

Regulatory and Market Pathways: the pharma sector

Leigh Hancher
University of Tilburg
Allen & Overy LLP

Types of competition

- Therapeutic competition - original products competing with each other
- Generic competition - out of patent competition - inter-brand
- Intra-brand competition!

EC Competition rules: Problems of application

- Relevant market test
- Dominance - market shares
- Substitutability

- Alternative - Art 81 - need consensus ad idem!

Types of abuse – Article 82

- Refusal to supply - Greek Glaxo case of Sept 16 '08. IMS Case - 2003
- Dual pricing? Spanish Glaxo case
- Art 82 list is not exhaustive
- Note special duties on dominant companies

Patent protection and SPC

- A patent gives a 20 year monopoly
- No European Patent - only national
- Products can also benefit from an SPC - supplementary patent certificate for additional 5 years

Marketing authorizations

- Central and Decentralized procedures
- Abridged procedures for generic products
 - prove essential similarity to original product
- No special procedures for parallel imports!
 - mutual recognition doctrine

Data exclusivity and marketing exclusivity

- Product licensing authorizations = expensive time consuming data production
- Generics cannot piggy back on originator data
- 8+2+1 year rule
- 8 year data and 2 year marketing exclusivity

The Astra Zeneca case (I)

- Major product Losec about to go out of basic patent
- Devised complex strategy to frustrate generic competition including taking out new patents, extending data and marketing authorizations etc on basis of false information
- Selective withdrawal of old versions of Losec so no reference products for generics/parallels

Astra Zeneca (II)

- AZ is fined Euro 60 million for abusing dominant position

What is the abuse?

- What is the Commission's views on the right to exercise IP rights?

The sector enquiry - Jan '08

- Sector wide inquiry under Reg 1/2003
- Unusual as launched by dawn raids on leading research and generic companies
- Follow up dawn raids
- Preliminary report Nov 28
- Commission discussion paper on art 82 - Dec 3 '08
- Further intersections in the regulatory and marketing pathways?