

Erasmus
School of
Law

EU Competition law and Healthcare

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With the support of the
Erasmus+ Programme
of the European Union

Erasmus University Rotterdam



Outline

- Introduction: EU Competition law
- EU Competition law and Healthcare: Providers and Purchasers
- Focus: Big Pharma and EU Competition law
- Recent developments
- Discussion

EU Competition law: Scope and Application

Scope:

- Cartels (Art. 101 TFEU)
- Abuse dominant position (Art. 102 TFEU)
- Merger control (Merger Control Regulation No. 139/2004)
- State aid (Art. 107 TFEU)

Application:

- Concept of undertaking
- Border crossing element

EU Competition law: Cartels

- Forbidden agreements, decisions, concerted practices
- Object or Effect: prevention, restriction or distortion competition
- Exceptions (art 101 (3) TFEU)

EU Competition law

- Abuse dominant position (Art. 102 TFEU)
 - What is dominant position?
 - Abuse
 - Examples
 - Remedies

EU Competition law & Health Care: Providers

- Hospitals *FENIN* (T-319/99)
- Ambulance services: *Ambulanz Glöckner* (C-475/99), abuse and “SGEI” (Art. 106(2) TFEU)

EU Competition law & Health Care: Buyers (Health Insurers)

- *Pouchet and Pistre* (C-160/91):
- *AOK Bundesverband* (C-264/01):

Big Pharma and EU Competition law: Parallel trade

- Dual pricing system (101(1)): GSK Spain C-501/06
 - Object or effect of harming consumers
 - 101(3) exception?
- Supply quota system (Art 102) GSK Greece (Syfait) case, C-468/06
 - Refusal to supply
 - GSK: “specific factors” pharma market should be taken into account

IPR: The cutting-edge of Competition law

- Protecting patent rights
- Patents and abuse dominant position: AstraZeneca (Case T-321/05)
 - Eur.Comm: € 60 m. fine misusing national patent systems (supplementary patent certificates, the SPC abuse), and national MA under 102 FTEU (deregistration abuse)
 - General Court:
 - upheld misleading representation patent offices
 - Annulled delisting abuse
 - Reduction fine
 - Appeal: fine for 'bullying' (C-457/10)

Recent developments: Pharmaceutical sector inquiry and beyond

- Reasons: “There’s something rotten in the pharmaceutical world” (Shakespeare, *Hamlet* Act I, scene IV)
- Scope
- Outcomes:
 - Industry trends
 - “tool-box” delay/blocking generics or enforcing patent rights?
 - Regulatory deficiencies

Discussion: What's next? Solutions

- Actions by European Commission
 - Antitrust: unannounced inspections in pharmaceutical sector
 - Monitoring exercise of patent settlements in pharma sector (6th, 2015)
 - Commission adopting decisions against *Servier*, *Lundbeck*, *J&J* and *Novartis* on delaying entry of generics