



Pharmaceutical Sector Inquiry : Presentation of the Preliminary Report

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“The views expressed are purely those of the writers and may not in any circumstances be regarded as stating an official position of the European Commission.”

Sector Inquiry into Pharmaceuticals in the EU

Outline

- Background of the Sector Inquiry (SI) and related findings
- Competition between originator and generic companies
- Competition between originator companies
- Comments on the regulatory framework

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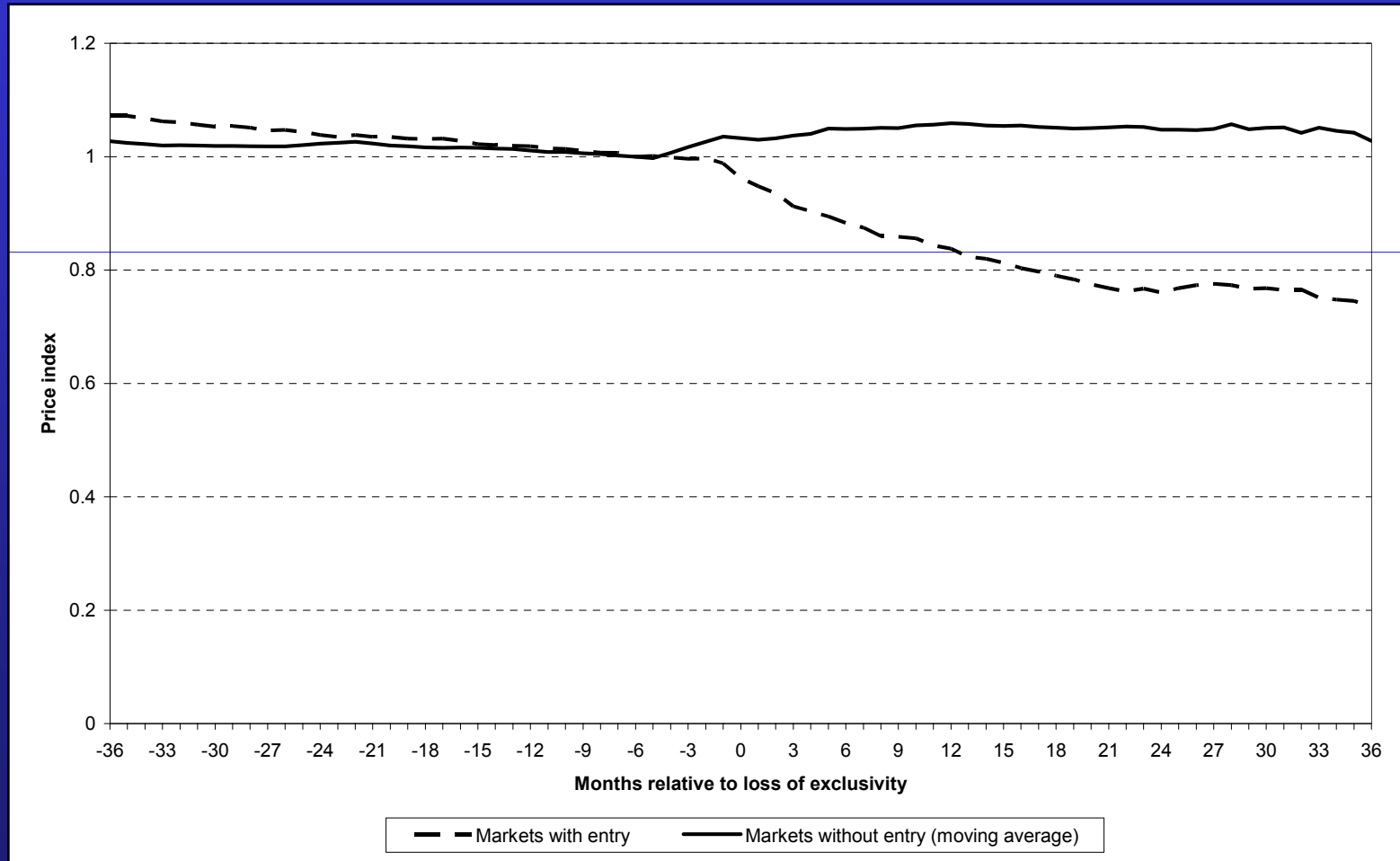
Background of the Sector Inquiry and related findings

- 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
- In depth analysis of 219 medicines

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Impact of generic entry

Development of average price with and without generic entry



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1st focus: competition between Originator and generic companies

Tool-box of originator companies

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

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Tool-box of originator companies

Patent strategies

- The Sector Inquiry does not put into question the importance of patent rights and of their efficient enforcement in the pharmaceutical industry.
- Patent strategies: aimed at extending the breadth and duration of protection (patent clusters)

Quotes of originator companies:

"I suppose we have all had conversations around "how can we block generic manufacturers" [...]. Don't play games in patenting new salt forms too late, the generics are starting earlier and earlier. Get claims on key intermediates that cover a number of routes [...] Process patents are not the biggest block but can put generics off if a superior chemistry job is done."

"Secondary patents will not stop generic competition indefinitely but may delay generics for a number of years, at best protecting the originator's revenue for a period of time."

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Tool-box of originator companies

Patent disputes and litigation

- 457 patent disputes were initiated in the EU, originator companies started 91%
- 698 litigation cases were initiated in the EU, originator companies started 54%

Final outcomes of patent litigation:

- Average duration of cases to reach final outcome: 2.8 years
- Interim injunctions granted in 112 cases, average duration 18 months
- Generic companies won more than 60% of patent litigation cases

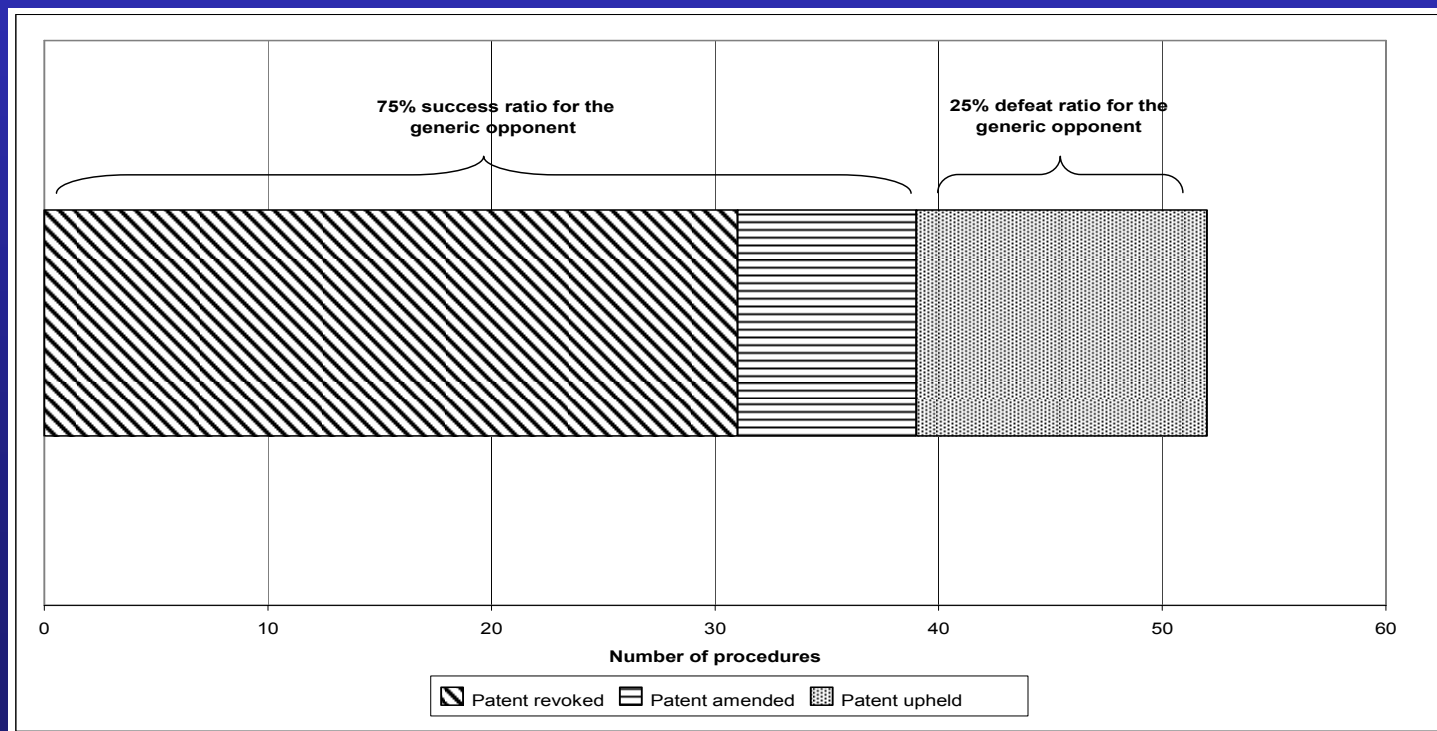
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Tool-box of originator companies

Patent Oppositions

Final outcomes of opposition before the EPO:

- 60% of opposition cases led to rejection of the patent
- Almost 80% of procedures before the EPO took more than 2 years

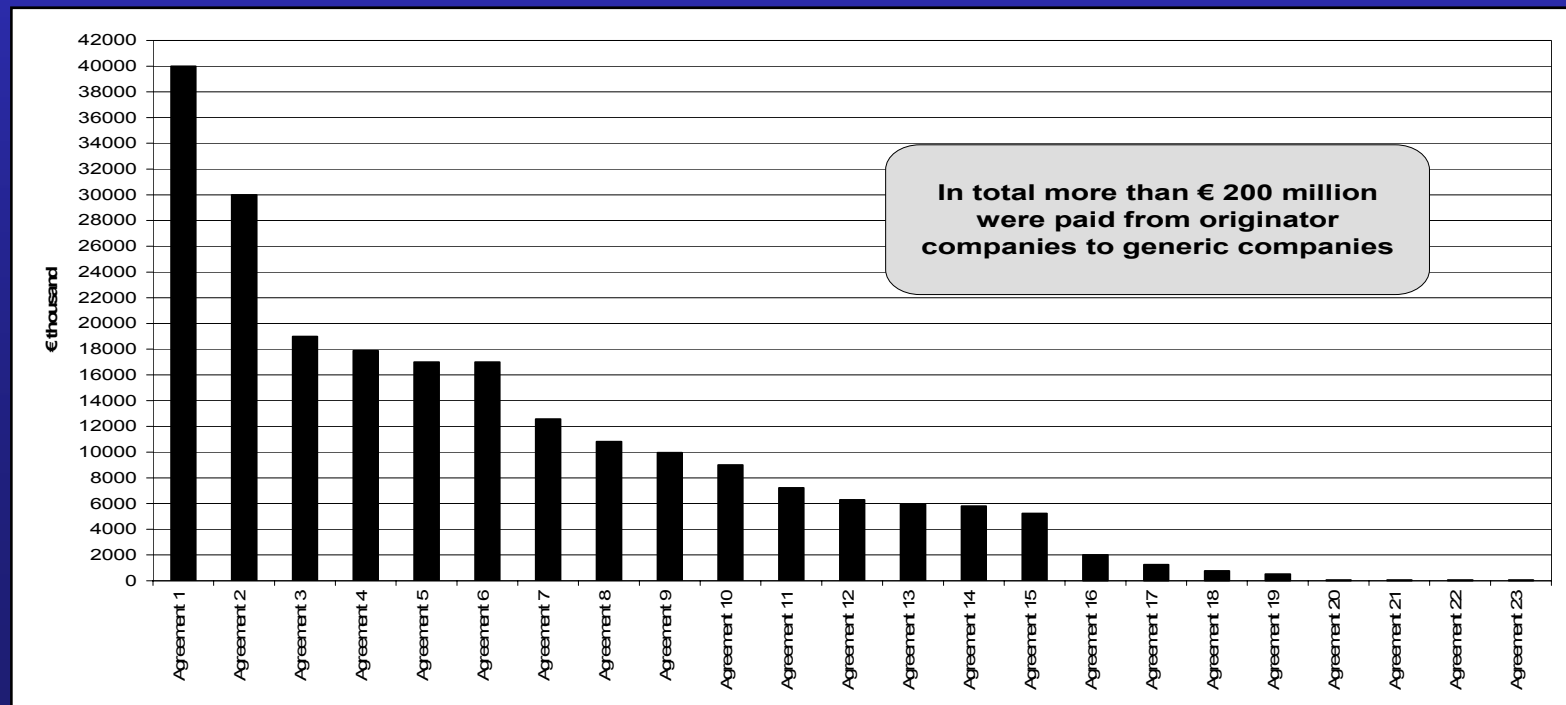


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Tool-box of originator companies

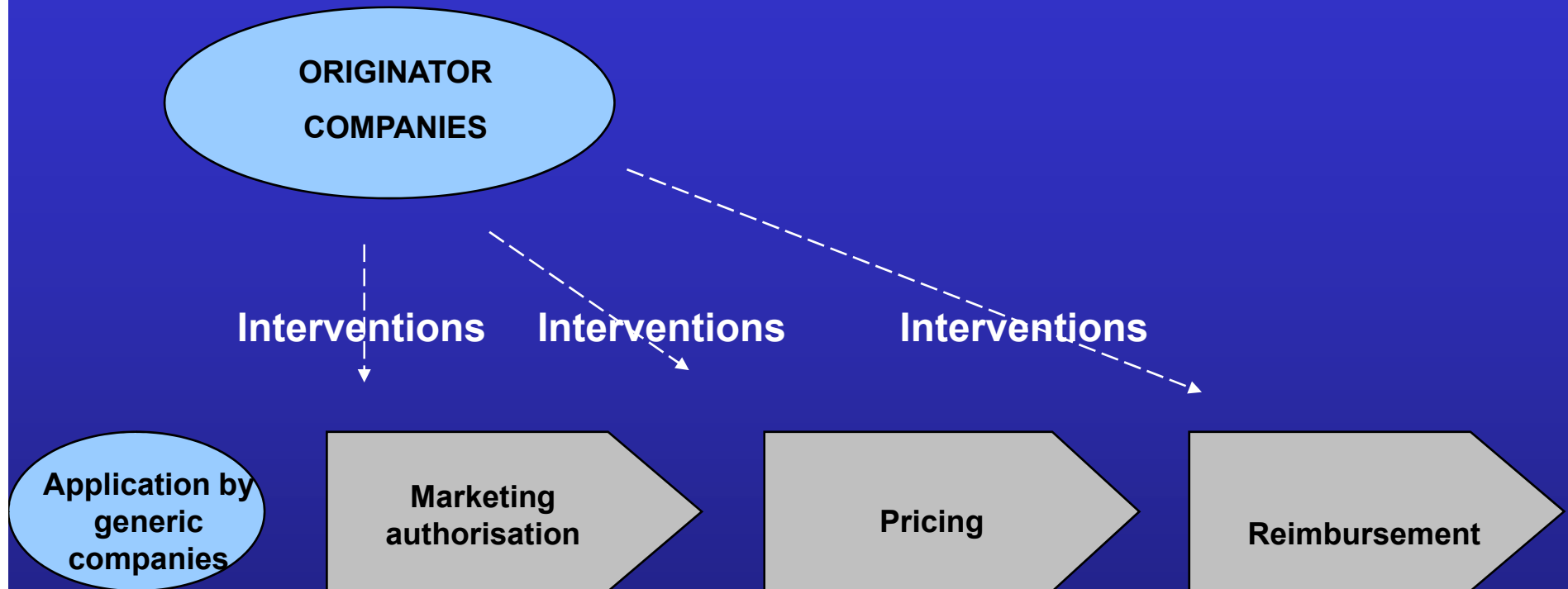
More than 200 settlement agreements

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



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Tool-box of originator companies – Interventions (regulatory bodies)



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Tool-box of originator companies

Life cycle strategies for follow-on products

- Originator companies launched second generation (follow-on) products for 40% of the medicines in our sample.
- Originator companies made intensive use of marketing and promotion strategies in order to switch patients to the second generation product before generic entry.

Example of Quotes:

“[Our second generation product] represents the most effective initiative to counter generic [versions of our first generation product]”

“if [generic products] come together with or prior to [second generation product] the switch rate is dramatically reduced. [...] Once [generic products] come in it becomes more difficult to get switches from [old originator product].”

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2nd focus: Competition between originator companies

Patent strategies: Defensive patenting

- SI does not put into question the importance of patent rights and of their efficient enforcement for the pharmaceutical industry.
- “Defensive” patents
- Quotes of originator companies:

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

“[...] Rights covering competitive alternatives [that is the products of competitors] are maintained in major markets until risk of competing products appearing is minimal“

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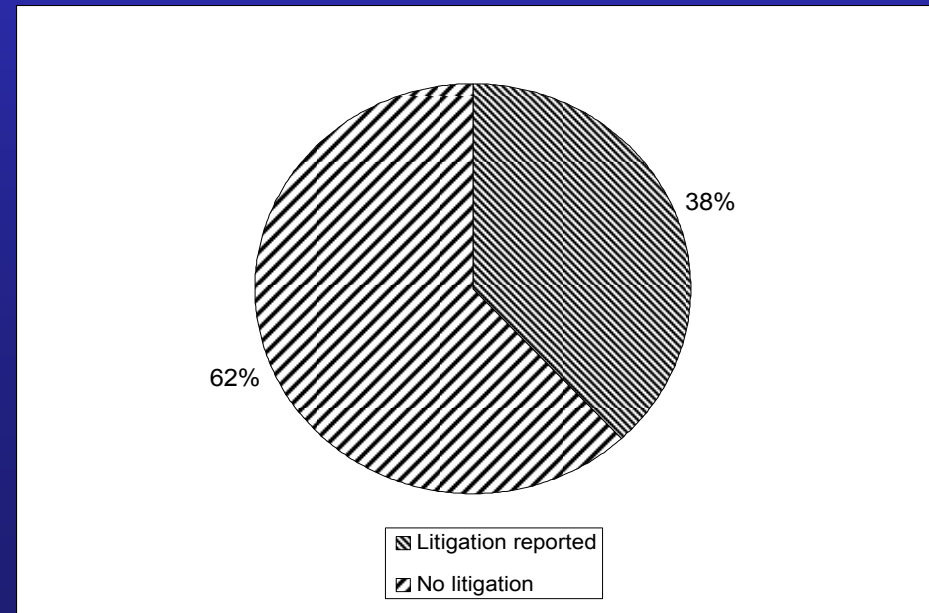
Competition between originator companies

➤ Potential overlaps and patent-related exchanges

- In 1100 instances overlap between products/R&D poles and patents of competing originator companies

➤ Patent litigation

- Almost 40% of respondent originator companies were involved in patent litigation with another originator company
- Two thirds of litigations between originator companies were settled, the majority of these settlements contained a licence agreement.



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3rd focus: Comments on the regulatory framework

Comments on the regulatory framework

The European patent system

- Both generic and originator companies support:
 - the creation of a Community patent
 - the creation of a unified and specialised patent judiciary in Europe
- Support for the Community patent and unified judiciary to be put in the context of:
 - 700 cases of patent litigation in the EU
 - Conflicting judgements reported in 11% of all final cases
 - Total cost of patent litigation estimated to exceed EUR 420m

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Comments on the regulatory framework

Marketing Authorisation

- Companies, industry associations and agencies reported bottlenecks in the marketing authorisation procedures which can lead to obstacles/delays and administrative burden
- Some originator companies also call for further international harmonisation of marketing authorisation procedures

Pricing and Reimbursement

- Originator companies complained about delays and uncertainty created by national pricing and reimbursement procedures
- Generic companies also complain about delays in particular since some Member States have introduced additional requirements to obtain pricing and reimbursement status

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- Main Comments during public consultation:
- [over 70 formal submissions from stakeholders]
- „First time that empirical analysis of this scope and density has been conducted: Useful basis to argue for certain solutions such as Community patent“
- „Confirmation of practices of used by originator companies to delay generic entry“
- “No proof of causality between toolbox instruments and delay of generic entry”

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Next steps

- Final Report expected before summer break 2009
- Preliminary Report is available at:

<http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/index.html>