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 annulls
  – 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?