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The EU Court of Justice dismisses the appeals of several manufacturers of medicines against the General Court's judgment upholding the Commission's pay-for-delay infringement decision *(Lundbeck)*

ANTICOMPETITIVE PRACTICES, INTELLECTUAL PROPERTY, PHARMACEUTICAL, MANUFACTURING, ADMISSIBILITY (COMPLAINT), JUDICIAL REVIEW, EUROPEAN UNION, PAY-FOR-DELAY

EU Court of Justice, *Lundbeck*, Case C-591/16 P, 25 March 2021

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On 25 March 2021, the Court of Justice of the European Union ("CJEU") dismissed the appeals by *Lundbeck*, *Merck KGaA* (and *Generics UK*), *Arrow*, *Alpharma* (and Xellia) and *Ranbaxy*, against the General Court's ("GC") judgment upholding the European Commission's ("Commission") 2013 pay-for-delay infringement decision.

Background

The case concerns the antidepressant containing the active pharmaceutical ingredient ("API") citalopram. Lundbeck's patents for the API and two processes to produce it were protected in a number of European countries until 2003 ("Lundbeck's original patents"). Over time, Lundbeck developed other processes for the production of citalopram, in respect of which it obtained various patents ("Lundbeck's new process patents").

In 2002, Lundbeck entered into settlement agreements concerning potential launches of generic versions of citalopram with Generics UK (at the time an indirect wholly-owned subsidiary of Merck KGaA), Alpharma, Arrow and Ranbaxy. Under the agreements, Lundbeck made payments to these producers of generic citalopram ("Other Providers") in various forms (e.g., direct payments, purchase of generic citalopram stock for destruction, and guaranteed profits in a distribution agreement). In exchange, the Other Providers agreed to cease or refrain from selling generic citalopram in the EEA as a whole or in specific Member States.

In 2013, the Commission adopted an infringement *Decision* against Lundbeck and each of the Other Providers, concluding that the agreements were "by object" restrictions of competition. In particular, the Commission found

that:

- Lundbeck and the Other Providers were at least potential competitors;
- Lundbeck transferred significant value to the Other Providers under the agreements;
- the value transfers were linked to acceptance by the Other Providers of limitations on market entry of generic products;
- the value transfers corresponded to (for Merck, Arrow, Alpharma) or considerably exceeded (for Ranbaxy) the profits the Other Providers expected to make from successfully entering with generic products;
- Lundbeck could not have limited entry in the same way by enforcing its patents, since the restrictions went beyond the rights of holders of process patents; and
- the agreements did not restrain Lundbeck from bringing infringement proceedings against the Other Providers if they entered with generic citalopram after expiry of the agreements.

On 8 September 2016, the GC *dismissed* the appeals against the Commission's decision.

The CJEU's findings

The two most important parts of the CJEU's judgments relate to the concept of "potential competition" and the characterisation of the agreements as "restrictions by object".

Potential competition

Relying on its *Paroxetine* judgment, the CJEU reiterated that "*in order to assess whether an undertaking that is not present in a market is a potential competitor of one or more other undertakings that are already present in that market, it must be determined whether there are real and concrete possibilities of the former joining that market and competing with one or more of the latter*". Specifically, it should be established whether the producer of generic products "*has in fact a firm intention and an inherent ability to enter the market, and does not meet barriers to entry that are insurmountable*", assessing whether the company had taken "*sufficient preparatory steps*" to enter (Lundbeck, paras. 52-57).

In relation to entry barriers, the CJEU held that the "existence of a patent which protects the manufacturing process of an active ingredient that is in the public domain cannot, as such, be regarded as such an insurmountable barrier, regardless of the presumption of validity attached to that patent", adding that "*it is not for the competition authority concerned 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 patent is valid and has been infringed*" (paras. 58-60).

Further, the CJEU held that the existence of potential competition must be examined "at the time when the settlement agreement in respect of the process patent dispute … was concluded", such 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 undertakings concerned at the time when that agreement was concluded*" (paras. 66-67). That said, following Advocate General Kokott's Opinion, the Court held that "*evidence relating to events subsequent to the*

conclusion of that agreement and, in particular, evidence relating to the subsequent outcome of the dispute which had justified the conclusion of that same agreement cannot be taken into consideration in order to assess and, where necessary, retrospectively to rebut the claim that the parties to that agreement were potential competitors at the time when it was concluded" (para. 68).

Thus, the CJEU concluded that the GC did not err in law when it found that evidence subsequent to the agreements (i.e., documents indicating how the parties perceived the strength of Lundbeck's new process patents when the agreements were concluded) could be considered. Nor did the GC commit error when it refused "*to take account of other evidence submitted by Lundbeck which is also subsequent to those agreements, that is to say, principally, the confirmation, by both the EPO Board of Appeal and the Netherlands Patent Office, of the validity of the crystallisation patent in all relevant aspects in 2009, as well as 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*". The CJEU clarified that there is a difference between evidence that may help to establish the parties' position when the agreements were concluded, on the one hand, and evidence unknown to the parties at that time that was incapable of "*shedding light on the existence or absence of a competitive relationship*" between them (paras. 70-72).

Finally, the CJEU held that the fact that the companies did not hold a marketing authorisation ("MA") for generic versions of citalopram when the agreements were concluded does not preclude potential competition. Potential competition may exist before the expiry of a compound patent, since producers of generic products want to be ready to enter the market as soon as that patent expires. The CJEU concluded that the Other Providers had taken necessary steps to obtain an MA (paras. 83-88).

Restrictions by Object

The CJEU reiterated that settlement agreements are restrictions by object only "*when it is plain … that the transfers of value … cannot have any explanation other than the commercial interest of both the holder of the patent at issue and the party allegedly infringing the patent not to engage in competition on the merits*". Thus, whether value transfers to potential entrants are sufficient to incentivise delayed or abandoned entry must be assessed case-by-case. However, there is no requirement that the value transfers "should necessarily be greater than the profits which that manufacturer of generic medicines would have made if it had been successful in the patent proceedings" (paras. 112-115).

The CJEU considered that, prior to the agreements, the parties were in dispute over whether Lundbeck's new process patents would prevent entry of generic citalopram, but concluded that it was "*principally the size of the reverse payments to the manufacturers of generic medicines which had induced them to accept the limitations governing their behaviour*". As a result, it concluded that the GC correctly characterised the agreements as restrictions by object (paras. 116-118).

This conclusion was not called into question by a number of arguments made by Lundbeck, including that the settlement agreements (paras. 120-135):

- were limited to the scope of Lundbeck's new process patents – the CJEU referred to the GC's judgment which stated that IP rights do not include "*the right to conclude agreements by which actual or potential competitors were paid not to enter the market*";

- did not contain any no-challenge clauses, unlike the agreements which gave rise to the Paroxetine judgment –

the CJEU held that the Other Providers "*had no incentive to challenge Lundbeck's new process patents after concluding the agreements*" given the values transferred to them.

Finally, the CJEU held that "*an examination of the 'counterfactual scenario', the purpose of which is to make apparent the effects of a given concerted practice, cannot be required in order to characterise a concerted practice as a 'restriction by object'*" (para. 140).

Comments

The judgment follows the CJEU's 2020 Paroxetine ruling. In a nutshell, the CJEU's key conclusions are as follows:

- **Potential competition:** a producer of generic products will be a potential competitor when it has real and concrete possibilities to enter the relevant market. Specifically, it must have a firm intention and inherent ability to enter, something that is assessed by reference to whether it had taken sufficient preparatory steps. Further, there must be no insurmountable entry barriers (where the mere existence of a process patent is not such a barrier). Finally, potential competition must be established at the time when the settlement agreement was concluded (although at least some subsequent evidence regarding the parties' positions at the time of settlement can be taken into account).

- **Restrictions by object:** settlement agreements are not always restrictive by object. They are restrictive by object only when the value transfers cannot be explained by a rationale other than a reduction in competition. A case-by-case assessment is required as to whether the value transfer to a potential entrant is sufficient to disincentivise entry.

Finally, there is an interesting procedural point in the Alpharma/Xellia judgment. The Commission was informed of the settlement agreements by the Danish competition authority in 2003. However, it did not start the administrative procedures in respect of Alpharma and Xellia until 2010 and 2011, respectively. In the meantime, it initiated its pharmaceutical sector inquiry in 2008. Alpharma and Xellia argued that the Commission infringed their rights of defence by failing to inform them in a timely manner of the existence of an investigation and of its objections, as a result of which they were unable to find certain exculpatory evidence.

The CJEU held that the GC erred in law by imposing an obligation of diligence on Alpharma and Xellia going back to 2003, given that this obligation applies only to the period after the initiation of an administrative procedure. That said, the CJEU added that when the Commission initiates a sector inquiry "*undertakings belonging to the sector concerned and, in particular, those which have concluded agreements expressly referred to in the decision initiating the inquiry, as was the case with Zoetis [now Alpharma] and Xellia, must expect that individual procedures may possibly be initiated against them in the future*". As a result, it concluded that Alpharma and Xellia "*cannot validly maintain that the Commission's initiation of the administrative procedure … had, by its lateness, infringed the rights of defence … and that the decision at issue should therefore be annulled*" (Alpharma, paras. 144-156).

See also Walid Chaiehloudj, Les Accords de Report d'Entrée, Concurrences, 2019