



## ASTRA ZENECA

### Abuse of government procedures in the pharmaceutical sector

On the 15th June 2005, the Commission adopted a decision fining AstraZeneca AB and AstraZeneca plc (AZ) EUR 60 million for having infringed Article 82 EC and Article 54 EEA by misusing public procedures and regulations in a number of EEA states with a view to excluding generic firms and parallel traders from competing against AZ's anti-ulcer product Losec<sup>(1)</sup>. The fine took into account that some features of the abuses — i.e. misuses of government procedures — can be considered novel.

#### The relevant market

The relevant market comprises national markets for so called proton pump inhibitors (PPIs) sold on prescription which are used for gastrointestinal acid related diseases (such as ulcers). AZ's Losec was the first PPI.

#### AZ's dominance on the national PPI markets concerned

The Commission's findings on dominance during the relevant years in the countries concerned were based on AZ's high market shares and position as incumbent on the PPI market, among other things.

The first mover in a pharmaceutical market is generally able to obtain and

maintain higher prices than later entrants to the market. The Commission's decision also considers the issue of monopsony buyers (i.e. national health systems) and price regulation. It observes that the bargaining power of monopsony buyers is considerably reduced vis-a-vis companies offering genuinely innovative new products (such as Losec). Moreover, the monopsony buyers are not in a position to control entry to the market.

#### Misuse of the regulatory system

AZ's first abuse involved misuse of a Council regulation adopted in 1992<sup>(2)</sup> creating a supplementary protection certificate (SPC) under which the basic patent protection for pharmaceutical products can be extended. The abuse essentially consisted of a pattern of misleading representations made by AZ as of mid-1993 before patent offices in a number of EEA countries in connection with its SPC applications for omeprazole (the active substance in AZ's product Losec). Due to this misleading information AZ obtained extra protection in several countries. The entry of cheaper generic versions of Losec

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<sup>1</sup> (1) Press release IP/05/737, 15.6.2005.

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<sup>2</sup> Council Regulation (EEC) No 1768/92 of the 18th June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ L 182, 2.7.1992, p. 1).



was thus delayed, entailing costs for health systems and consumers.

The Commission found that the use of such procedures and regulations may be abusive in specific circumstances, in particular where the authorities or bodies applying such procedures have little or no discretion.

The existence of remedies under other legal provisions cannot by itself exclude the application of Article 82 EC, even if they cover aspects of the exclusionary conduct. The Commission found in its decision that there is no reason to limit the applicability of competition law to situations where such conduct does not violate other laws and where there are no other remedies.

### **Misuse of drug authorisation procedures**

The second abuse took place towards the end of the 1990s and consisted of AZ's requests for the deregistration of its market authorisation for Losec capsules in Denmark, Norway and Sweden in a context where Losec capsules were withdrawn from the market and Losec MUPS tablets were launched in those

three countries. The selective deregistration removed the reference market authorisation on which generic firms and parallel traders arguably needed to rely at the time in order to enter and/or remain on the market.

The Commission found that through its conduct AZ sought to extend, and in part succeeded in extending, de facto the protection afforded well beyond the period provided for in the applicable rules.

This second abuse is also characterised by exclusionary intent in a regulatory context characterised by limited or no discretion on the part of the authorities concerned. Dominant companies have a special responsibility to use specific entitlements, whether private or public, in a reasonable way in respect of market access for other parties.

The Commission observed in its decision that single acts involving the launch, withdrawal or requests for deregistration would not normally as such constitute an abuse.

### **Source**

[Report on competition policy 2005](#), box 2 (page 37 in the English version).

### **For more information...**

- [Case information](#) (case COMP/37.507)
- Information on the procedure in the Court of Justice [AstraZeneca Vs Commission](#) (case T-321/05)