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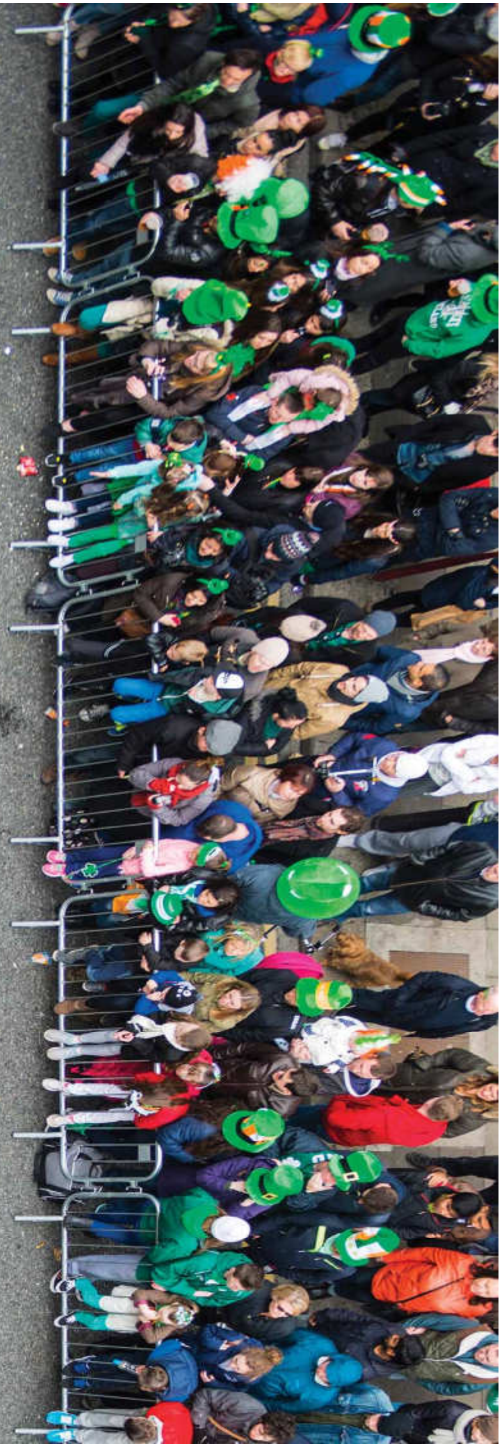
Pay-for-Delay Agreements



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Patent Settlements

Faced with potential new entry, the originator company may initiate litigation to enforce its patent

Pay-for-delay agreements: instrument for out-of-court dispute settlement

Typically associated with the pharmaceutical sector

The generic company undertakes to abandon its efforts to enter the market, in exchange for a consideration

Aimed at restricting early generic entry

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Intellectual Property Rights and the Pharmaceutical Sector

Patents:	• establish (usually for a period of 20 years) monopoly over an innovative product/process
Exclusionary nature, aimed at:	• protection of investments undertaken by originator companies • recoupment of R&D costs • incentive for further innovation
Characteristics of the pharmaceutical sector:	• heavily reliant on IP rights • very high investments in R&D • profitability positively correlated with R&D costs

Competition Law

Art. 101(1) TFEU prohibits “agreements between undertakings, decisions by associations of undertakings and concerted practices which […] have as their object or effect the prevention, restriction or distortion of competition”

Objective: maximisation of consumer welfare

The focus is primarily on allocative efficiency

In early patent settlement cases, American courts held that antitrust law was not applicable to the extent that the agreement fell within the exclusionary scope of the patent (“scope of patent test”)

However…

Patents and Generic Entry

— In many jurisdictions (including Greece) patent offices do not engage in a thorough examination of the substantive requirements

— Patents confer a **rebuttable** presumption of validity

— Generic companies may enter the market before patent expiry by:

- entering “at risk”;
- invoking patent invalidity as a counter-claim in infringement proceedings;
- requesting a declaration of “non-infringement”;
- challenging the patent before authorities/courts

EU Commission's Pharmaceutical Sector Inquiry

Final Report (2009) –
3 categories of settlements:

Category A:
do not restrict generic entry –
no competition concerns

Category B.i:
restrict generic entry but do not provide for value transfer
presumed lawful

Category B.ii:
restrict generic entry and contain value transfer from the originator to the generic company
("pay-for-delay" agreements or "reverse payment settlements")
likely to attract antitrust scrutiny

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Pay-for-delay Agreements

2 main theories of harm:

- elimination of the court's ability to examine and confirm or reject patent validity
- delayed generic entry is detrimental to consumer welfare – higher prices paid for a good enjoying patent protection of questionable validity
(price on average -25% upon generic entry / -40% in 2 years)

Value Transfer (I)

Not in itself illegal

The crucial element is the size of the transferred value

The transferred value is inversely proportionate to patent strength (the greater the uncertainty, the higher the value)

HOWEVER, patent validity is irrelevant for the purposes of the analysis – any patent holder may have the incentive to exclude potential competition

No inference of patent weakness, but strong inference of market power

Value Transfer (II)

Forms of value transfers:

- Direct payment (e.g. *Lundbeck*, *Servier*)
- Licensing agreements (see the Commission's *Technology Transfer Guidelines*, paras. 238-239)
- Distribution or co-promotion agreements (e.g. *Johnson & Johnson/Novartis*)
- Side deals

Value Transfer (III)

Scenario 1:

Transferred value ≈ Litigation costs

- **Objective assessment of patent validity**
- **No competition concerns**

Scenario 2:

Transferred value > Litigation costs

- **The parties divide the patent holder's monopoly rents and engage in market-sharing**
- **«the very anticompetitive consequence that underlies the claim for antitrust unlawfulness» (US Supreme Court, *FTC v. Actavis*)**
- **Likely falls within the scope of Art. 101 TFEU**

The *Lundbeck* Case

- Lundbeck: Danish pharmaceutical company, manufacturer of citalopram.
- Patent settlements between Lundbeck and four generic companies involved:
  - direct payments;
  - purchase of generic companies' stocks; and
  - guaranteed profits in a distribution agreement
- Infringement decision: settlements anti-competitive **by object**
- Fines: EUR 93.8 million on Lundbeck and a total of EUR 52.2 million on the generic companies
- On appeal (Case T-472/13), the GC upheld the Commission decision
- Further appeal pending before the CJEU (Case C-591/16)

The Servier Case

- Servier: implemented a strategy aimed at delaying generic entry in the market for perindopril
- Strategy included competing technology acquisition and a series of patent settlements (cash payments)
- Commission: Servier’s conduct infringed both Art. 101 (by object) and Art. 102 TFEU
- Analytical framework - elements considered:
  - originator and generic companies were at least potential competitors;
  - generic undertaking committed itself to limit, for the duration of the agreement, its independent efforts to enter the market; and
  - value transfer as a significant inducement
- Fines: EUR 427.7 million in total on Servier and five generic companies
- Appeal pending before the GC (Case T-691/14)

The Position in the US: The *Actavis* Case

— *FTC v. Actavis, Inc.* (2013)
Adoption of the rule of reason for the legal assessment of pay-for-delay agreements

— Rejection of the “scope of patent” test

— Effects analysis – 4 criteria:

- size of transferred value
- its scale, in relation to the anticipated future litigation costs
- its independence from other services for which it might represent payment
- lack of any other convincing justification

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Concluding Remarks

In anticipation of CJEU decision in *Lundbeck*:

- Approach under EU competition law sound, but needs further refining
- Is the market coverage of pay-for-delay agreements relevant? Market foreclosure plausible only if all potential competitors are kept out of the market
- The object/effect dichotomy not as sharp post-*Cartes Bancaires*
- There is evidence that following Commission’s enforcement actions, the number of pay-for-delay agreements in EU has been declining

Thank you

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