EU COURT OF JUSTICE RULES ON *LUNDBECK* PATENT SETTLEMENT AGREEMENTS

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EU Court of Justice Rules on *Lundbeck* Patent Settlement Agreements

By Marie Manley & Anne Robert

On March 25, 2021, the Court of Justice of the European Union published its judgments in the *Lundbeck* case. The CJEU dismissed the parties' appeals in their entirety and upheld the General Court's findings that Lundbeck and the generic manufacturers were potential competitors and that each of the patent settlement agreements entered into by the parties restricted competition "by object." The CJEU's legal analysis is largely based on its judgment from January 30, 2020 in the *Paroxetine* case. The CJEU nevertheless provides useful clarifications specific to the Lundbeck agreements and establishes a (novel) "specific duty of care" requiring companies to properly retain evidence, which may impact companies beyond the pharmaceutical sector. This article provides an overview of the CJEU's analysis and sets out some practical implications for companies to consider.

On March 25, 2021, the Court of Justice of the European Union ("CJEU") published six judgments assessing the patent settlement agreements entered into between Lundbeck (Case C-591/16 P) and several manufacturers of generic medicines. The CJEU dismissed the parties' appeals in their entirety. It upheld the findings of the General Court ("GC") that Lundbeck and the generic manufacturers were potential competitors and that each of the agreements restricted competition "by object" in violation of Article 101(1) of the Treaty on the Functioning of the European Union (TFEU). The Court's legal analysis is largely based on its judgment from January 30, 2020 in the *Paroxetine* case (Case C-307/18). The CJEU nevertheless provides helpful clarifications specific to the Lundbeck agreements.

In one of the judgments (C-611/16 P), the CJEU establishes a novel "specific duty of care" requiring companies to properly retain evidence in the context of a sector inquiry. This obligation may have wide-ranging implications for rights of defense of companies in the pharmaceutical sector and beyond.

I. BACKGROUND

Lundbeck entered into the agreements in 2002. At that time, the compound patent for Lundbeck's antidepressant medicinal product containing the active pharmaceutical ingredient citalopram had expired, but Lundbeck still held several process patents. The latter included patents for the production of citalopram using salt purification methods by crystallization and film distillation. In 2002/2003, Lundbeck planned to launch Cipralex (escitalopram), an antidepressant meant to treat the same patients as those previously treated with citalopram.

The agreements, which covered various geographic areas with some covering the entire European Economic Area, were aimed at settling disputes between the parties. The disputes related to the possible invalidity of Lundbeck's process patents and the possible infringement of those patents by the generic manufacturers had they entered the market with their generic citalopram products. All of the agreements entailed value transfers by Lundbeck to the generic manufacturers in return for the latter's commitment not to enter the market for the duration of the agreement. Some of the agreements allowed the generic manufacturers to distribute Lundbeck's own generic citalopram.

The European Commission ("Commission") was informed about the agreements at issue in October 2003 by the Danish Competition Authority. In January 2008, the Commission initiated its inquiry into the pharmaceutical sector. It issued its decision fining Lundbeck approx. €93.8 million and the generic manufacturers a total of €52.2 million in June 2013, more than 10 years after the agreements were concluded. Lundbeck and the generic manufacturers appealed the decision but the GC upheld the Commission's findings in September 2016 (Case T-472/13 for Lundbeck). In particular, the GC agreed with the Commission that the agreements at issue "were comparable to market exclusion agreements, which are among the most serious restrictions of competition" and thereby restricted competition "by object" (para. 435 of the GC's *Lundbeck* judgment).

II. ASSESSMENT OF POTENTIAL COMPETITION

The CJEU upheld the GC's finding that the parties were potential competitors at the time the agreements were concluded. It affirmed its "test," set out in the *Paroxetine* judgment, to assess whether potential competition exists. Whether a generic manufacturer is a potential competitor depends on whether it has "real and concrete possibilities" to enter the market and compete with the companies present on that market (paras. 54 and 55 of the Lundbeck judgment). This requires in particular an assessment as to whether the generic manufacturer has a "firm intention and an inherent ability" to enter the market, and "does not meet barriers to entry that are insurmountable" (paras. 56 and 57).

The CJEU clarified that although one has to take "due account of the regulatory constraints that are characteristic of the medicine sector and of the intellectual property rights" (para. 56), the existence of a patent, which protects the manufacturing process of an active ingredient that is in the public domain will not qualify as an insurmountable barrier to entry. This is regardless of the presumption of validity attached to that patent because, according to the CJEU, that presumption "sheds no light, for the purposes of applying Articles 101 and 102 TFEU, on the outcome of any dispute in relation to the validity of that patent" (para. 58).

Regarding Lundbeck's process patents, the CJEU agreed with the GC that it was not for the Commission to provide definite proof that the citalopram the generic manufacturers intended to market did not infringe Lundbeck's process patents. The fact that Lundbeck held such patents could not preclude a finding that there was potential competition (para. 61). The CJEU added that it is not necessary to demonstrate with certainty that the generic manufacturers would have entered the market and that such entry would necessarily have been successful (para. 63).

If no insurmountable barriers to market entry exist, the existence of potential competition presupposes only that the generic manufacturer has taken "sufficient preparatory steps to enable it to enter the market concerned within a period of time capable of putting competitive pressure" on the originator manufacturer. It is, however, according to the CJEU of "no relevance whether those steps will in fact be finalized in due time or will be successful" (para. 84). The fact that a generic manufacturer does not hold a marketing authorization at the time a patent settlement agreement is concluded will not exclude it from being considered a potential competitor of the originator manufacturer (para. 83).

The CJEU further confirmed that "additional factors" can be taken into consideration to assess whether potential competition exists. This may include subjective factors (such as the originator manufacturer's perception of the risk that the generic manufacturer presents to its commercial interests), provided that the assessment is not based exclusively or principally on those factors (para. 75).

III. EVIDENCE TO ESTABLISH THE EXISTENCE OF POTENTIAL COMPETITION

The CJEU clarified a number of general principles regarding the assessment of evidence submitted by the parties. It confirmed that "any evidence prior to, contemporaneous with or even subsequent to the conclusion of the agreement at issue may be taken into consideration if it is of such a nature as to throw light on the existence or absence of a competitive relationship between the [companies] concerned at the time when that agreement was concluded" (para. 67). However, evidence unknown to the parties at the time the agreement is concluded is not capable of having influenced their conduct on the market. The CJEU concluded that it can therefore not shed light on the existence or absence of a competitive relationship between them (para. 69).

On that basis, the CJEU found that the GC was right to take evidence subsequent to the agreements at issue (i.e., documents indicating how the parties perceived the strength of Lundbeck's process patents when the agreements were concluded) into consideration. It could, however, refuse to take account of other evidence submitted by Lundbeck also subsequent to those agreements, such as the confirmation by several patent offices of the validity of one of Lundbeck's patents or the fact that Lundbeck "had been 'granted preliminary injunctions or other forms of interim relief' in more than 50% of the proceedings it had initiated in 2002 – 2003" (paras. 70 to 72). This raises the question whether the CJEU's conclusion would have been different if Lundbeck had been granted some (or all) of those injunctions before it entered into the agreements.

IV. RESTRICTION OF COMPETITION "BY OBJECT"

At the outset of its analysis as to whether or not the agreements at issue restricted competition "by object," the CJEU confirmed that the concept of a restriction "by object" must be interpreted strictly. It can be applied only to those agreements "which 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 for the view to be taken that it is not necessary to assess their effects" (para. 112).

The CJEU clarified that patent settlement agreements relating to disputes over a process patent for the manufacture of an active ingredient that is in the public domain, which have the effect of delaying the market entry of generic medicines in exchange for monetary or non-monetary transfers of value "cannot be considered to be 'restrictions by object' in all cases for the purpose of Article 101(1) TFEU" (para. 113).

That said, the CJEU added that such agreements will restrict competition "by object" if it is "plain from the examination of the settlement agreement concerned that the transfers of value […] cannot have any explanation other than the commercial interest of [the parties] not to engage in competition on the merits" (para. 114).

This will in particular be the case if the net gain of the transfers of value from the originator manufacturer to the generic manufacturer was "sufficiently significant actually to act as an incentive" to the generic manufacturer to refrain from entering the market concerned. The net gain does, however, not necessarily have to be greater than the profits the generic manufacturer would have made if he would have been successful in the patent proceedings (para. 115).

The CJEU noted a number of facts specific to the Lundbeck agreements and that it was mainly the size of the reverse payments that had induced the generic manufacturers to accept the limitations governing their behavior (para. 117). The CJEU concluded on that basis that the GC was right to characterize the agreements as restrictions "by object" (para. 118). The CJEU explained in particular that Lundbeck had not "in any way" argued that the value transfers could be justified (para. 118). There was "no basis for Lundbeck's attempt to rely on the fact that the agreements at issue are a legitimate expression of its intellectual property rights" (para. 123). The GC had stated in that context that the companies had not demonstrated that the restrictions set out in the agreements at issue were "objectively necessary in order to protect their intellectual property rights" (para. 458 of the GC's Lundbeck judgment). The CJEU moreover found that Lundbeck had not mentioned "any pro-competitive effect associated with those agreements" in the appeal to rebut the characterization of the agreements as restrictions of competition "by object" (para. 136).

V. COUNTERFACTUAL SCENARIO AND NOVELTY OF THE INFRINGEMENT

Regarding the necessity to examine the counterfactual scenario, the CJEU found that this was not required to characterize a concerted practice as a restriction "by object" "unless the clear distinction between the concept of 'restriction by object' and the concept of 'restriction by effect' […] is to be held not to exist" (para. 140).

Moreover, according to the CJEU, for an agreement to be considered to be restrictive of competition "by object," it is "in no way necessary that the same type of agreement has already been censured by the Commission." That remains the case "even if [such an agreement occurs] in a specific context, such as that of intellectual property rights" (para. 130). The CJEU also found that it was "at the very least foreseeable" that the agreements at issue could lead to penalties (para. 161).

VI. "SPECIFIC DUTY OF CARE" TO RETAIN EVIDENCE

In one of the judgments, the CJEU assessed the parties' argument that the GC made an error of law by not properly assessing whether their rights of defense had been violated. According to the parties, the Commission had failed to inform them in a timely manner of the existence of an inquiry and of its objections regarding them. As a result, they did not have certain exculpatory evidence available to them. The CJEU found that the GC erred in law by imposing on the parties an obligation of diligence to keep any document, which might prove useful to their defense. The GC derived that duty of diligence from case law that is applicable only to the period *after* the initiation of the administrative procedure by the Commission. For the parties at issue, this would have been only as of 2010 and 2011 when the procedure against them was launched. However, the CJEU did not annul the GC's ruling on that basis but considered that a substitution of grounds had to be made (para. 149 of the CJEU's judgment in Case C-611/16 P).

The CJEU went a step further and found that the GC was entitled to impose on the parties a (novel) "specific duty of care," which required them to ensure that "information enabling details of their activities to be retrieved is retained properly in their books or records, in order, in particular, that they have in their possession the necessary evidence in the event of subsequent administrative action or judicial proceedings" (para. 151). As a result, even companies which have not yet been put on notice of an investigation "must expect that individual procedures may possibly be initiated against them in the future."

This duty of care arose because the parties were aware of the fact that the Commission had opened its sector inquiry in January 2008 and that the objective of the latter was the examination of agreements concluded between pharmaceutical companies, such as patent settlement agreements. The CJEU held that this should have led the companies to "take precautions against the loss, due to the passage of time, of evidence that might prove to be useful to them in the context of subsequent administrative procedures or judicial proceedings" (para. 152). The CJEU further noted that "sector inquiries are an instrument designed to confirm suspicions of restrictions of competition in the sector concerned by those inquiries" (para. 153).

VII. PRACTICAL IMPLICATIONS

The CJEU's judgments confirm the legal "test" to determine whether a generic manufacturer qualifies as a potential competitor of an originator manufacturer and set out the general principles to assess whether a patent settlement agreement restricts competition "by object." Although the CJEU mostly upheld the GC's findings, and concluded that Lundbeck's agreements restricted competition "by object," a number of practical takeaways for companies can be noted:

- First, the CJEU provides clarifications and guidance relating to the specific facts and agreements at issue in this case. The CJEU refers on a number of occasions to the arguments put forward by Lundbeck and the generic manufacturers before the GC and explains why those did not change the outcome in this case.

- Second, the CJEU confirms that patent settlement agreements need to be assessed on a case-by-case basis and that not all agreements, even if they entail value transfers, will automatically amount to a restriction of competition "by object." Companies have the possibility to justify any monetary or non-monetary value transfers. They may also show that their agreements have pro-competitive effects.

- Third, the CJEU is careful to refer consistently to the fact that the patents at issue were patents which protected the manufacturing process of an active ingredient that was in the public domain. This bears the question whether the assessment may be different if the patent at issue is, for example, a compound patent.

- Fourth, although the CJEU's judgments are final for Lundbeck and the generic manufacturers in this case, several other cases are still pending before the EU Courts. Each of those presents its own facts and context. Those may therefore provide further guidance to companies. This may in particular be the case for the appeals before the CJEU involving, amongst others, originator manufacturer Servier (Case C-201/19 P and Case C-176/19 P). The appeals raise a number of additional questions, including whether or not the agreements at issue restricted competition "by effect" and how the relevant product market should have been defined under Article 102 TFEU. In addition, two other companies recently filed an appeal before the GC against a Commission decision fining them for allegedly having entered into a patent settlement agreement that restricted competition "by object" and "by effect." At Member State level, the Competition Appeal Tribunal ("CAT") in the United Kingdom is expected to issue its final judgment in the Paroxetine case soon. The CAT had referred the case to the CJEU for a preliminary ruling.

- Finally, with regard to the CJEU's novel obligation on companies to adopt a "specific duty of care" when they are subject to a sector inquiry, and "properly retain" evidence that may become useful in a potential follow-on investigation, this may have implications beyond the pharmaceutical sector. It may introduce a wider obligation on companies that are subject to a sector inquiry to retain documents as evidence for potential future individual investigations. This may raise a number of practical concerns, notably if such evidence relates to agreements or conduct that occurred many years prior to an investigation (as was the case for the parties in this case) or even the sector inquiry itself. Such evidence may often no longer exist. Therefore, companies should ensure that they have appropriate document retention policies and guidance in place, which would assist them in case of an investigation in the future.

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