COMMISSION

COMMISSION DECISION

of 15 June 2005

relating to a proceeding under Article 82 of the EC Treaty and Article 54 of the EEA Agreement

(Case COMP/A.37.507/F3 — AstraZeneca) [1]

(notified under document number C(2005) 1757)

(Only the English and Swedish texts are authentic)

(Text with EEA relevance)

(2006/857/EC)

On 15 June 2005, the Commission adopted a decision relating to a proceeding under Article 82 of the EC Treaty and Article 54 of the EEA Agreement. In accordance with the provisions of Article 30 of Regulation (EC) No 1/2003 [2], the Commission herewith publishes the names of the parties and the main content of the decision, including any penalties imposed, having regard to the legitimate interest of undertakings in the protection of their business secrets. A non-confidential version of the full text of the decision in the authentic languages of the case (English and Swedish) can be found at DG COMP's website at http://europa.eu.int/comm/competition/index_en.html

1. SUMMARY OF THE INFRINGEMENTS

Addresses and the nature of the infringements

The decision is addressed to the Swedish company AstraZeneca AB and the UK company AstraZeneca Plc (hereinafter 'AZ') due to their infringements of Article 82 of the EC Treaty and Article 54 of the EEA Agreement.

The infringements concern abuses by AZ of government procedures in seven EEA Contracting States aimed at excluding generic firms and — in the context of the second infringement — parallel traders from competing against AZ's pharmaceutical product Losec. The first abuse involved misuses of a Council Regulation [3] (hereinafter 'SPC Regulation') under which the basic patent protection for pharmaceutical products can be extended. The second abuse concerned misuses of procedures relating to the authorisation of marketing of pharmaceutical products.

Relevant market and dominance

The relevant market comprises national markets for so-called proton pump inhibitors (hereinafter 'PPIs') sold on prescription which are used for gastro-intestinal acid related diseases (such as ulcers). AZ's Losec was the first PPI. More specifically, the decision finds that a PPI market can be established at least from 1993 in Belgium, Denmark, Germany, the Netherlands, Sweden and the UK and from 1992 in Norway.

The decision finds that AZ held a dominant position on the PPI market in Belgium, the Netherlands, Sweden (from 1993 until the end of 2000), Norway (from 1994 until the end of 2000), Denmark and the UK (from 1993 until the end of 1999) and Germany (from 1993 until the end of 1997).

The first infringement

The first infringement of Article 82 of the EC Treaty and Article 54 of the EEA Agreement constitutes a single and continuous abuse and consists of a pattern of misleading representations made by AZ before patent offices in Belgium, Denmark, Germany, the Netherlands, Norway and the UK and before national courts in Germany and Norway.

The misleading information was initially provided by AZ in the context of its applications to several patent offices in June 1993 and December 1994 within the EEA for extra protection for omeprazole (the active substance in AZ's product Losec) in the form of so-called supplementary protection certificates.

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[1] Opinion of the Advisory Committee (OJ C 291, 30.11.2006).

[2] OJ L 1, 4.1.2003, p. 1. Regulation as amended by Regulation (EC) No 411/2004 (OJ L 68, 6.3.2004, p. 1).

[3] SPCs are granted pursuant to Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (OJ L 182, 2.7.1992, p. 1).

The second infringement

The second infringement of Article 82 of the EC Treaty and Article 54 of the EEA Agreement constitutes a single and continuous abuse and consists of AZ's requests for the surrender of its market authorisations for Losec capsules in Denmark, Norway and Sweden combined with its withdrawal from the market of Losec capsules and launch of Losec MUPS tablets in those three countries.

2. **FINES**

The decision finds that the nature of the infringements and their geographic scope are such that the infringements must be qualified as serious.

The qualification of the infringements as serious takes into account that the abuses in this case present some specific and novel features regarding the means used and cannot be said to have been clear-cut ones.

The decision also takes account of the fact that AstraZeneca Plc is only jointly and severally liable for the infringements with effect from the merger between Astra AB (currently AstraZeneca AB) and Zeneca Plc on 6 April 1999.

The fine of EUR 60 000 000 is divided as follows. AstraZeneca AB and AstraZeneca are jointly and severally liable for EUR 46 000 000 whereas AstraZeneca AB is solely liable for EUR 14 000 000.