



# A dose of competition: EU antitrust law in the pharmaceuticals sector

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# Outline

## Introduction

- Abuse of procedure
  - AstraZeneca
  - Pfizer
- Sector inquiry
- Reverse payments
  - Lundbeck
  - Actavis

## Conclusions



# Introduction

- Innovation versus cost control
- Parameters of competition
  - IPRs
  - versus competition law
  - and internal market objective (parallel trade)
- Modes of competition
  - Therapeutic competition (originators)
  - Interbrand competition (originators versus generics)
  - Intrabrand competition (originators versus parallel importers)



## Abuse of procedure I: AstraZeneca (2012)

- Exclusive rights based on
  - Patent + supplementary protection certificates + market authorisation
  - Interbrand competition
- Abusive behaviour under Article 102 TFEU
  - Misrepresentation of the effective date of market authorisation
  - Strategic repackaging and withdrawing market authorisation
- Restriction by object
  - Not necessary to demonstrate intent
  - Not necessary to show effects



## Abuse of procedure II: Pfizer Italy (2014)

### Context

- Double patenting → delaying generic entry
- European Patent Office revokes patent application
- Decision suspended during appeal

### Procedure

- Italian competition authority relies on AstraZeneca
- Lazio administrative court sees lawful exercise of IPR
- Council of State annuls
  - Legitimately obtained IPRs irrelevant
  - Objective of market foreclosure
  - Abuse of procedure = use for different purpose



# Sector inquiry 2008-2009

## Industry-wide data collection (2000-2007)

- Findings: low innovation and abuse of IPRs
- Tactics delaying entry of generics = limit interbrand competition
  - Generics lower prices by 40% over 1st two years
  - Delays to market average 7 months
  - Foregone savings 20%

## Measures proposed

- Enhanced antitrust enforcement
- Streamlining EU patent law and market authorisation
- Improving pricing and reimbursement rules, Transparency Directive



# Patent settlements and pay for delay

Settlements as legitimate way to resolve patent issues

Versus strategic use of patent settlements to limit competition

- Reverse payments from IPR holder to entrant
- Share monopoly rents by value transfer
- As way to delay generics market entry

Pay for delay: broader category than patent settlements

- Critical are patent settlements limiting entry with value transfer
- Clash between IPR and antitrust clearest



# Pay for delay Commission Decisions

## Lundbeck (2013)

- Molecule patent expired, process patents
- ‘Playing a losing hand slowly’
  - Protect monopoly rents, pay €67 million
  - Create window for second generation product
  - UK prices drop 90% after collapse of the agreement
- Art 101 TFEU applied to agreements largely outside the patent
- Keeping competitor out of market → infringement by object
- Approach also deemed valid within the patent

Fentanyl (2013) pay for delay; Servier (2014) patent settlement





## ***Actavis* (2013): a US perspective**

No CJEU cases yet but US Supreme Court precedent

### Essential elements

- Large reverse payment to alleged infringer
- Non-compete requirement
- Consumer harm

### Rule of reason applied

- Not necessary to litigate patent first
- Infringement likely absent justification
- Antitrust does not deter bona fide settlements

→ Antitrust can “trump” IPR v dissent: no restraints within patent



# Conclusion/points for elaboration

Antitrust enforcement in pharmaceuticals sector

- So far limited at national level
- Damages cases so far largely absent

However innovative approach by Commission

- Moving on from parallel imports
- To abuse of procedure and pay for delay

Antitrust problem v lawful behaviour from an IPR perspective

- Less respect for IPR
- More EU cases but no ruling by CJEU yet
- Using antitrust to fill gaps in patent law/other market access regulation?