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Pay-For-Delay Agreements Under EU Competition Law – A Comment on Paroxetine

(case C-307/18 – Generics (UK) and others v Competition and Markets Authority)

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1. Background: Pay-for-delay agreements in the spotlight for the past ten years

Pay-for-delay agreements in the pharmaceutical industry have, for the past few years caught the attention of competition authorities, and, in particular, of the European Commission: following its 2008-2009 sector inquiry into the pharmaceutical sector[2], the European Commission found that settlement agreements between originators/innovators or patent holders and generic manufacturers were delaying the entry in the market of generic drugs, even after the expiry of the originator's patent. These agreements, usually reached as part of patent litigation settlements, can entail a payment or a transfer of economic value between a soon-to-expire patent owner (the innovator or manufacturer of the originator medicine) and a generics manufacturer, the effect of which is to cause a delay in the entry in the market of the generic; in such cases, the European Commission argues, there is an

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[2] See European Commission, *Communication from the Commission: Executive Summary of the Pharmaceutical Sector Inquiry Report,* and technical annexes, adopted on 8 July 2009, available at https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/.

infringement of Article 101 TFEU[3], as the companies involved will have reached an agreement the object of which is to restrict competition. Most notably, once such an agreement is qualified as an infringement by object, the Commission will not be required to show anticompetitive effects in the market[4].

Indeed, in the sector inquiry, the Commission reviewed several iterations of these agreements, and found that in general agreements that pose no restriction on the ability of the generic manufacturer, or that while restricting their entry in the market, do not entail any transfer of value through a reverse payment (so-called "Type A" and "Type B-I" agreements) should not be deemed restrictive of competition, while "Type B-II" agreements, where a restriction on the ability of the generic manufacturer to enter in the market is compensated with a reverse payment[5], should constitute an infringement of competition rules by object, as the reverse payment would be tantamount to a profit-sharing agreement between the originator and the generic manufacturer resulting from a delay in the latter's entry in the market.

As a consequence of these findings, the European Commission started a detailed monitoring of patent settlements which led to a series of high-profile investigations (and fines worth several hundred of million euros for art. 101 TFEU infringements): Lundbeck – Citalopram (case AT.39226, Commission Decision of 19 June 2013), Johnson&Johnson – Fentanyl (case AT.39685, Commission Decision of 10 December 2013), Servier - Perindopril

[3] Treaty on the Functioning of the European Union.

[4] While not purporting to provide in the confines of this comment a general overview of the "object v *per se*" debate between European Competition Law and United States Antitrust law, it should be pointed out that *pay-for-delay* agreements have also caught the attention of US Courts and Antitrust authorities, with a more fluid approach: if the Federal Trade Commission held the view that agreements of this nature should be deemed *presumptively* illegal for violation of Section 1 of the Sherman Act, in private litigation US courts would usually find that reverse payment agreements would be valid as long as the agreement itself pertained to a still-valid patent, which would inevitably lead to a *rule of reason v per se illegality* divide in jurisprudence, finally settled by the U.S. Supreme Court, in its 2013 *FTC v Actavis* decision, which decided upon a *rule of reason* approach, mandating justifications for such payments to be considered before a conclusion on their anticompetitive effect can be reached (*FTC v Actavis, 133 S. Ct. 2223*).

[5] Which can take the form of lump sum payments, distribution or licensing agreements or any other form of value transfer from the originator to the generic manufacturer.

(case AT.39612, Commission Decision of 9 July 2014) and, most recently, Teva – Modafinil (case AT.39686, Commission Decision of 26 November 2020)[6].

So far, the European Union General Court ("General Court") has already issued its judgements on the Lundbeck – Citalopram and on the Servier – Perindopril cases, upholding the European Commission's decision[7]. Those decisions were appealed to the Court of Justice, which is expected to deliver its final rulings in 2021, but *Paroxetine* offers a preview of the Court's framework of review for *pay-for-delay* agreements[8], and has already been extensively quoted by Advocate General J. Kokott in her recent opinion in the Lundbeck case[9].

2. Background to Paroxetine

Paroxetine resulted from a reference for a preliminary ruling under art. 267 TFEU from the CAT, in proceedings opposing GSK and five generics manufacturers on the one hand, and the CMA on the other, in relation to the CMA's decision of 12 February 2016 finding that the six companies had taken part in unlawful agreements under the Competition Act 1998 (the UK competition law) and Article 101 (and 102) TFEU, concerning several settlement agreements entered into by GSK with those generic manufacturers to put an end to litigation concerning GSK's paroxetine related patents.

In this case, while the originator's patent for the active ingredient of paroxetine had already expired, the originator's manufacturing process patents were still valid: generics

[6] The *Teva – Modafinil* case closes the ten-year round of investigations into patent settlement agreements launched by the European Commission following its 2009 Sector Inquiry final report. See European Commission press release IP/20/2200, available at https://ec.europa.eu/commission/presscorner/detail/en/ip_20_2220.
[7] See Judgement of the General Court of 8 de September 2016, Case T-427/13 (Lundbeck v Commission), ECLI:EU:T:2016:449, and Judgement of the General Court of 12 December 2018, Case T-691/14 (Servier and Others v Commission), ECLI:EU:T:2018:922.
[8] Additionally, as the *Paroxetine* ruling was issued in a preliminary reference procedure (and not in an appeal procedure) the Court will usually provide its guidance on interpretation of European Union Law to the national referring court (in this case, the CAT), in a more pedagogic way, even if sometimes risking a more nuanced approach to settled case law. This has been especially significant in object cases, where the Court has found room to expand the boundaries of the notion of restriction of competition by object to a *very-close-to* effects analysis (see, *e.g.* Judgement of the Court of 14 March 2013, Case C-32/11 (Allianz Hungária and Others v Gazdasági Versenyhivatal), ECLI:EU:C:2013:160).
[9] See Opinion of Advocate General Kokott, delivered on 4 June 2020, Case C-591/16 P (Lundbeck v Commission), ECLI:EU:2020:428. Most notably, Advocate General Kokott also submitted an opinion in the *Paroxetine* case. See Opinion of Advocate General Kokott, delivered on 22 January 2020, Case C-307/18 (Generics (UK) Ltd v CMA), ECLI:EU:C:2020:28, which was in essence followed by the Court in this ruling.

manufacturers could therefore enter in the market for paroxetine, as long as they did not infringe patented manufacturing processes: ensuing attempts from generics manufacturers to enter the market resulted in litigation around the issue of generics manufacturers impinging on GSK's patents, to questions raised by the generics companies on the validity of the patents themselves. This litigation would eventually be settled when GSK offered payments to the generics companies in exchange for their desisting from patent invalidity claims and for not marketing paroxetine rival products in the UK market; in addition, GSK arranged for its exclusive distributor of paroxetine in the UK to supply the generics companies with paroxetine for resale in the UK with a guaranteed profit margin.

The CMA found that these agreements resulted in an infringement to competition, as these generic companies were in effect potential competitors with the originator manufacturer and had agreed to delay (albeit for a certain period) their entry in the market, where they would be able to compete with the originator's branded medicine, in exchange for a payment or transfer of an economic value.

Faced with appeals from the six companies and with the Commission's own cases on pay-for-delay agreements still waiting a final decision from the Court of Justice[10], the CAT decided to request guidance from the Court of Justice.

3. The Court's findings

a. Potential competition

On the issue of potential competition, the Court recalled settled case law according to which in order to find an infringement of Article 101 (1) TFUE in relation to horizontal agreements, coordination must take place between companies which are competitors, at least potentially: for an horizontal agreement to have a "negative and appreciable effect on competition within the internal market", it must involve undertakings operating at the same level of production or distribution[11].

[10] When the CAT decided to ask the Court of Justice for a preliminary ruling (March 2018), only the Commission's *Lundbeck* decision had been reviewed by the General Court.
[11] *Paroxetine*, para. 31 and 32.

However, in this case, the companies were not actually competing: the generics manufacturers had announced their intentions to enter in the market for paroxetine, but their actions were thwarted by the originator's legal actions to enforce its patents; they settled with the originator before competing. This is why the Court very clearly states that "it is only the concept of 'potential competition' that is at issue, given that the manufacturers of generic medicines who concluded the agreements at issue with GSK had not entered the market for paroxetine at the time when those agreements were concluded."[12]

The assessment of the Court reads out as a clear roadmap for assessing potential competition, while providing the referring court the tools to evaluate which criteria to use when determining when a company not present in a market is a potential competitor of another company already present in that market: firstly, the court must consider the structure of the market and the economic and legal context in which it operates, and in a case concerning the pharmaceutical sector, pay special attention to the regulatory constraints that play a significant role in the competitive assessment in this sector; secondly, intellectual property rights must also be considered, in light of their legal protection under EU Law; thirdly, the "perception of the established operator"[13] must also be accounted for: if the originator agrees to make transfers of value to a manufacturer or generics in exchange for a delay in its market entry, there is a clear indication that the originator regards the generic manufacturer as a potential competitor, and, as the Court points out, "the greater the transfer of value, the stronger the indication"[14].

Once all these are factored in, then the referring court may consider if the generics manufacturer had taken the necessary steps to have access to the market (including at regulatory, supply and distribution levels), if it had challenged the originator's patents and if it had adopted a marketing strategy aiming at challenging the market, in order to conclude that this challenger "has a firm intention and an inherent ability to enter the market"[15].

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[12] *Paroxetine,* para. 35.
[13] *Paroxetine,* para. 42. How a company perceives its competition in the market it operates in is becoming a growingly relevant factor in the competitive assessment undertaken by competition authorities, either in antitrust investigations or in merger control proceedings. As the Court points out, "*if the latter* [the company not present in the market] *is perceived as a potential entrant to the market, it may, by reason merely that it exists, give rise to competitive pressure on the operator that is established in that market.*" (loc. cit.).
[14] *Paroxetine,* para. 56.
[15] *Paroxetine,* para. 44.

Finally, the challenger must not meet "barriers to entry that are insurmountable"[16]: as the patents' validity can be legally challenged and contested patent rights do not amount to insurmountable barriers[17].

Here, the Court takes some care in explaining that competition law does not thwart patent law nor intellectual property rights, nor that special consideration should not be given to the legal protection afforded by these rights by the referring court. The point is that the issue of patent protection is not an obstacle for a challenger to take all necessary steps to enter the market, namely as soon as the patent expires or its validity is successfully challenged, and therefore is no obstacle to its qualification as a potential competitor.

b. Restriction by object

Arguably, the Court's findings in relation to the qualification of these agreements as restrictions by object are the most relevant part of the decision: not in respect of any additional clarification to the notion of restriction by object, but for reaffirming a coherent case law that has been outlined since the Cartes Bancaires judgement in 2014[18]: the category of object restrictions must be interpreted strictly and regard to the legal and economic context in which the companies operate must be an integral part of the assessment of the agreements or concerted practices under discussion; at the same time, restrictions by object are not a closed set of behaviors, as any agreement can be considered a restriction by object if it is inherently deleterious to competition. This is an admittedly high bar to pass, in particular in what concerns "non-cartel" agreements, where the inherent damage to competition is easier to demonstrate. Finally, the inherent damage to competition must be assessed taking full consideration of the context in which the parties to the agreement operate.

It is therefore relevant to note that the Court starts is assessment by stating what these agreements are not: market-sharing or market-exclusion agreements[19]. In fact, the Court concluded that the part of the agreements ending the patent disputes was genuine, and as

[16] *Paroxetine,* para. 58.
[17] *Paroxetine,* para. 50 to 53.
[18] See Judgment of the Court of 11 September 2014, Case C-67/13 P (Groupement des Cartes Bancaires v Commission), ECLI:EU:C:2014:2204.
[19] *Paroxetine,* para. 77.

such could not be regarded as an agreement bringing to an end "entirely fictitious disputes"[20] or aiming at market-sharing or exclusion.

Additionally, and in a somewhat convoluted way, the Court recalled that the exercise of an intellectual property right, under some circumstances, might fall under the prohibition of Article 101 (1) TFEU[21], that the prohibition does not make a distinction between agreements whose purpose is to put an end to litigation and those concluded with other aims[22], that settlement agreements whereby a company accepts the validity of a patent and delay their entry in the market are liable to have effects that restrict competition[23], and that an agreement providing that a patent will not be challenged may also restrict competition within the meaning of Article 101 (1) TFEU[24]; however – and this is the relevant finding – not all settlement agreements whereby a generics manufacturer, having assessed its chances of successfully challenging the validity of the patent, decided to abandon its plans to enter the market and settle with the originator manufacturer are restrictions by object[25].

It is worthwhile noting that in paras. 77 to 83 of the judgement, the Court is essentially guiding the referring court through the minutiae of competition law: not all agreements between competing undertakings are restrictions of competition; and not all restrictions of competition are restriction by object.

If all settlement agreements may not be deemed restrictions of competition, the Court then proceeds to assess the defining feature of these pay-for-delay agreements: the actual payment or transfer of value of economic nature between two companies as part of their litigation settlement.

Here the Court takes again a very cautious approach: the fact that such an agreement involves a transfer of value is not, in itself, sufficient to qualify it as a restriction by object, since "those transfers of value may prove to be justified, that is, appropriate and strictly necessary, having regard to the legitimate objectives of the parties to the agreement"[26].

[20] *Paroxetine,* para. 76.
[21] *Paroxetine,* para. 79.
[22] *Paroxetine,* para. 80.
[23] *Paroxetine,* para. 81.
[24] *Paroxetine,* para. 82.
[25] *Paroxetine,* para. 83.
[26] *Paroxetine,* para. 85.

Only in cases where there is no other justification for the payment other than the interest of the parties in putting competition aside should the referring court find a restriction of competition by object.

Thus, all transfers of value (pecuniary and not pecuniary) between the two companies have to be individually assessed to determine if the value transferred to the generics manufacturer is shown to be "sufficiently beneficial to encourage the manufacturer of generic medicines to refrain from entering the market concerned and not to compete on the merits"[27] (even if below the value of the profits the generics manufacturer would generate following entry in the market), thus meriting the qualification of restriction by object.

Finally, the Court addressed the reconciliation of the notion of restriction of competition by object with the evaluation of pro-competitive effects resulting from those settlements.

This is arguably one of the most controversial – and possibly least understood – points in the mechanics of application of Article 101(1) and (3) TFEU: Article 101 (1) TFEU prohibits agreements that restrict competition; Article 101 (3) TFEU allows for hitherto prohibited agreements in light of their positive economic outcome. If positive competitive effects are to be weighed when applying Article 101 (1) TFEU, what is then the point of Article 101 (3) TFEU?

Here, the Court followed closely Advocate General KoKott's opinion[28]: firstly, legitimate objectives may, under certain circumstances, authorize agreements, even if they restrict competition; secondly, the case law mandates that agreements have to be assessed in context, i.e, the agreement must be assessed in the circumstances of the individual case having regard to all relevant factors; thirdly, if the benefits resulting from an agreement give rise to question its anticompetitive object, than the assessment must move to an analysis of the effects; fourthly, positive effects secondary to an agreement do not warrant an effects analysis, once it is clear that they were not the primary aim of the parties.

In conclusion, the Court found that positive effects have be considered when applying Article 101 (1) TFEU, as they are "elements of the context of that agreement"[29] : but they

[27] *Paroxetine,* para. 94.
[28] See Opinion of Advocate General Kokott (cit.), para. 150 et seq.
[29] *Paroxetine,* para. 103.

have to be demonstrated, relevant and specifically related to the agreement in order to determine a switch to an effects analysis (thus precluding a finding of an object restriction), or, at least, to cast a "reasonable doubt" as to whether the settlement agreement caused a sufficient degree of harm to competition[30].

While it is for the referring court to assess such effects, the Court did go so far as to assert that, in this case, the positive effects brought about by the settlement agreements were "not only minimal but probably uncertain"[31].

4. Conclusion

The Court's position in *Paroxetine* should not be overestimated[32].

Paroxetine reaffirms the Court's case law on the relationship between Competition Law and intellectual property rights, while signaling that their legitimate exercise by patent holders may indeed restrict competition and be caught be the prohibition of Article 101 (1) TFEU. It confirms that the qualification of any restriction as an object restriction should not be regarded by competition authorities as a competition policy instrument to be used whenever an agreement impinges on the parties' freedom, regardless of the contextual circumstances in which the parties operate and presents a clear overview of the contextual analysis warranted for agreements which fail to be easily qualified as market-sharing or collusion-like agreements.

The judgement clarifies the legal tests for *pay-for-delay* agreements to be reviewed by the European Commission and national competition authorities in a more nuanced, and balanced, perspective than a pure by object approach would suggest.

This should impact not only forthcoming rulings by the Court of Justice in *Lundbeck* and *Servier,* but importantly it clearly signals what the Court expects the competition authorities

[30] *Paroxetine,* para. 107.
[31] *Paroxetine,* para. 110.
[32] Pablo Ibáñez Colomo considers it *seminal.* Pablo Ibáñez Colomo, *The Legal Status of Pay-for-delay Agreements in EU Competition Law: Generics (Paroxetine)* (September 16, 2020). Forthcoming in (2020) 57 Common Market Law Review, available at SSRN: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3693746.

to adhere to in their investigations to complex agreements and arrangements between companies, including horizontal cooperation agreements.