Pharmaceutical Sector Inquiry

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IBC Advanced EC Competition Law 2009

London, 22 April 2009

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Sector Inquiry into Pharmaceuticals in the EU

Outline

- Introduction: the pharmaceutical sector
- Purpose of the Sector Inquiry
- Main findings Preliminary Report
- Next steps

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Introduction

Pharmaceutical sector:

- Supply side: two main types of companies
  - Originator companies (develop and supply new medicines); highly R&D intensive
  - generic companies (supply medicines that are off-patent)
- Demand side: complex interplay between
  - patients
  - doctors
  - insurance providers/reimbursement system
  - pharmacists

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Introduction (2)

- Important role of
  - Patent system
  - Regulatory framework (market authorisation / pricing / reimbursement)

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Sector Inquiry into Pharmaceuticals in the EU

Background of the Sector Inquiry

- Opening of the sector inquiry on 15 January 2008
- Observations leading to the launch of the inquiry
  - Delayed market entry of generic medicines
  - Less market entry of new originator medicines
- Sector inquiry investigates underlying causes
  - Focus on company behaviour
  - Importance of the regulatory framework

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1st focus

Competition between originator companies and generic companies

- Impact of generic entry
- Practices of originator companies

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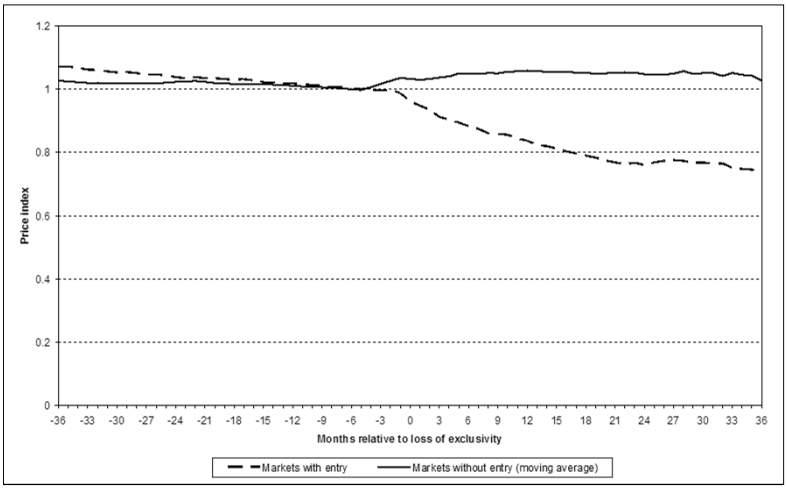
Originator - generic competition

Impact of generic entry

Development of average price with and without generic entry



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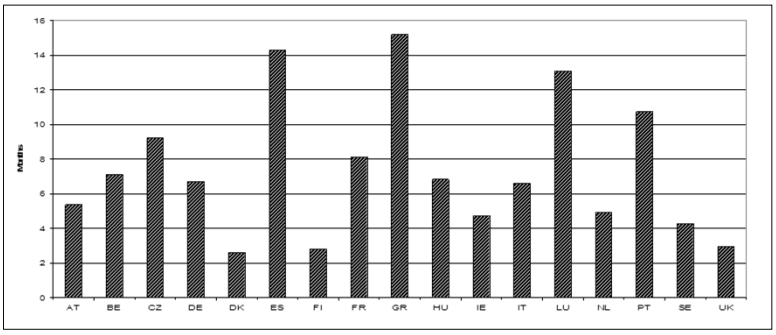
Originator - generic competition

Average time to generic entry:

- 7 months for the sample (weighted average)
- 4 months for the most valuable medicines
- Considerable variations across Member State



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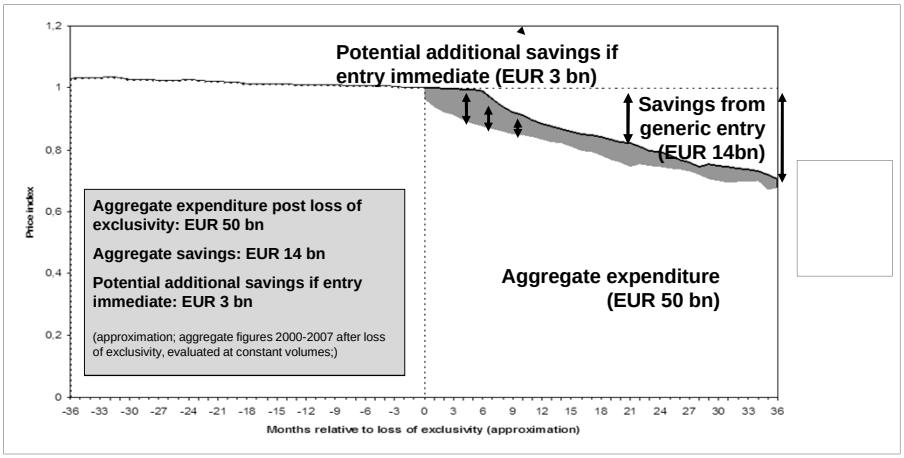
Originator - generic competition

Impact of generic entry

Savings from generic entry

- Sample of 17 Member States
- Actual savings of € 14bn with generic entry delayed by 7 months
- Potential savings of € 3bn more if generic entry is immediate



Originator - generic competition

Practices of originator companies discussed in the PR:

- Patent strategies
- Patent disputes and litigation / EPO opposition
- Settlement agreements
- Interventions before authorities
- Life cycle strategies for follow-on products

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Originator - generic competition

Practices - Patent strategies

- Note: the Sector Inquiry does not put into question the importance of patent rights and of their efficient enforcement in the pharmaceutical industry.
- Finding: use of patent strategies aimed at extending the breadth and duration of protection
  - extensive patent clusters
  - timing of patenting

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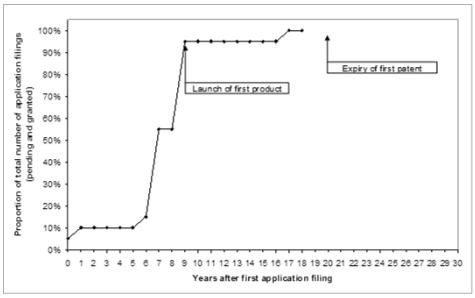
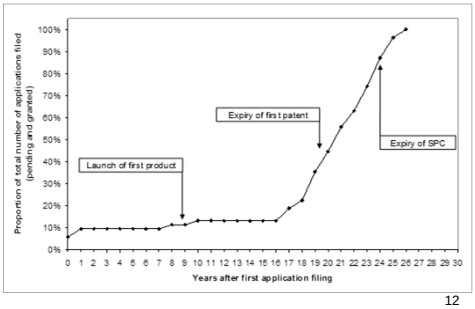
Originator - generic competition

"Conventional" life cycle patent portfolio



"Late" life cycle patent portfolio



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Originator - generic competition

Practices - Patent dispute and litigation

- 698 litigation cases were initiated in the EU, originator companies started 54%. Generic companies won more than 60% of patent litigation cases
- Average duration of litigation cases to reach final outcome: 2.8 years
- Interim injunctions granted in 112 cases, average duration 18 months

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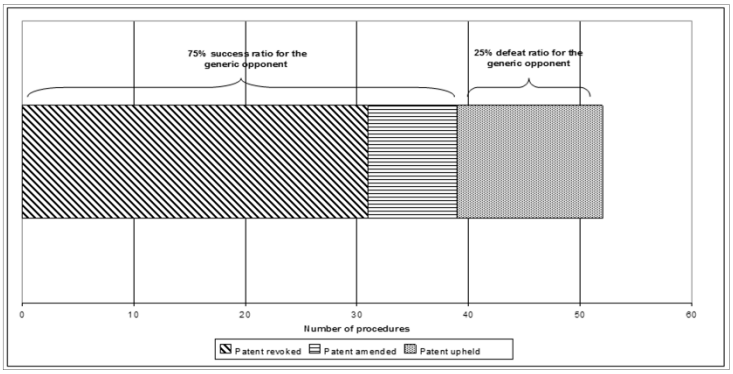
Originator - generic competition

Practices – oppositions before the EPO

- Generic companies won majority of opposition cases
- Almost 80% of procedures before the EPO took more than 2 years



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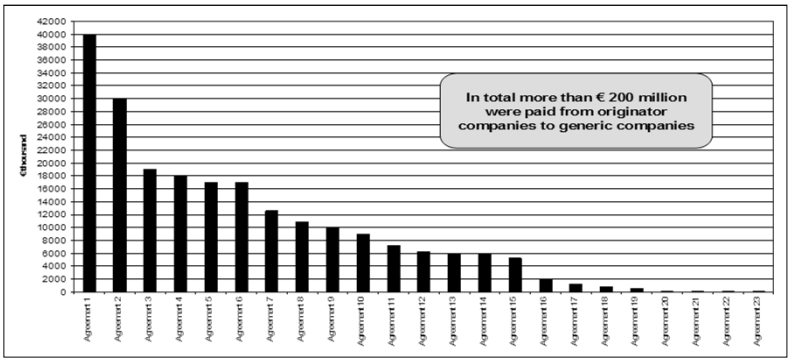
Originator - generic competition

Practices – settlements

More than 200 settlement agreements

- No limitation of generic entry: 108
- Limitation of generic entry: 99
  - No value transfer: 54; with value transfer: 45



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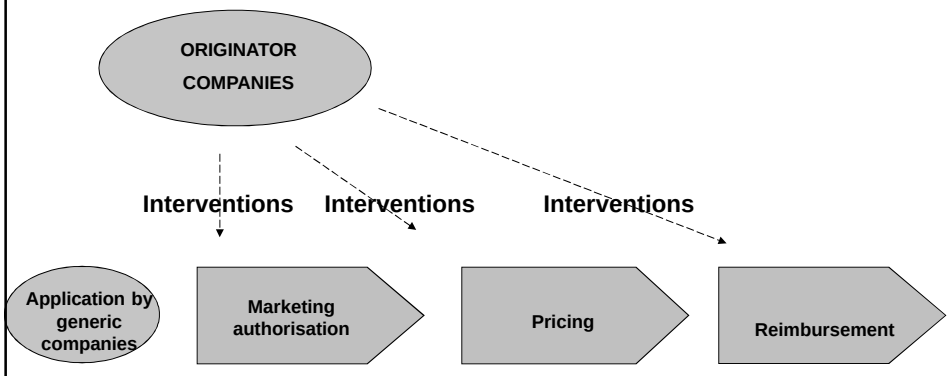
Originator - generic competition

Practices - Interventions (regulatory bodies)



- Extremely low percentage of cases where courts upheld claims against decisions of MA bodies
- Procedures with interventions lasted ~ 4 months longer

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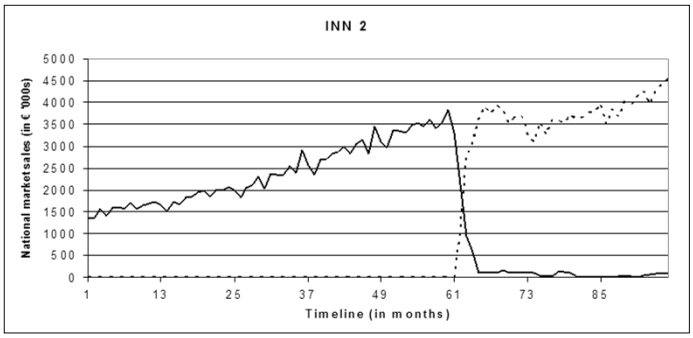
Life cycle strategies for follow-on products

- Context: originator companies launched second generation (follow-on) products for 40% of the medicines in our sample.
- Intensive use of marketing and promotion strategies in conjunction with other strategies to switch patients to the second generation product before generic entry.



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2nd focus

Competition between originator companies

- Patent strategies
- Patent-related exchanges / litigation
- Agreements between originator companies

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Patent strategies: Defensive patenting

- Finding: use of “defensive” patents

  Quote of originator companies (example):

  » *“We identify options to obtain or acquire patents for the sole purpose of limiting the freedom of operation of our competitors […]”*

- Note: the sector inquiry does not put into question the importance of patent rights and of their efficient enforcement for the pharmaceutical industry

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3rd focus

Comments on the regulatory framework

- European patent system
- Marketing Authorisation
- Pricing and Reimbursement

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Public consultation on Preliminary Report:

- Public consultation concluded on 31 January 2009
- Over 70 formal submissions from stakeholders
  - Certain commentators confirming practices used by originator companies to delay generic entry.
  - Others question causality between toolbox instruments and delay of generic entry
  - Preliminary Report perceived as useful basis to argue for certain solutions such as Community patent

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Sector Inquiry into Pharmaceuticals in the EU

Next steps

- Final Report expected before summer 2009

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