1. Introduction

On 15 June 2005 the Commission adopted a decision (‘Decision’) fining the Swedish company AstraZeneca AB and the UK company AstraZeneca Plc (together ‘AZ’) 60 million euros due to their infringements of Article 82 of the EC Treaty and Article 54 of the EEA Agreement.

The infringements involve misuses by AZ of public procedures and regulations in a number of EEA states aimed at excluding generic firms and parallel traders from competing against AZ’s anti-ulcer product Losec.

In 1979, Astra AB (currently AstraZeneca AB), a Swedish research based company, had filed patent applications in Europe in respect of omeprazole (the active substance in Losec). Losec’s basic patent protection therefore by and large expired across Europe in 1999. Losec is one of the most successful products in pharmaceutical history with annual sales reaching around six billion euros towards the end of the 1990s.

AZ’s first abuse involved misuses of the patent system; or more specifically of a Council Regulation adopted in 1992 (1) under which the basic patent protection for pharmaceutical products can be extended (‘SPC Regulation’). The idea underlying the SPC Regulation is to compensate pharmaceutical companies for the often long period which elapses between the start of the term of the basic patent and the point in time when the product receives a market authorisation. The second abuse concerned misuses of procedures relating to the authorisation of the marketing of pharmaceutical products. The fine takes into account that some features of the abuses can be considered as novel.

2. The first infringement — misuse of the patent system

2.1. The 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 United Kingdom and before national courts in Germany and Norway.

The misleading information was provided by AZ in the context of its two rounds of applications (in June 1993 and December 1994) to several patent offices 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 (SPCs). Under the SPC Regulation the basic patent protection for active substances in medicines can be extended by a maximum of five years.

The Decision raises no objections to AZ’s incorrect interpretation of the relevant legislation. Therefore, the proceedings and outcome in Hässle AB v. ratiopharm GmbH (2) concerning the interpretation of the relevant provisions of the SPC Regulation are not decisive for the finding of an abuse in this case and any lack of clarity concerning the interpretation of the SPC Regulation cannot constitute an objective justification for the behaviour.

The Decision considers that the conduct did not constitute normal competition and that it cannot be explained as the result of alleged errors or unauthorised behaviour by patent agents and counsel acting on behalf of AZ.

2.2. The effects of the infringement

Through the misleading information in connection with its SPC applications for omeprazole, AZ obtained extra SPC protection in several countries. Such intellectual property protection constitutes the principal barrier to entry for generic versions of an original medicine (in this case Losec). Thereby, the entry of cheaper generic versions of Losec was delayed, entailing additional costs for health systems and consumers.

AZ’s competitors were forced to bring lengthy and costly litigation to invalidate AZ’s SPCs. In some countries AZ was able to bring patent infringement proceedings against generic firms by invoking the SPCs it had obtained through its misleading representations. In addition, AZ’s conduct caused uncertainty, delays and disruption of generic firms’ preparations for market entry.


(2) Case C-127/00 Hässle, in particular paragraph 79.
2.3. The use of public procedures and regulation to foreclose competition

The Decision finds that the special responsibility of a dominant undertaking also covers the use of public procedures and regulations. The use of such procedures and regulations may be abusive in specific circumstances where there is a clear intent to foreclose competition on the part of a dominant company, in particular where the authorities or bodies applying such procedures have little or no discretion. Such a regulatory context existed in this case as the patent offices largely accepted the data submitted by the SPC applicants at face value. Moreover, limited information on applications for and grants of SPCs was available to the competitors.

The Decision observes that the acquisition of a right may constitute an abuse. Behaviour in the process leading up to the acquisition of a right may therefore also constitute an abuse. Considering that AZ’s initial misleading representations were made well before the grant of the rights in question, the finding of an abuse cannot affect the subject-matter of the said rights.

2.4. The existence of other remedies (apart from competition law)

The existence of other specific remedies cannot by itself exclude the application of Article 82 even if they may cover aspects of the exclusionary conduct. The Decision finds 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. The purpose of competition law is to sanction behaviour with anticompetitive objects or effects. Such behaviour may also give rise to liability under other laws regardless of any anticompetitive effects it may have. Moreover, the scope of remedies under patent laws is very limited in this case. There would be no sanctions apart from the annulment of the SPCs. For example, no sanctions would be imposed against failed attempts to obtain SPCs through misleading information.

3. The second infringement — misuse of procedures relating to the marketing of pharmaceutical products

3.1. The infringement

The second infringement of Article 82 of the EC Treaty and Article 54 of the EEA Agreement constitutes a single and continuous abuse (from 19 March 1998 until the end of 2000) consisting of AZ’s requests for the deregistration of its market authorisation 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.

A key purpose underlying the conduct was to exclude competition from generic firms and parallel traders. The Decision does not object to the withdrawal of Losec capsules from the market and/or the launch of the Losec tablets as such. The core of the second abuse consists in the selective deregistration which removed the reference market authorisation on which generic firms and parallel traders originally needed to rely at the time to enter and/or remain on the market.

AZ deregistered its market authorisation for Losec capsules selectively only in countries where it thought this strategy would block or delay generic market entry or parallel imports.

The Decision finds that through its conduct, AZ sought to extend de facto the protection afforded by patents, SPCs and data exclusivity well beyond the period provided for in the applicable rules considered reasonable by the legislator.

Patents, SPCs and data exclusivity are designed to reward innovation, while the purpose of a market authorisation is not an entitlement to exclude competitors but the right to market a pharmaceutical product.

While the Decision does not contend that the purpose of a market authorisation is to facilitate entry of generic products, it states that in the specific circumstances of this case, the deregistration of a market authorisation may be an element of the abuse.

The Decision finds that the conduct did not constitute standard practice at the time. It also finds that there were no objective justifications for the behaviour. For example, AZ’s requests for deregistration were not based on public health considerations. Nor can the conduct find any justification in the relevant pharmaceutical legislation in the light of the actual motives underlying the conduct.

Nevertheless, the Decision observes that single acts involving the launch, withdrawal or requests for deregistration would not normally as such constitute an abuse and that — due to changes in the relevant EC pharmaceutical legislation — the second abuse cannot be repeated.

3.2. The effects of the infringement

Through its strategy, AZ aimed to prevent and in part succeeded in preventing the authorisation of generic versions of Losec as well as excluding
parallel trade in Losec, artificially partitioning the internal market. Thereby, the entry of cheaper generic and parallel imported versions of Losec was delayed, entailing additional costs for health systems and consumers.

3.3. The use of government procedures and entitlements as well as the relevance of the regulatory context

The second abuse is not an abuse of intellectual property rights. The abuse concerns the use of public procedures in a regulatory context characterised by limited or no discretion on the part of the authorities concerned. As mentioned (see point 2.3 above), such behaviour can be qualified as abusive in specific circumstances if there is a clear intent to exclude competitors. Moreover, 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.

4. The relevant market comprising proton pump inhibitors

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

The Decision finds that during the relevant years in the countries concerned the previous generation of anti-ulcer products (H2 blockers) did not exercise a significant competitive constraint on the PPIs. This conclusion is based on the 1997 Notice on the definition on the relevant market.

Throughout the 1990s there was a clear one-side substitution pattern whereby PPIs progressively replaced H2 blockers in respect of all acid-related diseases and conditions. Evidence of substitution in the recent past will normally be fundamental for product market definition. Over this period PPIs were also in general considerably more expensive than the H2 blockers.

The Decision specifically takes into account the special features of the pharmaceutical sector, such as the regulatory context including price regulation. The Decision finds that pharmaceutical companies offering therapeutically superior products (such as Losec) to the authorities are generally able to extract higher reimbursable prices than those set for previous generations of less effective medicines.

The Decision also takes account of the relevant products' characteristics and uses, non-price factors relevant to the competition in pharmaceutical prescription markets as well as the impact of certain actual events on the market (‘natural events’) (such as the lack of impact on prices of and demand for PPIs following the entry of cheaper H2 blockers).

5. AZ's dominance on the national PPI markets concerned

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

The Decision's findings on dominance are based on a number of factors including AZ's high market shares and position as incumbent on the PPI market.

The first mover in a pharmaceutical market is generally able to obtain and maintain higher prices than later entrants to the market. AZ, as the first mover into the PPI market, was indeed in general able obtain and maintain higher prices than later entrants onto the PPI market (such as Takeda and Byk Gulden). The ability to maintain a higher price constitutes evidence of market power as it reflects the company's bargaining power vis-à-vis national buying organisations or the ability (to the extent that a company can price freely) to charge a price premium above the reimbursement level.

The 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-à-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.