



Astra Zeneca Future Outlook

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Article 102 TFEU

Quick Reminder of the Basics

- » Any **abuse** by one or more undertakings
- » of a **dominant** position
- » within the common **market** or in a substantial part of it shall be prohibited as incompatible with the common market in so far as it may affect trade between Member States.

AstraZeneca : The Commission Decision

Relevant Market

- » National markets for proton pump inhibitors (PPI) sold on prescription which are used for gastrointestinal acid related diseases (such as ulcers)
- » Previous generation of anti-ulcer products (H2 blockers) did not exercise a significant competitive constraint on the PPIs
 - PPIs progressively replaced H2 blockers in respect of all acid-related diseases and conditions in the 1990s
 - PPIs were also in general considerably more expensive than the H2 blockers

The Commission Decision Dominance

- » high market shares (Omeprazole/Losec)
- » first mover advantage (higher prices than later entrants such as Takeda)
- » bargaining power of national health systems considerably reduced vis-à-vis companies offering genuinely innovative new products

The Commission Decision

1st abuse

- » “Intentionally misleading” SPC applications
 - incorrect information re first marketing authorization
 - in B, DK, D, NL, NO, UK (pattern of behavior)

- » Consequences
 - AZ obtains extension of rights it is not entitled to
 - market entry of competing PPIs delayed
 - AZ’s dominance in PPIs extended

The Commission Decision

2nd abuse

- » AZ launches new formulation for Losec (tablets instead of capsules)

- » Withdraws marketing authorization for original formulation
 - in certain selected countries only
 - shortly before patent expiry
 - pursuant to a plan
 - no objective justification (e.g. public health)

- » Consequences
 - entry by generics or parallel imports delayed
 - AZ dominance extended

The Commission Decision

Lessons

- » Patent acquisition may under circumstances be unlawful (*Tetra Pak I*, *Astra Zeneca* (1st abuse))

- » Misuse of a legitimate administrative process may constitute an abuse where
 - it forms part of a plan to restrict competition, and
 - there is no objective justification for use of the process (*Astra Zeneca* (2nd abuse))

The Commission Decision Lessons

- » Extending dominance as a result of “intentionally deceptive” behavior may lead to an abuse (*Astra Zeneca* (1st abuse)/*Rambus*)

The Appeal

Potential Impact

- » Astra Zeneca – narrowly related to many aspects of the sector inquiry
 - Patent thickets
 - large numbers of patents/applications round a core innovation creates legal uncertainty and may delay generic entry (quality of patents may not be strong)
 - AZ first abuse
 - Interference in authorization procedures
 - objections lodged to applications for marketing authorizations (MAs) and pricing and reimbursement (P&R) status for generics with the intention of delaying generic entry
 - AZ first and second abuse

The Appeal

Potential Impact

- Misleading marketing
 - use of advertising/information campaigns to cast doubt on safety/effectiveness of generic medicine
 - AZ first abuse

- Evergreening
 - strategies for extending exclusivity by obtaining secondary patents and launching follow-on products
 - AZ first and second abuse

The Appeal

AZ arguments

- » Market definition : Commission wrongly excluded H2 blockers
- » Dominance : Commission did not analyze dominance issues in wider market
- » Abuse 1 : only if dishonestly obtained rights are enforced or capable of being enforced
- » Abuse 2 : no obligation to maintain MA for product no longer marketed merely to facilitate generic market entry
- » Factual evidence lacking or incorrectly analyzed

The Appeal Analysis

- » Key = market definition

- » If market definition is upheld – dominance too

- » If dominance is established, abuse is likely
 - Documents show exclusionary intent
 - No credible objective justifications

Private Enforcement ?

Thank you for your attention !