Competition Policy & Ensuring access to Generic medicines

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views expressed are personal

Life cycle management – *AstraZeneca* case & beyond

Parallel imports

Policy Screening

The *AstraZeneca* decision
15 June 2005

(soon available on:
http://europa.eu.int/comm/competition/index_en.html)

Life cycle management – *AstraZeneca* case & beyond

- ***AstraZeneca* – The Facts:**
  - 1979, Astra AB (currently AstraZeneca AB), a Swedish research based company filed patent applications in Europe in respect of omeprazole (otherwise known as Losec).
  - Losec's basic patent protection by and large expired across Europe in 1999.
  - Losec's annual world-wide sales were reaching around € 6 billion by the end of the 1990s.

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- ***AstraZeneca* – The Facts (cont'd):**
  - **First abuse:** Beginning '93, AZ engaged in a pattern of misrepresentations to patent attorneys, national courts and patent offices in the EEA to get unwarranted SPCs for omeprazole.
  - **Second abuse:** In '98/'99, AZ operated a strategy of withdrawing its 'Losec' capsules, replacing them with 'Losec' tablets, and requesting selectively the deregistration of the marketing authorisation for the capsules in Denmark, Norway and Sweden.

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- ***AstraZeneca* – Effects of the First Abuse:**
  - *De facto* extension of AZ's exclusivity from the SPC rules beyond the period provided for by the legislator.
  - Entry of cheaper generic versions of Losec was delayed ➔ additional costs for health systems and consumers.
  - Competitors forced to bring or defend lengthy & costly patent litigation ➔ raising rivals' costs.
  - All this caused uncertainty, delays and disruption to generic market entry.

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- ***AstraZeneca* – Assessment of the First Abuse:**
  - AZ pleaded mistaken interpretation of the rules due to lack of clarity.
  - COM did not hold AZ's incorrect interpretation of the SPC rules against it but found their lack of clarity ≠ an objective justification for its behaviour.
  - In essence, a dominant undertaking has a special responsibility vis-à-vis its use of public regulatory procedures = abuse in specific circumstances.

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- ***AstraZeneca* – Assessment of the First Abuse (cont'd):**
  - **Such circumstances exist where:**
    - There is a clear intent to foreclose competition.
    - Public authorities have little or no discretion & accept data submitted by applicants at face value.
    - Limited information on applications for and grants of SPCs was available to competitors.

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- ***AstraZeneca* – Assessment of the First Abuse (cont'd):**
  - **In such circumstances:**
    - Acquisition of a right may constitute an abuse.
    - Conduct leading up to the acquisition of a right may also constitute an abuse.
    - Finding of an abuse cannot affect the subject-matter of the right.

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- ***AstraZeneca* – Assessment of the First Abuse (cont'd):**
  - There is no reason to limit the applicability of competition law to situations where abusive conduct does not violate other laws and where there are no other remedies.
  - Existence of other remedies cannot by itself exclude the application of competition law even if they may cover aspects of the exclusionary conduct.

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- ***AstraZeneca* – Assessment of the First Abuse (cont'd):**
  - The purpose of competition law is to sanction behaviour with anticompetitive object or effect.
  - Such behaviour may also give rise to liability under other laws regardless of any anticompetitive effects it may have.
  - The scope of other remedies is very limited in this case ➔ no sanction other than the annulment of the SPCs.

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- ***AstraZeneca* – Effects of the Second Abuse:**
  - *De facto* extension of AZ's exclusivity beyond the period provided for by the legislator.
  - Selective deregistration of Losec capsules in countries where AZ thought its strategy would block or delay generic market entry.
  - Mere withdrawal without exclusionary motive ≠ an abuse but there was no other objective justification for the withdrawal e.g. health grounds.

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- ***AstraZeneca* – Assessment of the Second Abuse:**
  - Here too abuse concerns the use of public regulatory procedures where authorities have limited or no discretion.
  - But here there is no element of fault apart from AZ's clear intent to exclude competitors.
  - Here too dominant companies have a special responsibility to use their legal entitlements, in a reasonable manner vis-à-vis the market access needs of others.

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- ***AstraZeneca* – The Market:**
  - These special responsibilities only arise in the case of firms that are dominant on a relevant market.
  - Relevant market = proton pump inhibitors (PPIs) sold on prescription which are used for gastro-intestinal acid related diseases (such as ulcers).
  - A PPI market was found in the seven EEA countries (Belgium, Denmark, Germany, the Netherlands, Norway, Sweden and the United Kingdom) from at least 1993.
  - Losec was the first PPI.

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- ***AstraZeneca* – The Market (cont'd):**
  - 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 was based on evidence of one-side substitution pattern whereby PPIs progressively replaced H2 blockers in respect of all acid-related diseases and conditions in the 1990s.
  - Over this period PPIs were also in general considerably more expensive than the H2 blockers.

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- ***AstraZeneca* – The Market (cont'd):**
  - COM found that companies offering therapeutically superior products (such as Losec) to the public health authorities are generally able to extract higher reimbursable prices than those set for previous generations of less effective medicines.

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- ***AstraZeneca* – The Market (cont'd):**
  - COM also took account of:
    - The products characteristics and uses of PPIs and H2 blockers.
    - Non-price factors relevant to competition in pharmaceutical prescription markets, such as mode of action
    - Actual events on the market ('natural events') such as the lack of any price or demand impact on PPIs following the entry of cheaper H2 blockers.

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- ***AstraZeneca* – Dominance:**

COM found that AZ held a dominant position on the PPI market in Belgium, the Netherlands, Norway, Sweden (1993-2000), Denmark, the United Kingdom (1993-1999) and Germany (1993-1997).

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- ***AstraZeneca* – Dominance (cont'd):**
  - AZ's dominance was based on the following factors:
    - AZ's high market shares and position as incumbent on the PPI market.
    - Az's first mover advantage enabling it to obtain and maintain higher prices than later entrants to the market.
    - The bargaining power of monopsony buyers (i.e. national health systems) was considerably reduced vis-à-vis companies offering genuinely innovative new products (such as Losec).
    - National health systems are not in a position to control entry to the market which are the remit of patent offices and licensing authorities.

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- ***AstraZeneca* – The Fine:**
  - AZ was fined € 60 million.
  - The fine takes into account the novelty of the abuses.

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So what is next?

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Case T-321/05 ***AstraZeneca AB & AstraZeneca plc v Commission***, (2005/C 271/47)

(summary available on: http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/oj/2005/c_271/c_27120051029en00240024.pdf)

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- ***AstraZeneca* – The Appeal:**
  - ***AstraZeneca appealed COM's decision to the CFI on 25 August 2005***
  - ***The grounds for appeal on the relevant market:***
    - Commission mistakenly defined the relevant market as PPIs used for the treatment of gastrointestinal acid related diseases, excluding histamine receptor antagonists from the relevant market.

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- ***AstraZeneca* – The Appeal (cont'd):**
  - ***The grounds for appeal on the abuse:***
    - Misleading representations made in the course of applications for intellectual property rights cannot in law amount to an abuse unless and until the dishonestly obtained rights are enforced or are capable of being enforced.
    - Properly interpreted, Article 82 did not impose on them an obligation to maintain a marketing authorisation for a product they no longer marketed, merely because it would make it easier for generics and parallel traders to compete with it.