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Pay-for-delay: Review of the ECJ judgment in Lundbeck (Citalopram)

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At a Glance

The Court of Justice of the European Union (ECJ) has confirmed that pay-for-delay agreements with generic manufacturers ready to enter the market violate EU antitrust rules.

Key Points:

- Pay-for-delay agreements are a form of patent dispute settlement in which a generic manufacturer acknowledges the patent of the originator and agrees to refrain from marketing its generic product for a specific period of time. In return, the generic manufacturer receives from the originator payment or other value.

- Pay-for-delay agreements fall within Article 101 TFEU (the prohibition of anticompetitive agreements) only if the parties to the agreement are competitors or potential competitors. If there is a real and concrete possibility — absent the agreement — of the generic manufacturers entering the market and competing with the originator on that market, the generic manufacturers qualify as potential competitors. The mere existence of such an agreement with generic manufacturers not yet present on the market also provides a strong indication that the generic manufacturers are potential competitors.

- Not all pay-for-delay agreements are anticompetitive as such (restriction "by object"). A case-by-case analysis is required. An agreement will be restrictive by object if the net gain of the transfer of value from the originator to the generic manufacturers (i.e., the payment) is sufficiently significant to act as an incentive to the generic manufacturers to refrain from entering the market and competing on the merits.

- The size of the transfer of value is key: if the agreement is linked to the generic manufacturer's anticipated profits/turnover post-entry or to the damages that could have been paid if the generic manufacturer had succeeded in litigation against the originator, then it is likely to be considered anticompetitive by object.

- The judgment reinforces the European Commission's (EC's) efforts to fight against pay-for-delay agreements and makes it more difficult for companies to conclude settlements without facing antitrust scrutiny. However, it is clear that agreements in which (i) there is no restriction on the ability of the generic manufacturer to market its products, and (ii) there is a restriction on the ability to market the generic product (e.g., a non-challenge or non-infringement clause) but without any pay-for-delay (or reverse payment) will not infringe EU competition law.

- Pay-for-delay agreements in the pharmaceutical sector remain in the enforcement spotlight of the US antitrust authorities. US courts use the rule of reason to evaluate whether pay-for-delay agreements violate antitrust laws. Even though the number of settlements with reverse payments appears to have declined in the last decade, today, the Federal Trade Commission's (FTC's) pay-for-delay enforcement is focused on non-cash reverse settlements.

Background

Lundbeck is a pharmaceutical company that researches new medicinal products and brings them to the market (an originator). Between 1977 and 1985, Lundbeck made successful applications for patents for citalopram — a blockbuster antidepressant — as well as two processes that produce citalopram. Lundbeck subsequently obtained additional patents for other, more effective processes for the production of citalopram. The basic patents expired in January 2002 in most Western European countries. Generic manufacturers had been taking steps to enter the market with cheaper versions of citalopram after the expiry of the basic patent, but Lundbeck launched or threatened to launch patent

infringement proceedings against those manufacturers. Lundbeck reached an agreement with each of the four generic manufacturers (Merck, Alpharma, Arrow, and Ranbaxy) under which the generics received payment from Lundbeck in exchange for a promise to stay out of the citalopram market for a period of time.

In June 2013, the EC fined Lundbeck and the generic manufacturers for delaying market entry of generic medicines. According to the EC, Lundbeck agreed with each of the generic manufacturers to delay the market entry of cheaper generic versions of Lundbeck's branded citalopram. According to the EC decision, Lundbeck paid generic manufacturers to delay the launch of their version of the drug once the basic patent had expired. At the time of the agreements, Lundbeck still held related process patents.

In September 2016, the General Court (GC) upheld the EC's decision and ruled that pharmaceutical pay-for-delay agreements breach EU antitrust rules.

On 25 March 2021, the ECJ entirely dismissed Lundbeck and others' appeals. The ECJ confirmed its judgment in the *Generics (UK) (Paroxetine)* case, in which it laid for the first time the foundations of its thinking regarding pay-for-delay agreements.

Key themes of the ECJ judgment

Notion of potential competition

Lundbeck contested that it and the generic manufacturers were potential competitors. Indeed, Article 101 TFEU in this context is applicable to coordination between companies that are in competition with each other, if not actually, then at least potentially. Absent (at least potential) competition between the companies involved, Article 101 TFEU is inapplicable.

The ECJ rejected this argument. In order to assess whether the generic manufacturers that were not present in the market were a potential competitor of the originator (which was already present in the market), the EC (or national competition authorities) have to determine whether there are real and concrete possibilities of the generic manufacturers joining that market and competing with the originator.

Relevant factors in this assessment include determining whether:

- The generic manufacturer has a firm intention and an inherent ability to enter the market, and has taken sufficient preparatory steps (e.g., obtained the required marketing authorisations; holds an adequate stock of the generic product; taken steps to challenge the process patents held by the originator; concluded supply agreements with active pharmaceutical ingredients suppliers; initiated marketing efforts). Whether these steps have been finalised or whether they will be successful is irrelevant.

- There are insurmountable barriers to market entry. The ECJ has confirmed that the existence of a *process* patent for an active ingredient already in the public domain is not an insurmountable barrier. The presumption of patent validity, the uncertain outcome of disputes concerning validity, or the existence of interim injunctions do not undermine a finding that the originator and a generic manufacturer are potential competitors. In the *Lundbeck* case, Lundbeck's compound patent had expired, and there were other processes available to produce citalopram that were non-infringing. The generic manufacturers therefore did not face insurmountable barriers to market entry.

- There are additional factors. In this respect, the conclusion of a pay-for-delay agreement between the originator and generic manufacturers not yet active on the market is a strong indication of potential competition.

Pay-for-delay as "by object" restrictions of competition

Lundbeck challenged the classification of the pay-for-delay agreements as "by object" restrictions of competition. Before the GC, Lundbeck relied on the *Actavis* US Supreme Court precedent. In that case, which concerned similar agreements, the Supreme Court refused to apply a *per se* approach (similar to by object restrictions) and instead assessed the agreement under the rule of reason. The GC ultimately rejected the parallel with the US.

Need for a case-by-case analysis

The distinction between restrictions by object and restrictions by effect is important in EU competition law. Once the regulator has established that an agreement has as its object the restriction of competition, there is no need to take account of the agreement's concrete effects. In other words, for the purpose of applying Article 101 TFEU, no actual anticompetitive effects need to be demonstrated if the agreement has a restriction of competition as its object. A by object restriction exists when the coordination reveals in itself a sufficient degree of harm to competition.

The ECJ reaffirmed its position that the concept of restriction by object must be interpreted narrowly and can only be applied to agreements that reveal — in themselves and having regard to the content of their provisions, their objectives, and the economic and legal context of which they form part — a sufficient degree of harm to competition. However, it is not necessary for the concerned type of agreement to already have been censured by the EC to qualify as a restriction by object. Reading between the lines, the ECJ considered that the Lundbeck agreements with the generic manufacturers were akin to a cartel. There is a vast amount of experience and evidence showing that cartels are among the most harmful anticompetitive behaviour and thus qualify as by object restrictions. Interestingly, while the judgment does not openly qualify the agreements as a cartel, the press release accompanying the judgment refers to a "*cartel seeking to delay*" entry.

In the *Lundbeck* case, the EC accepted that not *all* pay-for-delay agreements are necessarily problematic from a competition law perspective. The ECJ confirmed this line of thinking when it stated that such agreements cannot be considered to be restrictions by object in all cases. A case-by-case analysis is necessary. If there is an alternative rationale for the agreement, the agreement should not be treated as a by object restriction .

Lack of alternative procompetitive rationale

However, it was plain from the examination of the Lundbeck agreements that they did not have any purpose other than to protect the commercial interest of the holder of the patent and dissuade the party allegedly infringing the patent from engaging in competition on the merits.

In other words, when the net gain of the transfers of value from the manufacturer of originator medicines to the generic manufacturers (i.e., the payment) is sufficiently significant to act as an incentive to the manufacturer of generic medicines to refrain from entering the market and, consequently, to not compete on the merits with the manufacturer of the originator medicines, the agreement will be characterised as a restriction by object.

In the *Lundbeck* case, the reverse payments broadly corresponded to the profits that the generic manufacturers expected to make if they had entered the market or to the damages that could have been paid to them if they had succeeded in litigation against Lundbeck. The ECJ added that there is no requirement that the net gain should necessarily be greater than the profits that the generic manufacturers would have made if they had been successful in the patent proceedings.

The ECJ also found that the generic manufacturers had made considerable efforts to prepare for their market entry and that they did not intend to desist from those efforts on account of Lundbeck's new process patents. Consequently, it was principally the size of the reverse payments that induced the generic manufacturers to accept the limitations governing their behaviour.

The ECJ therefore concluded that the net gain of the transfers of value provided for by the agreements in question could only be explained by the commercial interest of both Lundbeck and the generic manufacturers to not engage in competition on the merits.

Finally, the ECJ clarified that there is no need to conduct a "counterfactual analysis" when an agreement constitutes a restriction by object. If the object is clearly anticompetitive, the EC and national competition authorities do not need to conduct additional analysis.

Interaction between EU competition law and intellectual property

Pay-for-delay cases are peculiar since the originator typically benefits from patent protection. Consequently, these cases often involve an instance in which market entry by a generic manufacturer is — allegedly — precluded by an intellectual property right (IPR).

EU competition law does not question the existence of IPRs. As such, it is legal for the patent holder to conclude with a party allegedly infringing that patent a settlement agreement that does not exceed the scope and duration of the remaining validity of that patent. Such agreement constitutes an expression of the IPR of that holder. This point was acknowledged by the EC in its decision: "*It is not, of course, as such illegal to settle patent disputes. Patent dispute settlements are, in principle, a generally accepted, legitimate way of ending private disagreements. They can also save courts or competent administrative bodies such as patent offices' time and effort and can therefore be in the public interest*".

However, EU competition law can question the way in which IPRs are exercised. The ECJ confirmed this by stating that a "*patent does not permit its holder to enter into contracts that are contrary to Article 101 TFEU*". The ECJ found that the agreement between Lundbeck and the generic manufacturers went beyond the specific subject matter of Lundbeck's IPRs: while the right to oppose infringements falls with the subject matter of the patent, the right to enter into agreements by which actual or potential competitors are paid to not compete by entering the market does *not* fall within the subject matter of the patent. In the ECJ's view, the only purpose of the agreement was to delay entry, not to settle patent disputes.

If there is a patent dispute between the parties, it is for public authorities and not private companies to ensure compliance with statutory requirements. As put by the ECJ: "*It is unacceptable for undertakings to attempt to mitigate the effects of legal rules which they consider excessively unfavourable by entering into restrictive arrangements intended to offset those disadvantages on the pretext that those rules have created an imbalance detrimental to them*".

Finally, the ECJ confirmed that it is not for the competition regulators to carry out a review of the strength of the patent at issue 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. In the *Lundbeck* case, the ECJ confirmed that the generic manufacturers were potential competitors, facing no insurmountable barriers to market entry since (i) Lundbeck's compound patent had expired, and (ii) there were other processes available to produce citalopram that were non-infringing. Consequently, the generic manufacturers could enter the market without infringing Lundbeck's IPRs.

Sources

The ECJ judgment can be found here and its accompanying press release here.

The GC judgment can be found here.

The EC decision can be found here.

Contacts

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