Court of Justice of the European Union
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Press and Information

Judgment in Case C-457/10 P
AstraZeneca v Commission

The Court dismisses the appeal of the AstraZeneca group, which abused its dominant position by preventing the marketing of generic products replicating Losec

AstraZeneca AB and AstraZeneca plc belong to a pharmaceutical group ('AZ') which is active worldwide in the sector of the invention, development and marketing of pharmaceutical products. One of the main products marketed by AZ is known as 'Losec' (a treatment for ulcers).

By decision of 15 June 2005[1], the Commission imposed a fine of €60 million on those companies for having committed two abuses of a dominant position.

First, the Commission found that AZ had made deliberately misleading representations to the patent offices of certain Member States. Those representations sought to obtain or maintain supplementary protection certificates[2] for Losec, granting an extension of the protection under the patent, to which AZ was not entitled or to which it was entitled for a shorter duration, in order to keep manufacturers of generic products away from the market.

Secondly, AZ was penalised for having submitted requests for deregistration of the marketing authorisations for Losec capsules in Denmark, Sweden and Norway in order to delay or make more difficult the marketing of generic medicinal products, and to prevent parallel imports of Losec.

AstraZeneca plc and AstraZeneca AB brought an action before the General Court for annulment of the Commission's decision.

By a judgment of 1 July 2010[3], the General Court rejected most of the arguments put forward by AZ. However, it annulled in part the Commission's decision so far as concerns the finding of the second abuse. The General Court held that, although the Commission had proved that the deregistration of the marketing authorisations for Losec capsules in Denmark, Sweden and Norway were such as to delay the entry to the market of generic medicinal products in those three countries and, furthermore, to prevent parallel imports of Losec in Sweden, the Commission had not proved that that latter effect had been produced in Denmark and in Norway. The General Court therefore reduced the amount of the fine imposed jointly and severally on AstraZeneca AB and AstraZeneca plc to €40.25 million and fixed the fine imposed on AstraZeneca AB at €12.25 million.

AstraZeneca AB and AstraZeneca plc lodged an appeal before the Court of Justice to have that judgment of the General Court set aside.

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[1] Commission Decision C (2005) 1757 final of 15 June 2005 relating to a proceeding under Article 82 [EC] and Article 54 of the EEA Agreement (Case COMP/A.37.507/F3 – AstraZeneca)

[2] A supplementary protection certificate may be obtained by the holder of a national or European patent. Its purpose is to extend the protection conferred by that patent for an additional maximum period of five years so that the holder will have the benefit of a maximum period of 15 years of exclusivity from the first marketing authorisation (which is itself issued for a period of 10 years).

[3] Case T-321/05 *AstraZeneca* v *Commission*, see also Press Release No 67/10.

By today's judgment, the Court rejects the arguments advanced by the two companies, concerning, inter alia, errors of law allegedly made by the General Court in respect of the assessment of two abuses and the determination of the amount of the fines.

As regards, in particular, the first abuse of a dominant position concerning supplementary protection certificates, the Court observes that EU law prohibits a dominant undertaking from eliminating a competitor and thereby strengthening its position by using methods other than those which come within the scope of competition on the merits.

The Court concludes on this issue that the General Court was fully entitled to hold that AZ's consistent and linear conduct, which was characterised by the notification to the patent offices of misleading representations and the lack of transparency by which AZ deliberately attempted to lead the patent offices and judicial authorities into error in order to keep for as long as possible its monopoly on the medicinal products market, was a breach of competition on the merits and therefore an abuse of a dominant position.

So far as concerns the second abuse of a dominant position, the Court has held that the deregistration of the marketing authorisations, without objective justification and after the expiry of the exclusive right granted by EU law, with the aim of hindering the introduction of generic products and parallel imports, also does not come within the scope of competition on the merits.

In respect of the fine imposed on the companies, the Court is of the opinion that the General Court did not err in law in concluding, inter alia, that, in the absence of mitigating circumstances or special circumstances, the abuses must be characterised as serious infringements, and consequently the amount of the fine cannot be reduced for those reasons.

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.

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