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?