General Court of the European Union
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Press and Information

Judgment in Case T-321/05
AstraZeneca v Commission

The General Court essentially upholds the decision of the Commission which found that the AstraZeneca Group abused its dominant position by preventing the marketing of generic products replicating Losec

However, the fine of €60 million has been reduced to €52.5 million because the Commission failed to prove that the deregistration of the marketing authorisations of the medicinal product in certain Member States was capable of having an impact on parallel imports

By decision of 15 June 2005[1] the Commission imposed on AstraZeneca plc (United Kingdom) and its subsidiary, AstraZeneca AB (Sweden), a fine of €46 million, and an additional fine of €14 million on AstraZeneca AB for having abused their dominant position by using the patent system and the procedures for marketing pharmaceutical products with the sole purpose of preventing or delaying the market entry of generic medicinal products competing with their anti-ulcer product, Losec, or of preventing parallel imports of Losec.

First, the Commission found that AstraZeneca made deliberately misleading representations to the patent offices in Germany, Belgium, Denmark, Norway, the Netherlands and the United Kingdom in order to obtain supplementary protection certificates for Losec that conferred extended patent protection. That extension of protection was designed to compensate for the period prior to the grant of the marketing authorisation for the pharmaceutical product, during which AstraZeneca was not able to market that product. The Commission found that AstraZeneca had concealed from the national patent offices the date on which it had obtained its first marketing authorisation and that this enabled it to obtain supplementary protection for its medicinal product to which it was not entitled.

Second, AstraZeneca was sanctioned for having deregistered the Losec capsule marketing authorisations in Denmark, Norway and Sweden in order (i) to delay and make more difficult the marketing of generic medicinal products and (ii) to prevent parallel imports of Losec. At the material time, EU law required that the marketing authorisation of the reference medicinal product still be in force in the Member State concerned in order that a marketing authorisation for a generic medicinal product could be granted in accordance with a simplified procedure, which was faster and less burdensome for an undertaking applying for that authorisation. AstraZeneca's deregistration of the Losec capsule's marketing authorisations had the effect of preventing the use of that simplified procedure and thus of making the acquisition of marketing authorisations for generic medicinal products more time-consuming and more difficult, thereby delaying their marketing.

AstraZeneca plc and AstraZeneca AB brought an action before the Court for annulment of the Commission's decision or, at the very least, for a reduction of the fines imposed.

In today's judgment, the Court rejects most of the arguments put forward by AstraZeneca and finds that it committed two abuses of a dominant position. With respect to the first abuse of a dominant position, the Court finds inter alia that AstraZeneca did indeed make misleading representations to the national patent offices. As regards the second abuse of a dominant position, the Court states

[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).

inter alia that the fact that pharmaceutical undertakings are normally entitled to request the deregistration of marketing authorisations for their products does not cause such conduct to escape the prohibition laid down in Article 82 EC. However, the Court annuls the Commission's Decision so far as concerns the deregistrations of the Losec capsule marketing authorisations in Denmark and Norway, inasmuch as it was found in that decision that those actions were capable of restricting parallel imports.

The Court considers that, in view of the legal context, the Commission failed to prove that the deregistrations of the marketing authorisations were capable of preventing parallel imports of Losec in Denmark and Norway, and, *a fortiori*, that the cessation or the sharp decline of parallel imports of Losec in those two countries was caused by AstraZeneca's conduct. In accordance with the principle that doubt must operate to the advantage of the addressee of the decision finding the infringement, **the Court decides to reduce the fine imposed jointly and severally on AstraZeneca AB and AstraZeneca plc by setting it at €40 250 000 and sets the fine imposed on AstraZeneca AB at €12 250 000.**

NOTE: An appeal, limited to points of law only, may be brought before the Court of Justice against the decision of the General Court within two months of notification of the decision.

NOTE: An action for annulment seeks the annulment of acts of the institutions of the European Union that are contrary to European Union law. The Member States, the European institutions and individuals may, under certain conditions, bring an action for annulment before the Court of Justice or the General Court. If the action is well founded, the act is annulled. The institution concerned must fill any legal vacuum created by the annulment of the act.

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