLI:EU:C:2020:52 at 146.

³¹ *Id.* at 150. Not the parallel that the conclusion of such an agreement could also not in itself constitute a restriction of competition by object under Article 101 (1) TFEU.

³² *Id.* at 151-153.

³³ *Id.* at 154.

³⁴ *Id.* at 162.

³⁵ Case C-413/14 P *Intel v. Commission* EU:C:2017:632

³⁶ *Id.* at 167.

³⁷ *Id.* at 170.

³⁸ *Id.* at 171.

³⁹ This is also noted by Pablo Ibañez Colomo on the ChillingCompetition blog:

<https://chillingcompetition.com/2020/02/07/case-c-307-18-generics-uk-and-others-v-cma-paroxetine-a-major-landmark-in-the-case-law-i-principles/>.

⁴⁰ Starting with Case 56/64, *Consten and Grundig*, Case 24/67 *Parke Davis & Co. v. Probel*, and Case 78/70 *Deutsche Grammophon*. More recent cases include Cases C-403/08 and C-429/08, *Football Association Premier League v. Murphy*.

⁴¹ Case C-307/18 *Generics (UK) and Others (Paroxetine)* ECLI:EU:C:2020:52 at 104.

⁴² C-209/10 *Post Danmark*, EU:C:2012:172.

⁴³ C-67/13 P *Cartes Bancaires*, ECLI:EU:C:2014:2204.

⁴⁴ C-413/14 P *Intel v. Commission*, EU:C:2017:632.