Court of Justice of the European Union
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Judgment in Cases C-586/16 P Sun Pharmaceutical Industries and Ranbaxy (UK) v Commission, C-588/16 P Generics (UK) v Commission, C-591/16 P Lundbeck v Commission, C-601/16 P Arrow Group and Arrow Generics v Commission, C-611/16 P Xellia Pharmaceuticals and Alpharma v Commission, and C-614/16 P Merck v Commission

Press and Information

The Court of Justice dismisses the appeals of a number of manufacturers of medicines involved in an agreement seeking to delay the marketing of the generic antidepressant citalopram

The European Commission had imposed on them fines of almost € 150 million

From the late 1970's, the Danish pharmaceutical company Lundbeck developed and patented an antidepressant medicine containing the active substance known as citalopram. Once its original compound patent expired, Lundbeck continued to hold only a number of secondary patents which offered more limited protection. Manufacturers of generic versions of citalopram were therefore able to plan to enter the market.

In 2002 Lundbeck entered into agreements with undertakings active in the production or sale of generic medicines. In return for a commitment by the generic undertakings not to enter the citalopram market, Lundbeck made significant payments to them and, in particular, purchased their stock of generic products.

In October 2003 the Commission was informed of the agreements in question by the Konkurrence- og Forbrugerstyrelsen (KFST) (the Danish authority for the protection of competition and consumers). Following a sector inquiry launched in January 2008, which was followed by the investigation specifically concerning the agreements at issue, the Commission held, by the decision of 19 June 2013, [1] that Lundbeck and the generic manufacturers concerned were at least potential competitors and that the agreements at issue constituted restrictions of competition 'by object'. The amounts paid by Lundbeck for the purpose of preventing those producers from entering the citalopram market corresponded approximately to the profits that they could have made if they had successfully entered the market. The Commission therefore imposed a total fine of € 93.7 million on Lundbeck, whilst the generic manufacturers were fined a total of €52.2 million.

The appeals brought before the General Court of the European Union by the undertakings against the Commission's decision were dismissed by a number of judgments of 8 September 2016. [2]

Those undertakings brought appeals before the Court of Justice, seeking to have the judgments of the General Court set aside and the Commission decision annulled.

By the judgments delivered today, **the Court dismisses all the appeals.**

First, the Court of Justice holds that the General Court did not err in upholding the Commission's assessment that at the time the agreements were concluded, **Lundbeck and the manufacturers of generic medicines were potential competitors.**

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[1] Decision C(2013) 3803 final relating to a proceeding under Article 101 [TFEU] and Article 53 of the EEA Agreement (Case AT.39226 – Lundbeck).

[2] Judgments of the General Court of 8 September 2016, *Sun Pharmaceutical Industries and Ranbaxy* v *Commission*, T-460/13; *Arrow Group and Arrow Generics* v *Commission*, T-467/13; *Generics (UK)* v *Commission*, T-469/13; *Merck* v *Commission*, T-470/13; *Xellia Pharmaceuticals and Alpharma* v *Commission*, T-471/13 and *Lundbeck* v *Commission*, T-472/13 ; see also press release No 90/16.

The Court finds that in order to assess whether an undertaking which is not present in a market is a potential competitor with one or more other undertakings which are already present in the market, it must be determined whether there are real and concrete possibilities of the former joining that market and competing with the undertakings present in it. That criterion does not require in any way that it be demonstrated with certainty that the undertaking will in fact enter the market concerned and, a fortiori, that it will be capable, thereafter, of retaining its place there.

Specifically, with regard to agreements occurring in the context of the opening of the market for a medicine containing an active ingredient which has recently entered the public domain, it should be established whether the manufacturer of generic medicines has in fact a firm intention and an inherent ability to enter the market, and does not meet barriers to entry that are insurmountable.

As regards, in particular, the assessment of whether there are barriers to entry into the market concerned which are insurmountable, the Court notes 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.

Therefore, **the existence of such a patent cannot, as such, mean that a manufacturer of generic medicines who has a firm intention and an inherent ability to enter the market**, and who, by the steps taken, shows a readiness to challenge the validity of that patent and to take the risk of being subject, upon entering the market, to infringement proceedings brought by the holder of that patent, **cannot be characterised as a potential competitor of the manufacturer of the originator medicine concerned**. Furthermore, the Court also holds 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 that patent is valid and has been infringed.

Second, the Court finds that the General Court did not err in law in concluding that **the agreements at issue constitute restrictions of competition 'by object'**.

In that respect, the Court states that characterisation as a 'restriction by object' must be adopted when it is plain from the examination of the settlement agreements concerned that the transfers of value from the manufacturer of originator medicines to the manufacturer of generic medicines cannot have any explanation other than the parties' common commercial interest not to engage in competition on the merits. It is appropriate to assess on a case-by-case basis whether the net gain of those transfers of value was sufficiently significant actually to act as an incentive to the manufacturer of generic medicines to refrain from entering the market concerned and not to compete on the merits with the manufacturer of originator medicines. There is no requirement that the net gain 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. In addition, the Court states that, much like the position regarding the assessment of whether there is potential competition, an assessment of the strength of the process patents at issue or of the prospects of success of one or other of the parties to the settlement agreements concerned is not relevant for the purposes of characterising those agreements as a 'restriction by object' provided that that transfers of value are sufficiently significant.

Furthermore, the Court observes that it is not an inevitable requirement that agreements of the same type as the agreements at issue should have previously been censured by the Commission in order for those agreements to be considered a restriction of competition 'by object', even if the agreements occur in a specific field such as the field of intellectual property rights.

In the Court's view, **in order to be able to characterise a given agreement as a 'restriction by object', only the specific characteristics of that agreement are significant, from which it is necessary to infer any harmfulness for competition, where necessary following a detailed analysis of that agreement, its objectives and the economic and legal context of which it forms part**. The Court holds that the agreements at issue, which allowed the market entry of manufacturers of generic medicines to be delayed and which were accompanied by payments made by Lundbeck which, by virtue of their size, induced the manufacturers of generic medicines

not to continue their efforts to enter the market, belong to that category of practices which are particularly harmful to competition.

Third, the Court considers that **the General Court erred in law in imposing on Xellia Pharmaceuticals and Alpharma an obligation of diligence derived from case-law that is not applicable to the situation in which they found themselves**.

The General Court held that those manufacturers of generic medicines could not plead infringement of their rights of defence owing to the allegedly unreasonable length of the administrative procedure, since they had failed to comply with their obligation of diligence, which ought to have caused them, as from 2003, to keep any document which might prove useful to their defence.

In imposing, as from 2003, that obligation, applicable only to the administrative procedure, even though that procedure was not initiated in respect of Xellia Pharmaceuticals and Alpharma until the early 2010s, the General Court did err in law.

However, the Court of Justice has not set aside the General Court's decision. If a ground of a decision of the General Court reveals an infringement of EU law, but the operative part can be seen to be well-founded on other legal grounds, the Court of Justice may make a substitution of grounds. In that regard, the Court of Justice finds that, while the General Court could not impose on Xellia Pharmaceuticals and Alpharma the obligation of diligence applicable only to the administrative procedure, **those companies were, in light of the Commission having initiated the pharmaceutical sector inquiry in 2008, bound by a specific duty of care requiring them to ensure that information enabling details of their activities to be retrieved is retained properly in their books or records, in order that they have in their possession the necessary evidence, in the event of subsequent administrative action or judicial proceedings following that sector inquiry**.

NOTE: An appeal, on a point or points of law only, may be brought before the Court of Justice against a judgment or order of the General Court. In principle, the appeal does not have suspensive effect. If the appeal is admissible and well founded, the Court of Justice sets aside the judgment of the General Court. Where the state of the proceedings so permits, the Court of Justice may itself give final judgment in the case. Otherwise, it refers the case back to the General Court, which is bound by the decision given by the Court of Justice on the appeal.

The full text of the judgments (C-586/16 P, C-588/16 P, C-591/16 P, C-601/16 P, C-611/16 P and C-614/16 P) is published on the CURIA website on the day of delivery.

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