Antitrust and IP in the Pharmaceutical Sector – Current Legal Issues

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Important Recent Developments

- In EC
  - *Astra Zeneca*
  - *Boehringer* investigation
  - *GSK*
- In US
  - *Rambus*
  - *Shering/Plough*

Astra-Zeneca

- Commission Decision –15.06.2005
- Astra Zeneca fined €60 million for abuse involving patent registration
- Dominance in market for proton pump inhibitors (Losec was largest selling prescription medicine)
- Original patent protection was expiring

Astra-Zeneca

- Commission found two types of abuse
  - Provision of misleading information to national authorities to gain extended patent protection by "supplemental protection certificates"
  - Selective deregistration of market authorisation for Losec capsules – creating a barrier for marketing of generic products and sale of parallel-traded products
- Commission observed that market authorisation requirements were not intended to reward innovation – thus *no IP/Competition policy issues involved*

Boehringer Investigation

- Commission press release -- 1 April, 2007
- Case appears to involve applications for patents on combinations on compounds
  - Two patented compounds owned by applicant
  - Own patented compound with off-patent compound
  - Two third party compounds
- Abuse allegation reportedly concerns blocking of competing compounds/combination without adding innovation

GSK Cases

- Both cases involve situation where price regulation in Member State leads to significantly lower prices – possibility for arbitrage by parallel trade

GSK Spain (CFI judgement 27.09.06)

- GSK notified “dual-pricing” agreement under Regulation 17 – 81(3)
  - Protects incentives for innovation in high price countries
  - Ensures that consumers in low price countries have access to new drugs
- Commission rejected application on basis that benefits insufficiently proven
- CFI ruled that Commission had failed to make proper assessment of benefits

GSK -- Greece

- Following massive resale of Greek-origin product in Northern Europe GSK limited amount of product available in Greece
- Greek competition council referred question to ECJ regarding abusive refusal to supply (*Syfait)*
- Advocate General Jacobs argued that limit on supply was a reasonable and proportionate way of protecting GSK commercial interest
- ECJ declined to rule
- Greek competition council basically followed Jacobs

Rambus (FTC Decision (02.August.2006)

- FTC found that Rambus had engaged in a course of deceptive conduct intended to distort an important standard-setting process
- Rambus participated in the standard-setting body without disclosing its possession of patents covering technology incorporated in the standard

Settlement of Infringement Litigation (II)

- FTC challenged settlement
  - incumbent filed “follow-on” patent
  - infringement action against generic
  - settled for large sum (effectively splitting the monopoly profits for the period before a third rival could emerge)
- Court of Appeals reversed
  - Policy in favour of settlements
  - Commercial justification because of ability of generics producer to challenge without entry
  - No extension of market power beyond scope of presumptively valid patent

Schering Plough -- Anticompetitive Settlements of Infringement Cases

- US *Schering Plough* case presents question of when settlement of IP litigation could constitute antitrust violation
- Special rules (Hatch-Waxman Act) apply to generic manufacturers producing rival to newly off-patent drug
  - "First-in" gets a window as "only" generic
  - Generic producer entitled to challenge patents before putting product on market

Some Comments

- GSK parallel trade cases do not really impact directly on patent/antitrust interface
- Real issue is whether individual Member States can opt to support innovation by accepting higher prices or achieve budget goals through price reductions
- Commission cases on parallel trade in pharmaceuticals are really about market integration – not about classic competition policy concerns

Some Comments

- *Rambus* and *AstraZeneca* are examples of both systems grappling with IP-related activities that
  - do not infringe legal requirements of IP process
  - may result in significant consumer harm
- Both cases arguably abusive under a "sacrifice" test

Some Comments

- *Boehringer* is less straight-forward
  - Real question whether Competition authority (or court) is competent to assess whether an IP right rewards innovation
  - This issue has been avoided in previous IP/82 cases (*e.g.*, *Magill*, *Microsoft*) although it plays a role in the *Microsoft* remedies procedure
- *Shering Plough* is largely explained by peculiarities of US legislation – result would probably be different in EC