Pharmaceutical Sector Inquiry
Presentation of the Preliminary Report

28 November 2008

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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

Structure of the presentation

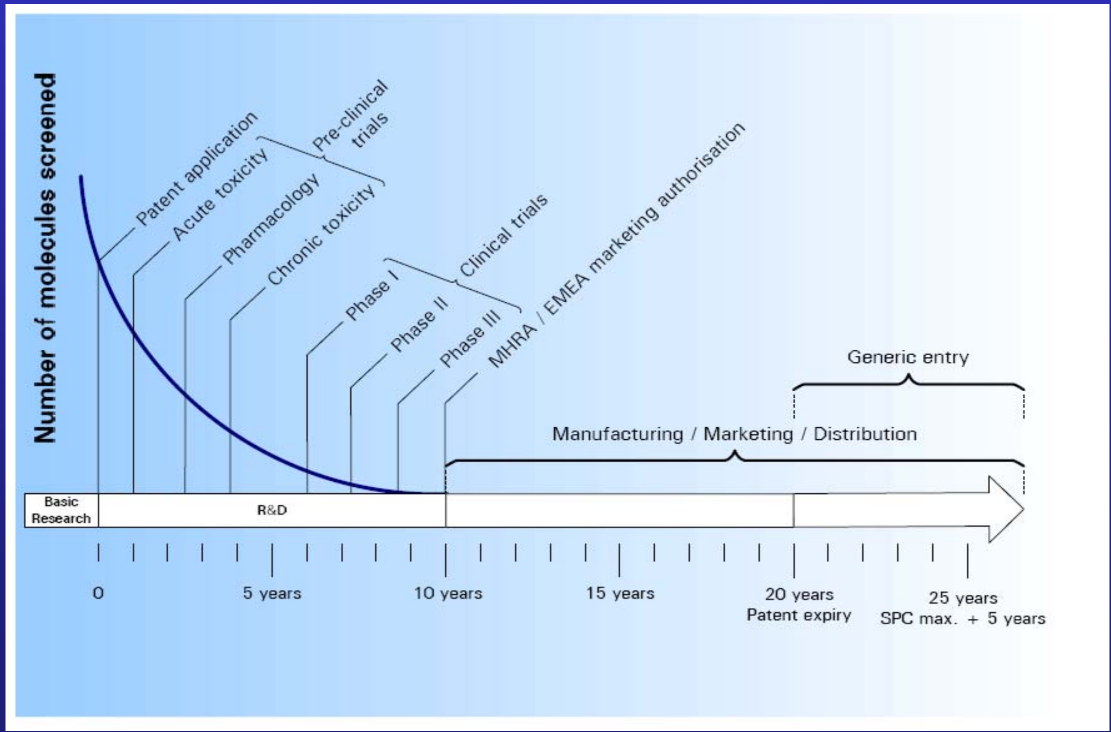
- Main market features
- Company practices that can cause delay of generic entry
- Company practices that can contribute to the decline/delay in innovation
- Comments on the regulatory framework

Main market features

The business model of originator companies

Conventional Product Life Cycle: Three main phases

1. R&D phase
2. Exclusivity phase
3. Post-exclusivity phase



Main market features

Originator companies' dependency on blockbusters

Company	Product name (INN)	EU27 turnover (€ thousand)	Global turnover (€ thousand)	Product share of company turnover (global)
Pfizer	Lipitor (atorvastatin calcium)	1,917,151	9,252,101	30%
GlaxoSmith Kline	Seretide/Advair (fluticasone + salmeterol)	1,795,800	5,108,540	18%
Johnson & Johnson	Risperdal (risperidone)	1,737,023	6,232,653	35%
Sanofi-Aventis	Clopidogrel (clopidogrel)	1,620,000	2,424,000	9%
Hoffmann-La Roche	Herceptin (trastuzumab)	1,345,193	2,954,041	13%
Nycomed	Pantoprazole (pantoprazole)	1,289,069	1,685,000	55%
Wyeth	Enbrel (etanercept)	1,159,947	1,492,201	13%
Johnson & Johnson	Eprex (epoetin alfa)	1,109,974	1,637,521	9%
Eli Lilly	Zyprexa (olanzapine)	1,059,341	3,473,927	27%
Novartis	Glivec (imatinib)	939,194	2,228,470	13%

1st focus

Competition between originator companies and generic companies

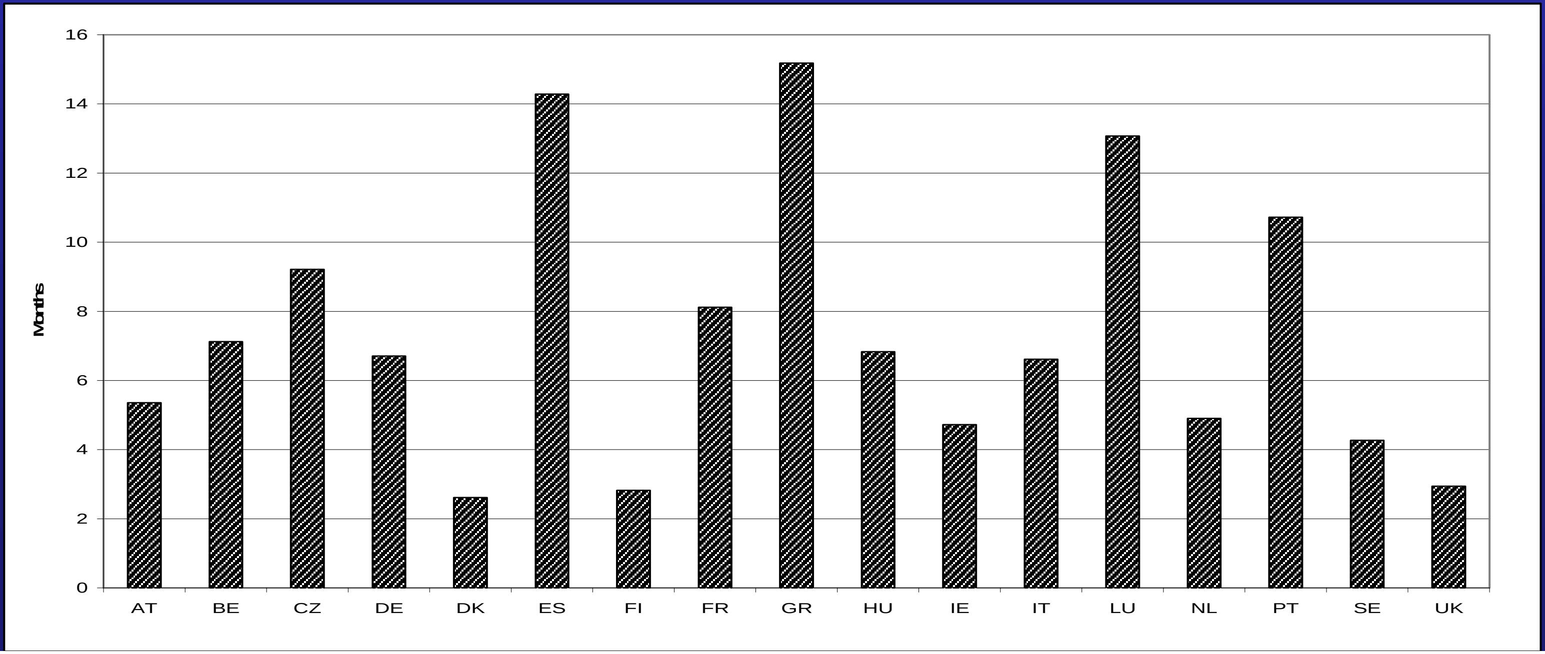
- Impact of generic entry
- Tool-box of originator companies

Impact of generic entry

Average time to generic entry:

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

Average time to generic entry after loss of exclusivity, by country



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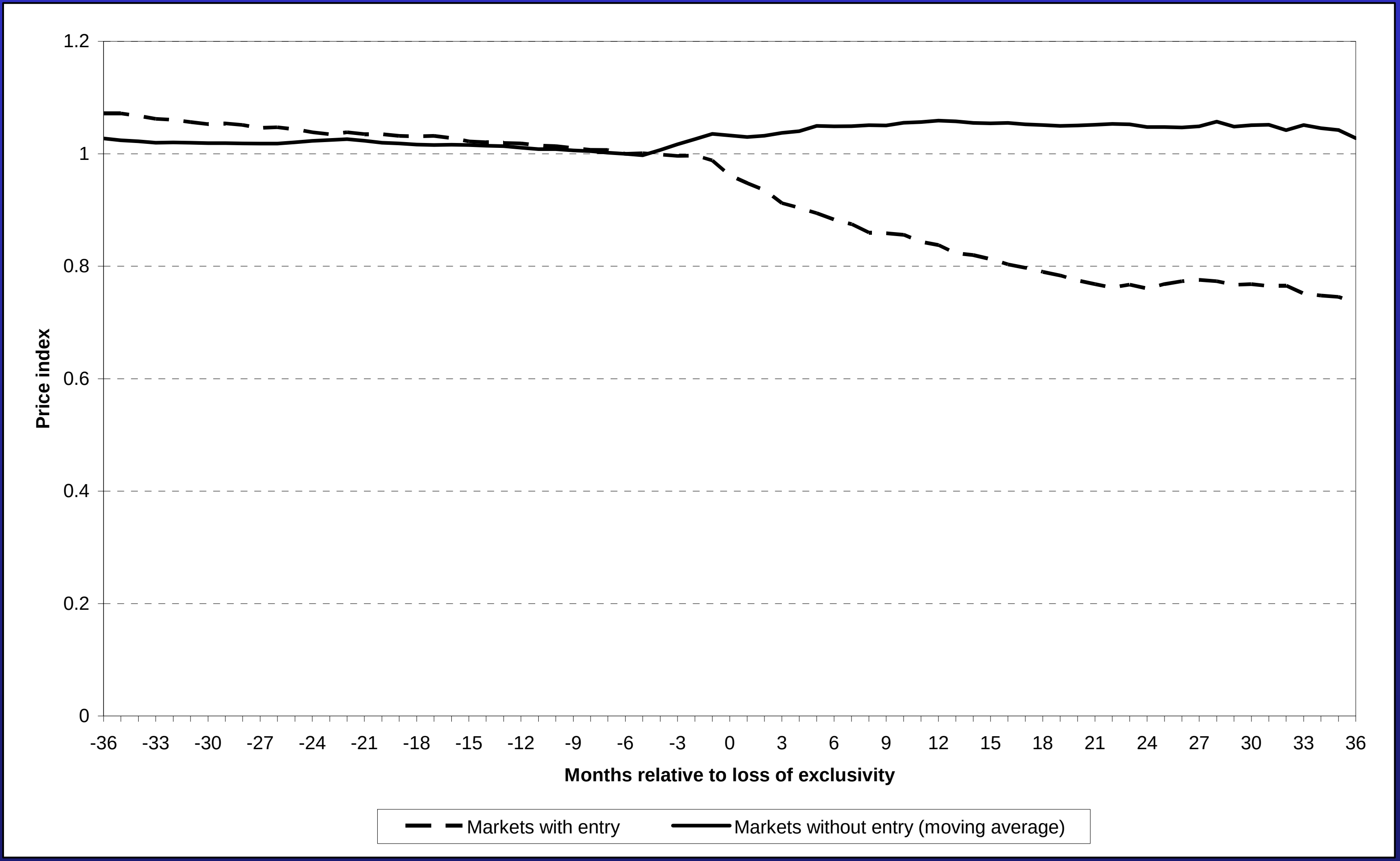
Impact of generic entry

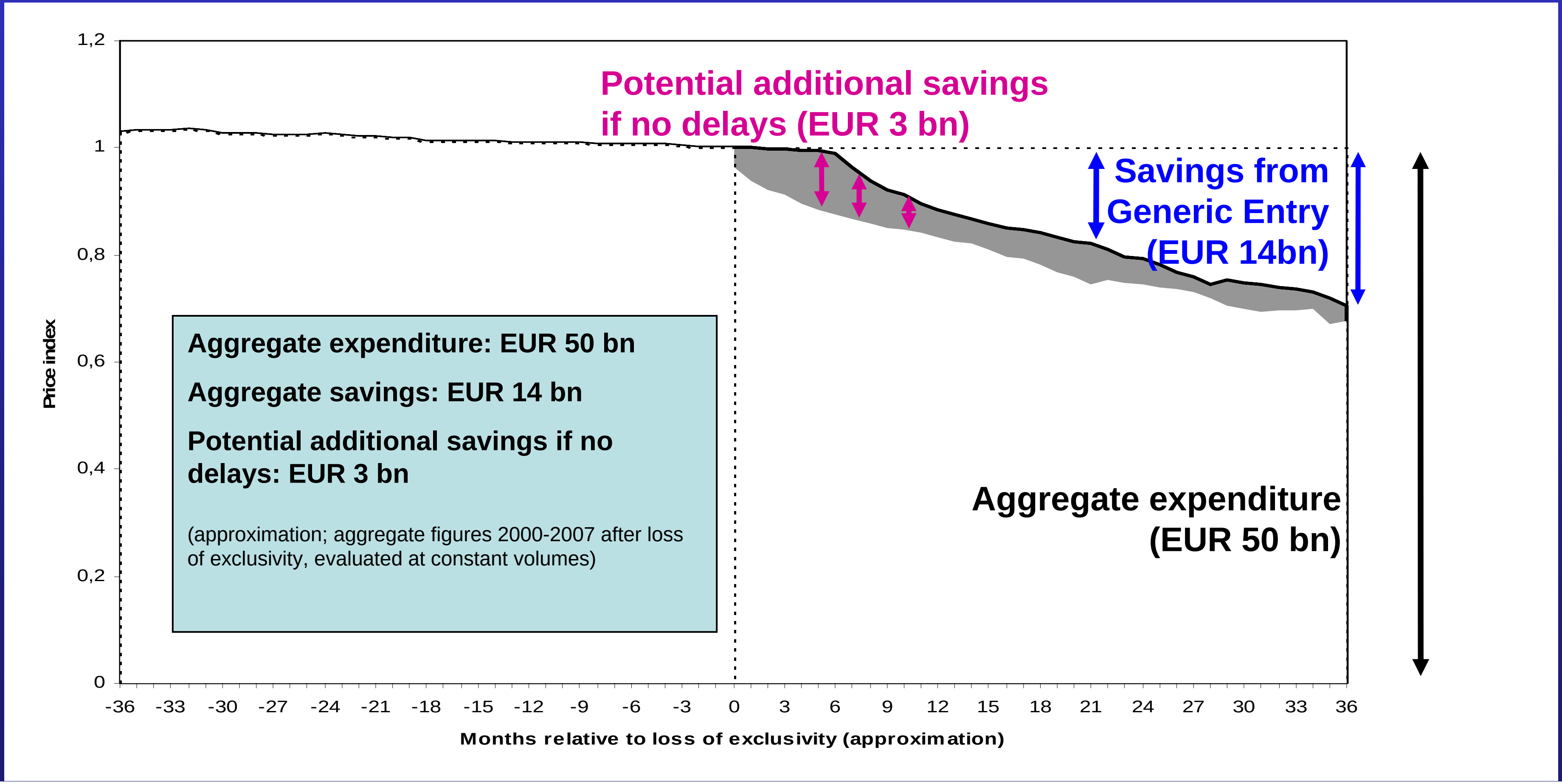
Development of average price with and without generic entry



Impact of generic entry

Savings from Generic Entry

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



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

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 for the pharmaceutical industry.
- Strategies: aimed at extending the breadth and duration of protection - patent clusters

Tool-box of originator companies

Patent strategies (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."

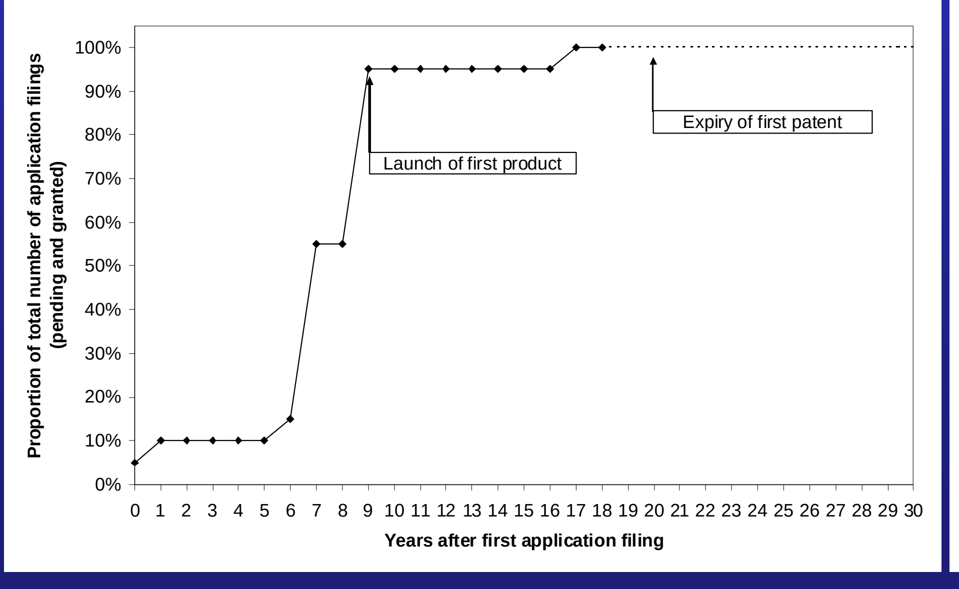
"[…] Inevitably there will be patents covering products on the market that can be, and will be challenged […] The strategy today is to try and provide a solid protection for the substance (has a limited time though) and a portfolio protecting different aspects of product providing extended protection both in brea(d)th and time but inevitable less solid and robust."

Tool-box of originator companies

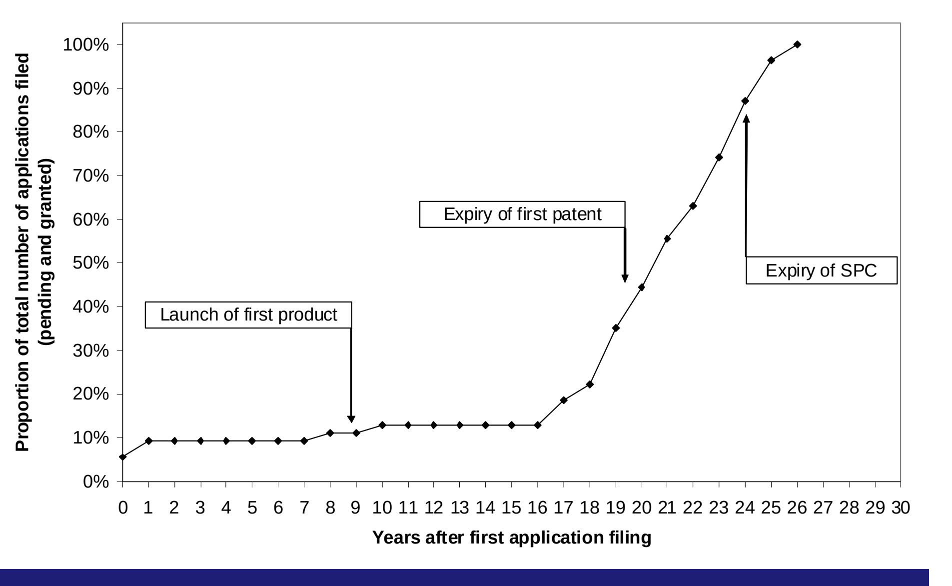
Patent strategies

Patent clusters of up to 1300 patents and patent applications for a blockbuster medicine EU-wide

"Conventional" life cycle patent portfolio



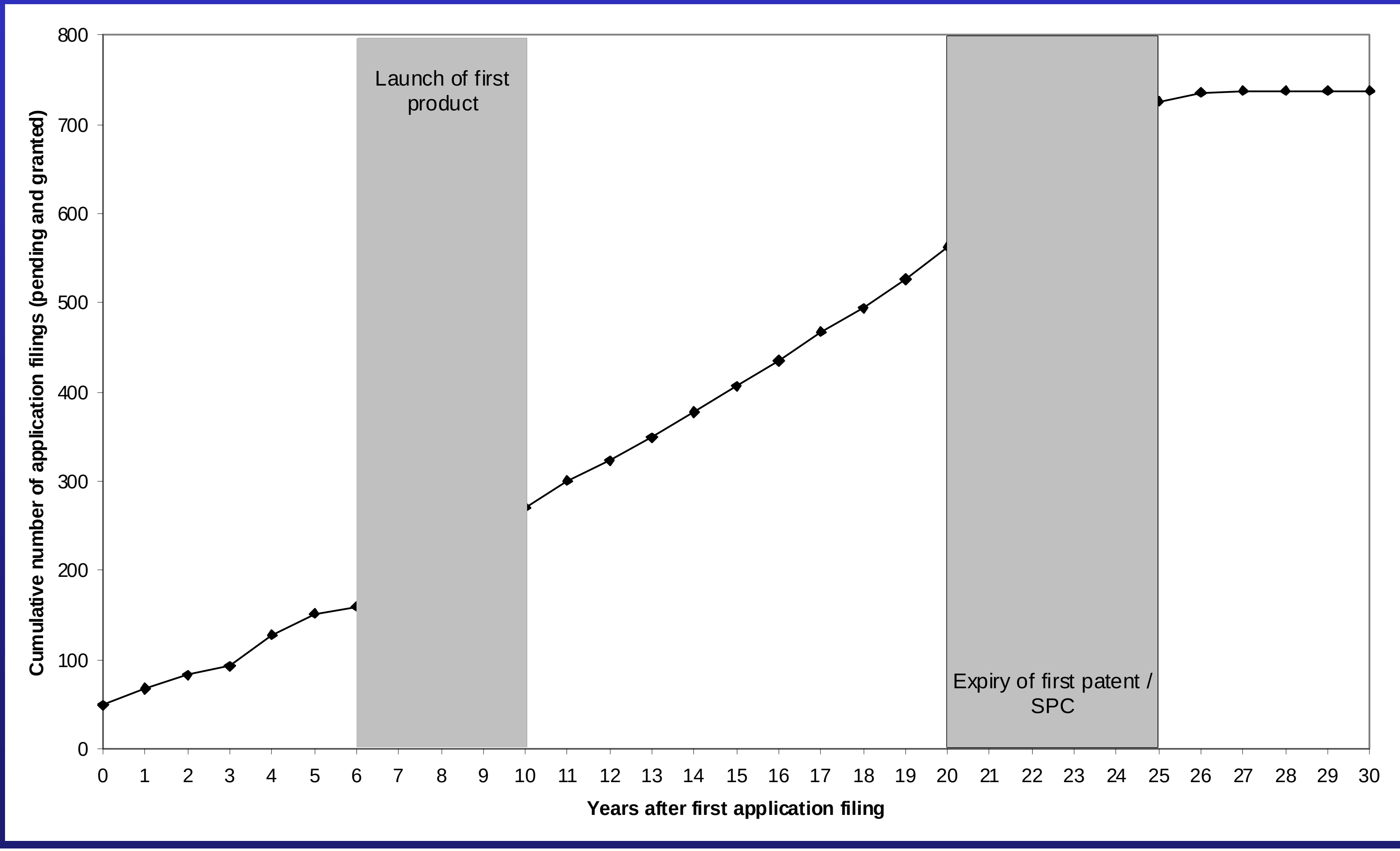
"Late" life cycle patent portfolio



Tool-box of originator companies

Patent strategies

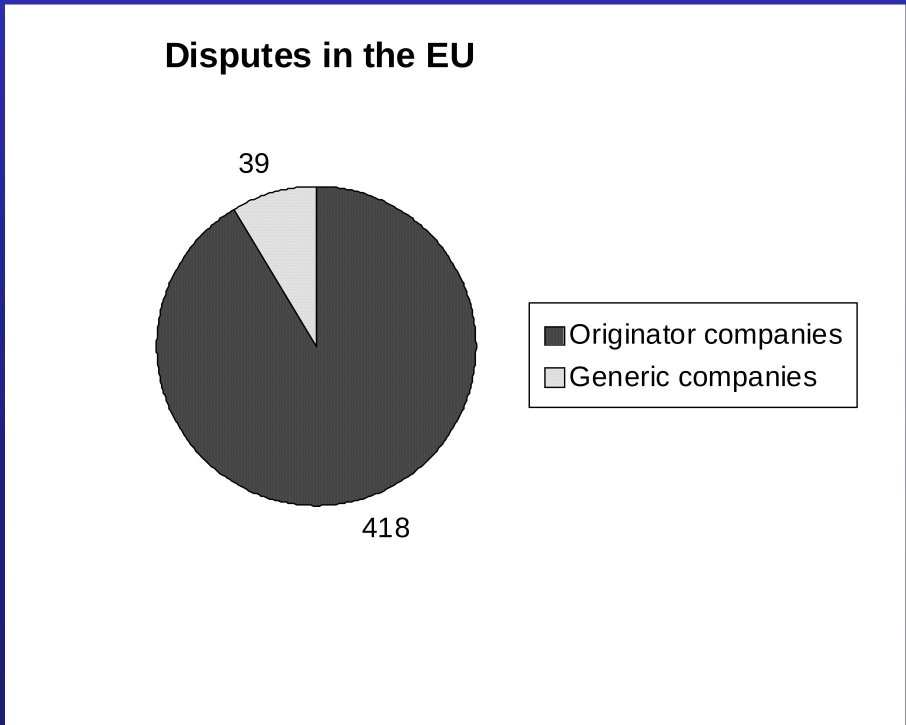
Development of Patent Application Filings for the top 20 best-selling medicines

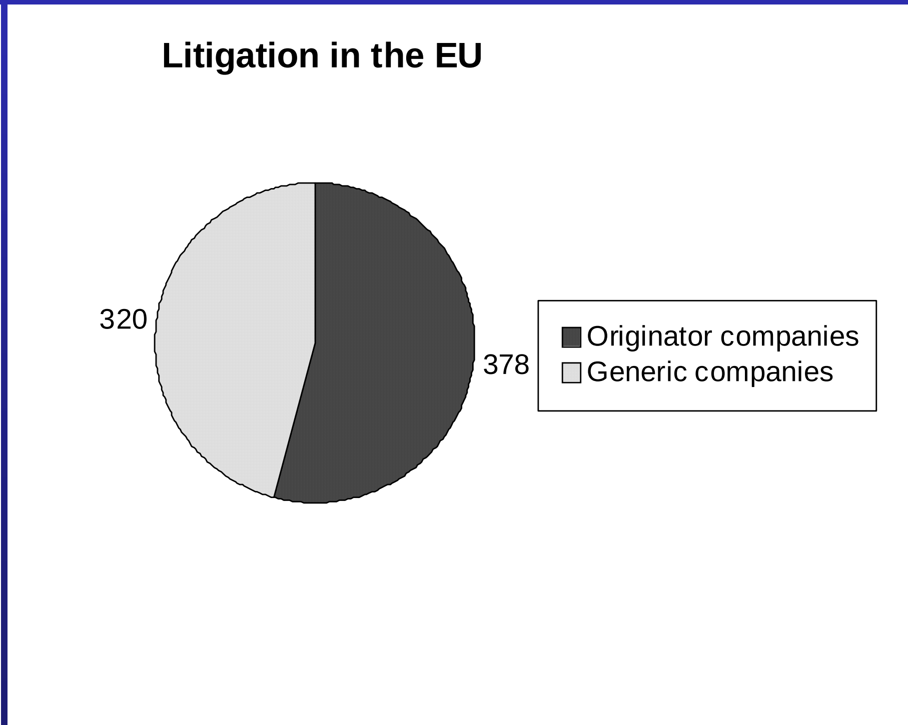


Tool-box of originator companies

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%

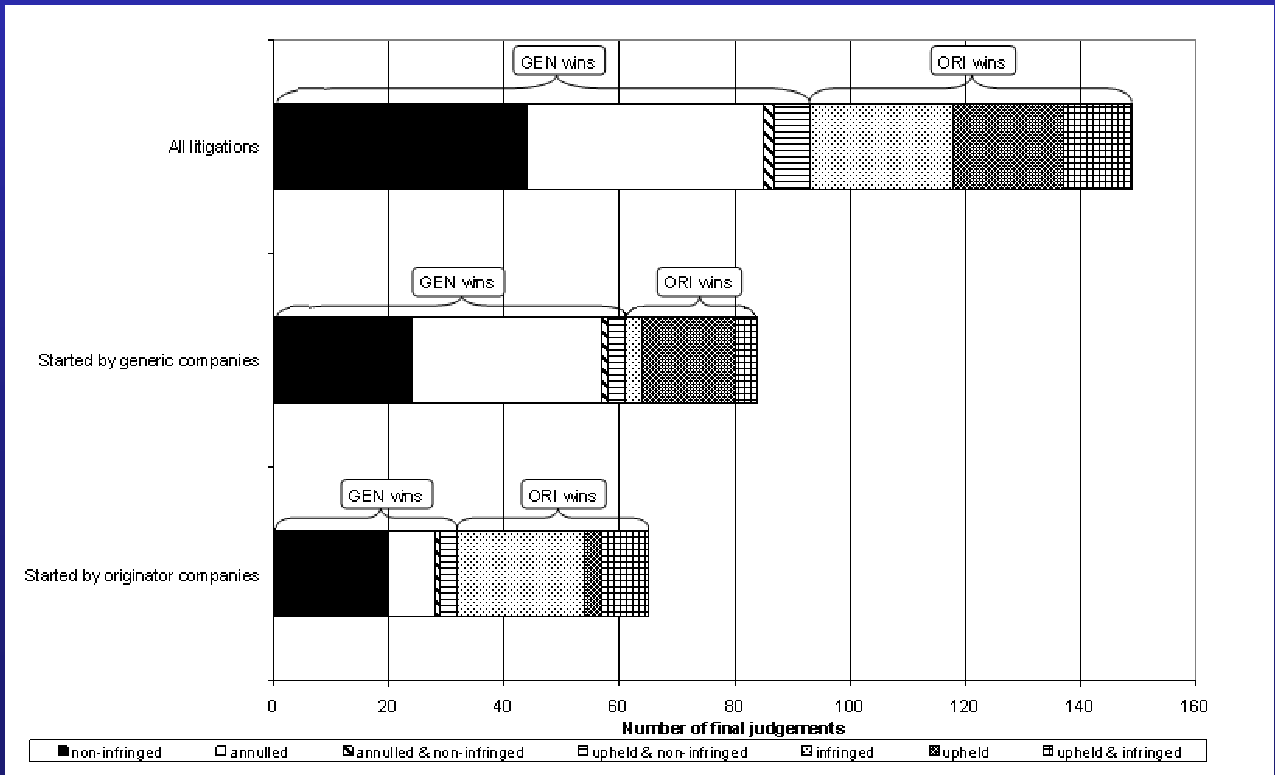




Tool-box of originator companies

Patent litigation

- Nearly 700 cases of patent litigation
- Generic companies won more than 60% of patent litigation cases



Tool-box of originator companies

Patent litigation

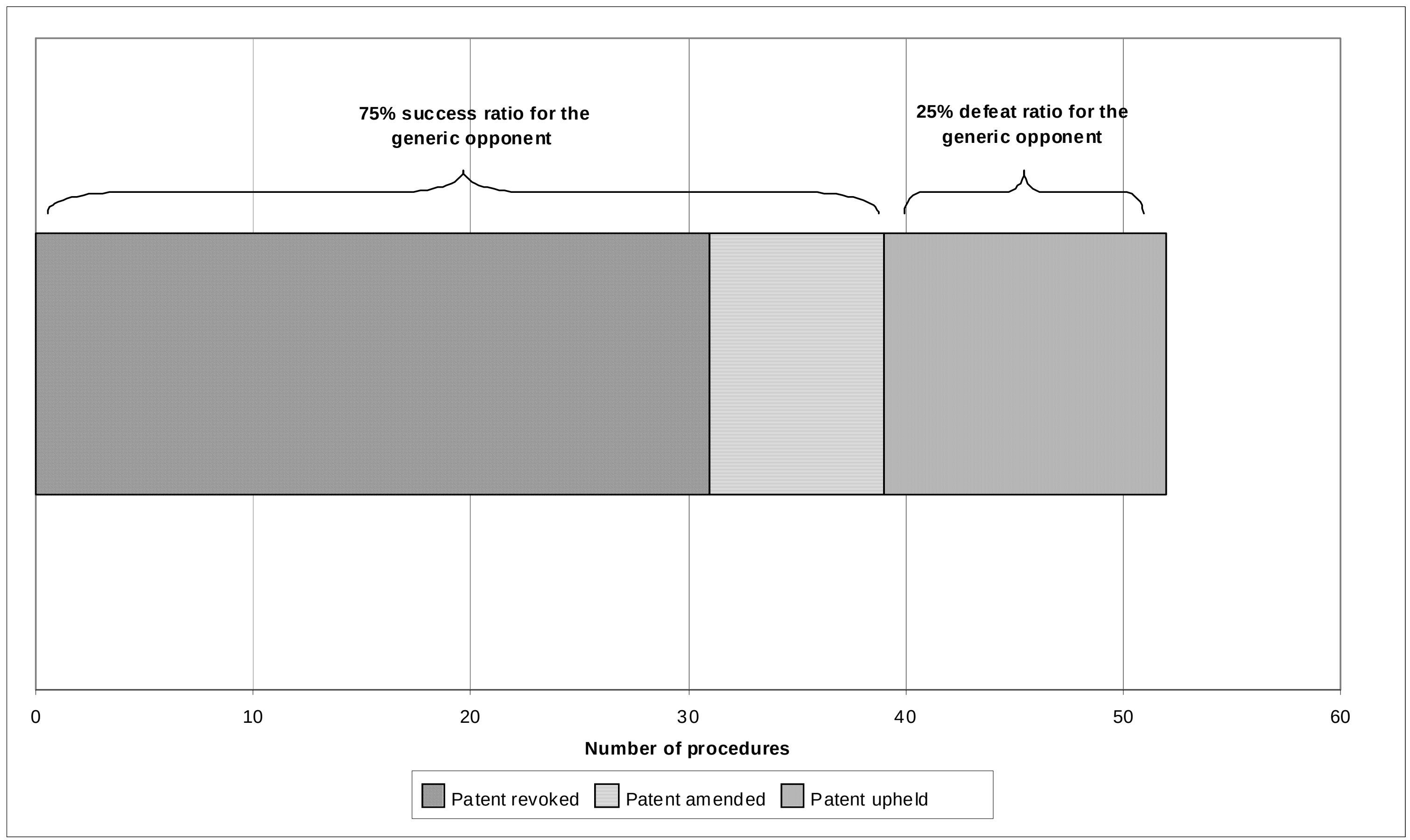
- Average duration of cases to reach final outcome: 2.8 years
- Interim injunctions granted in 112 cases: average duration 18 months

Tool-box of originator companies

Patent Oppositions

Final outcomes of opposition before the EPO

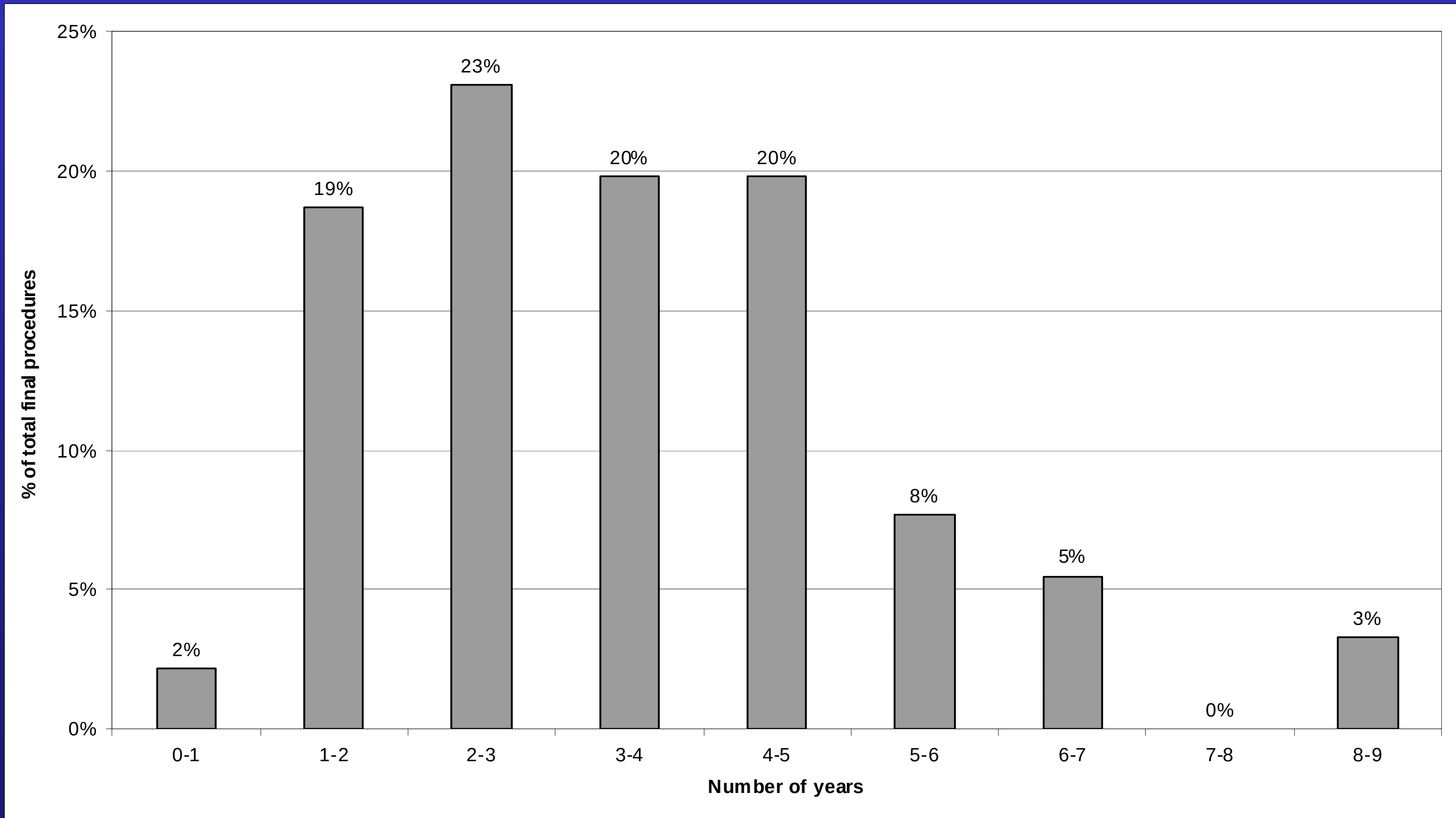
- Generic companies won 75% of opposition cases



Tool-box of originator companies

Patent Oppositions

- Almost 80% of procedures before the EPO took more than 2 years



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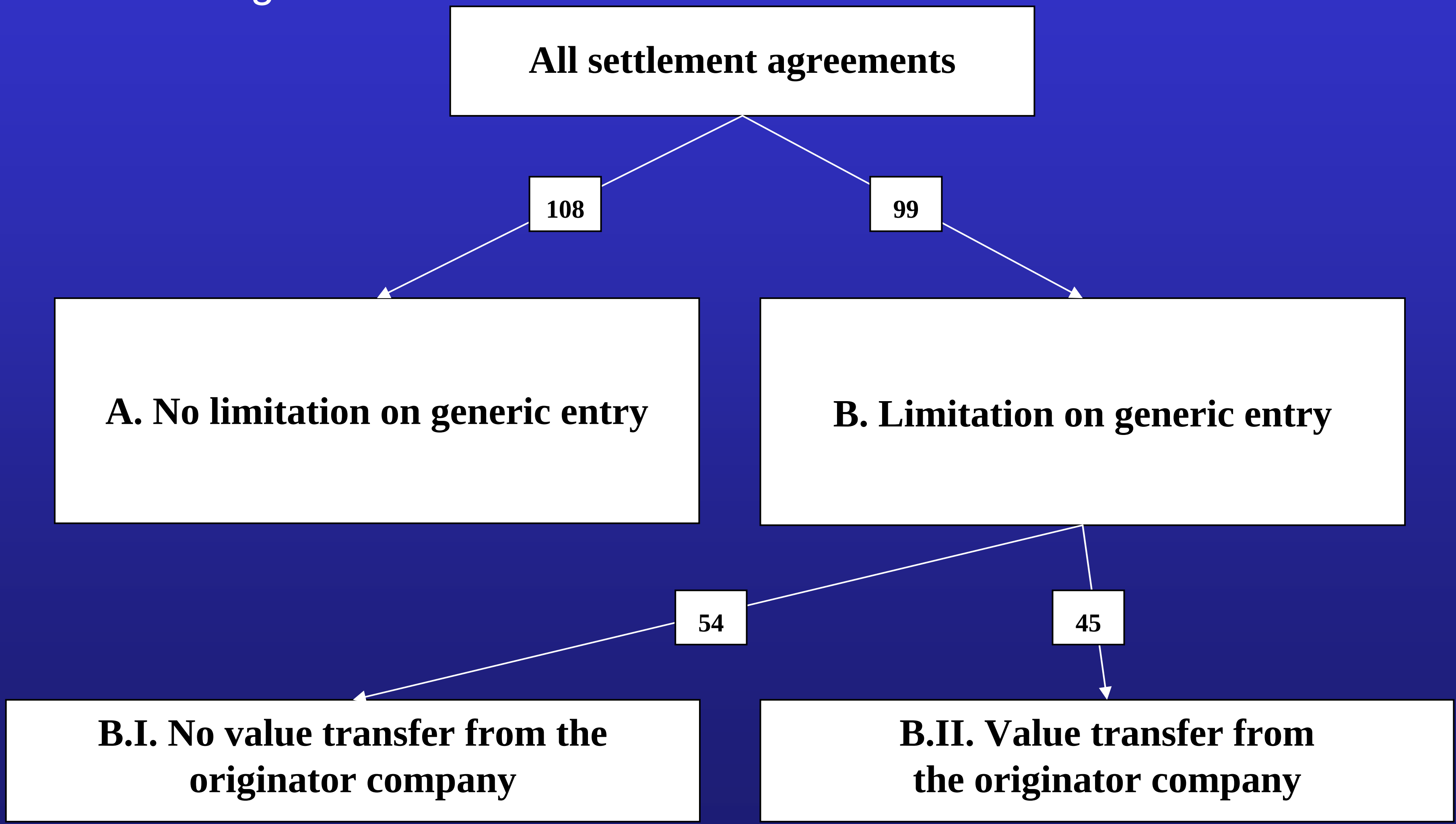
Tool-box of originator companies

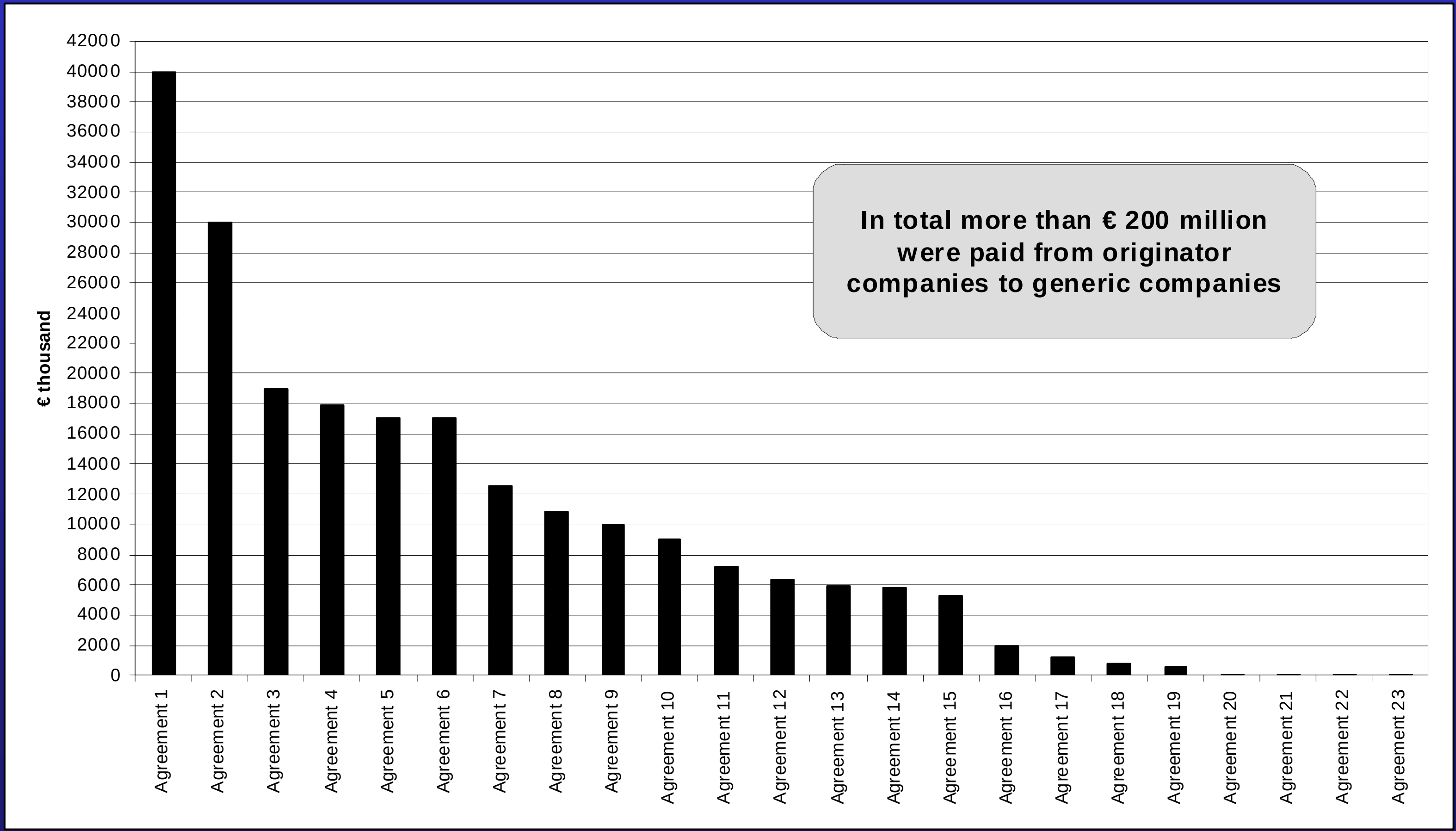
Settlement agreements



Tool-box of originator companies

Settlement agreements

- In total, more than € 200m were paid from originator companies to generic companies in settlement agreements limiting generic entry.



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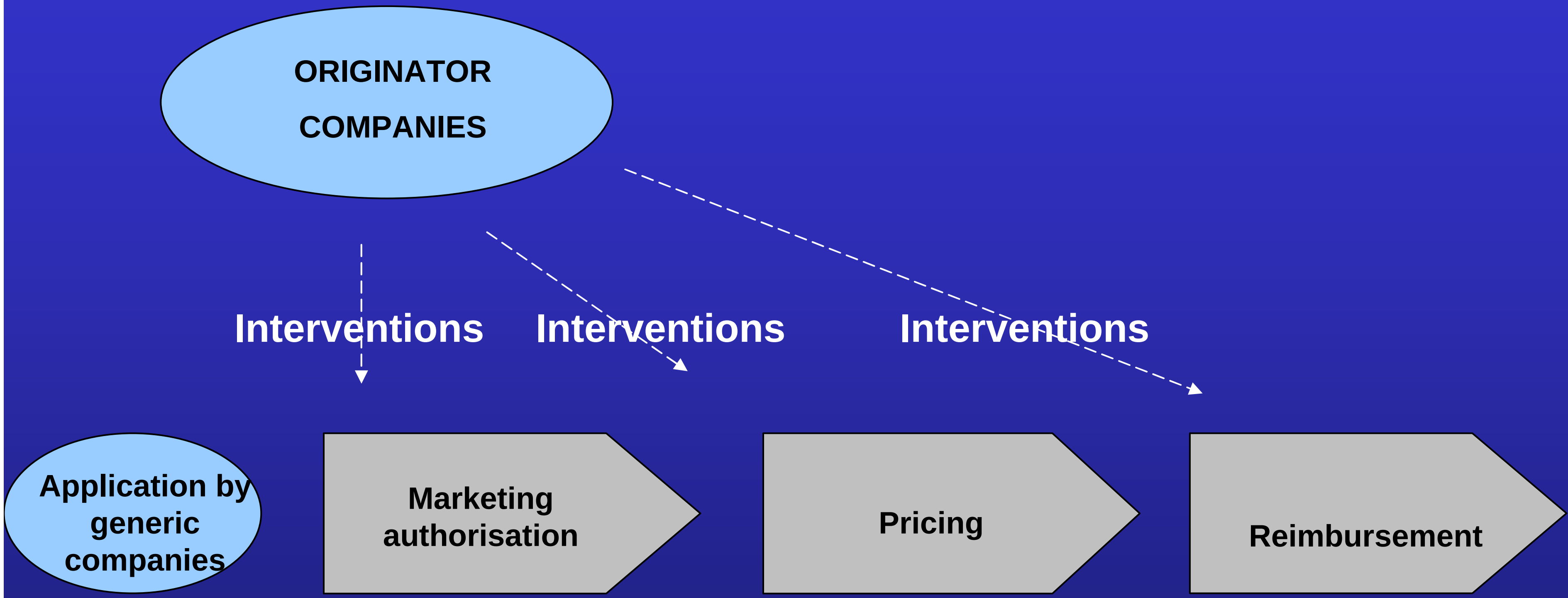
Tool-box of originator companies – Interventions (regulatory bodies)



- Originator companies intervene before national regulatory bodies claiming that generic products are not equivalent, less effective, less safe, of inferior quality or protected by patent.
- Originator companies also launch litigation against decisions of national regulatory bodies.

Tool-box of originator companies

Interventions (regulatory bodies)

- Originator companies won only
  - 2% of cases where court upheld claims against decisions of marketing authorisation bodies raising patent infringement and safety issues
  - 19% of cases where court upheld claims against decisions of marketing authorisation bodies regarding data exclusivity
- Interventions before marketing authorisation bodies delayed generic entry on average by 4 months
- Quote of originator company:

  "Interchangeability issues were used in [several countries] to limit generic erosion […] Outcome: extra [originator] product sales of USD 61m in 2 years compared to expected generic erosion. […].

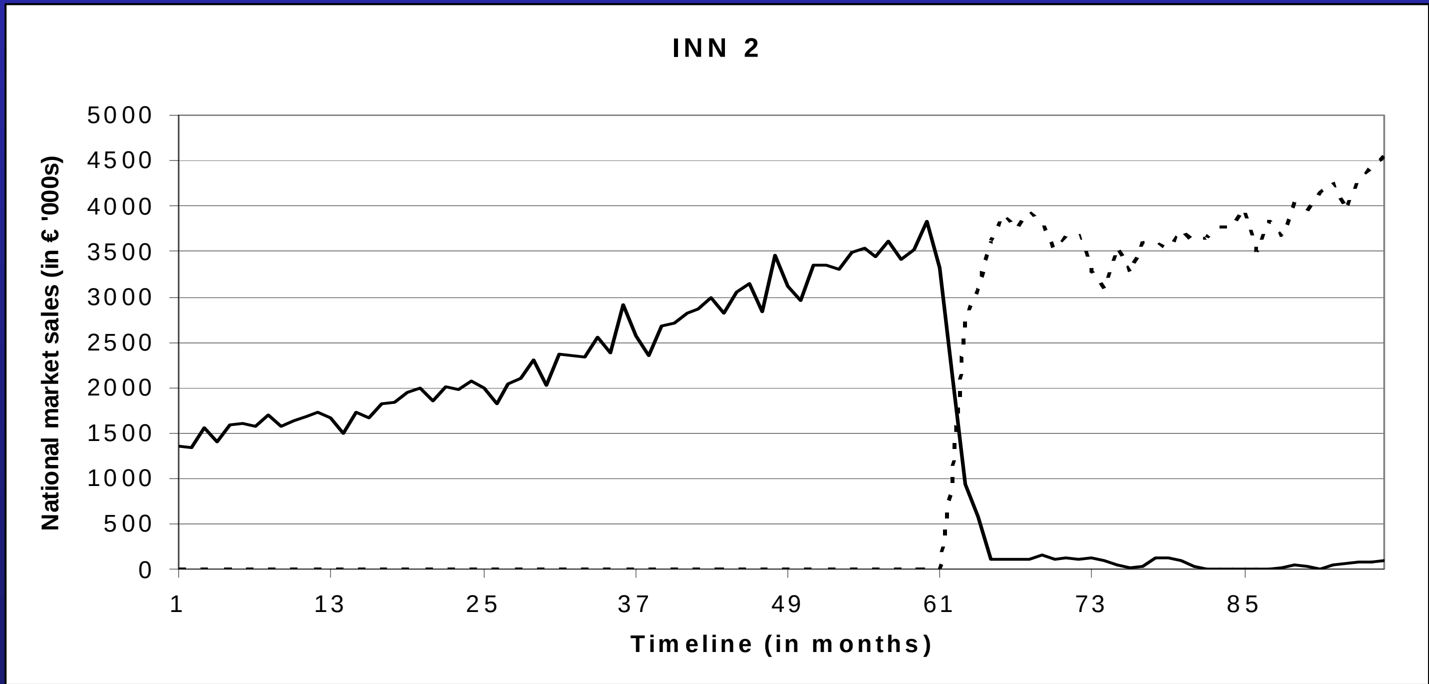
  Delayed market entry of [generic product] due to requirement for more robust efficacy and safety data. Delay of entry of […] results in USD 350m extra […] sales […]"

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.

Development of sales of second generation product vs. sales of first generation product



Tool-box of originator companies

Life cycle strategies for follow-on products

- Quotes of originator companies:

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

"[Our second generation product] is a new formulation of [our first generation product], launched initially as a line extension to maintain the growth momentum of the 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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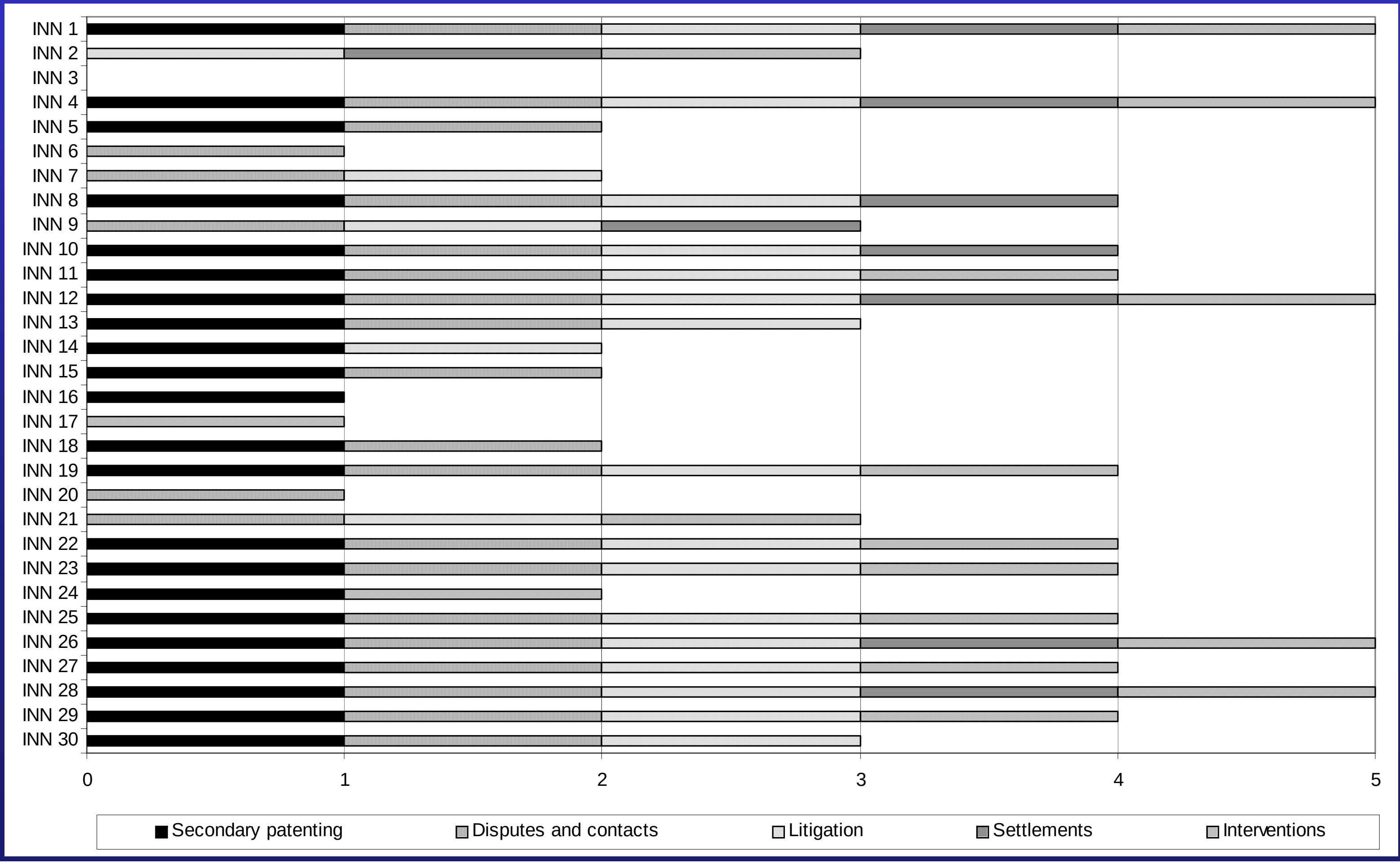
Tool-box of originator companies

Cumulative use of practices against generic companies

Number of tools used by originator companies for the top 30 best-selling products



2nd focus

Competition between originator companies

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

Competition between originator companies

Patent strategies: Defensive patenting

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

- “Defensive patents”

Competition between originator companies

Patent strategies: Defensive patenting

- 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 are maintained in major markets until risk of competing products appearing is minimal.“ (emphasis added)

  ”Defensive patents (“Limited list” patents) serve to protect compounds closely related to [our company’s] candidates or products. They do not cover [our company’s] candidates or products. They protect compounds that would be of interest to a direct competitor.”

Competition between originator companies

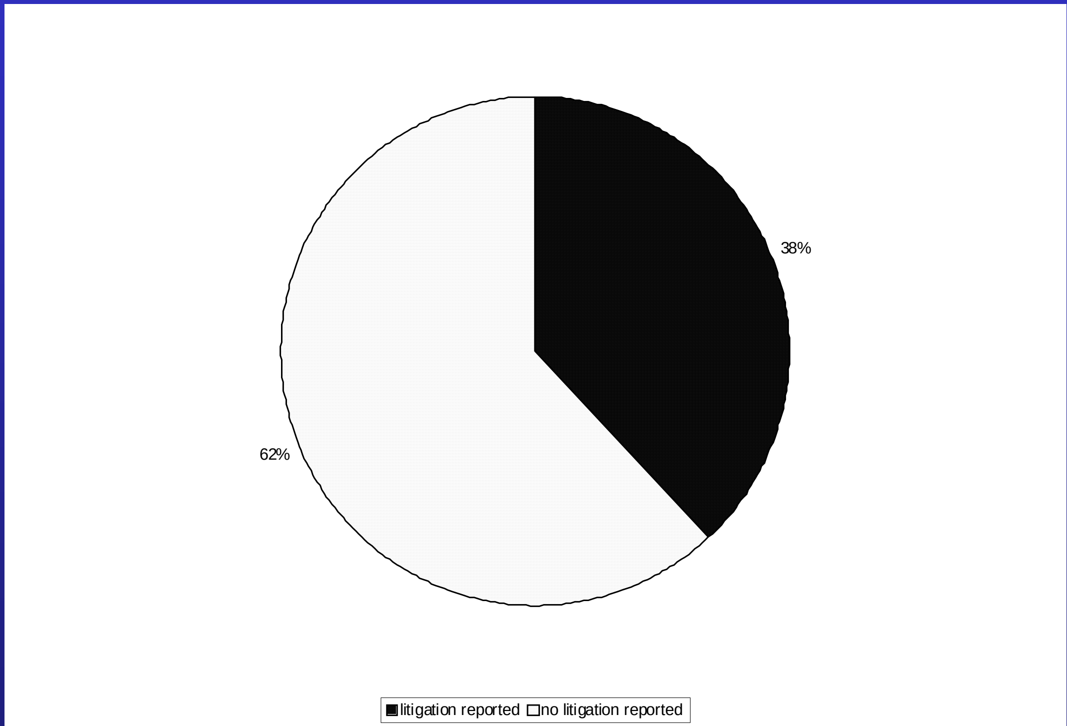
Potential overlaps and patent-related exchanges

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

- Requests for licence:
  - 99 requests for license.
  - Nearly 20% of refusals by patent-holder

Competition between originator companies

Patent litigation

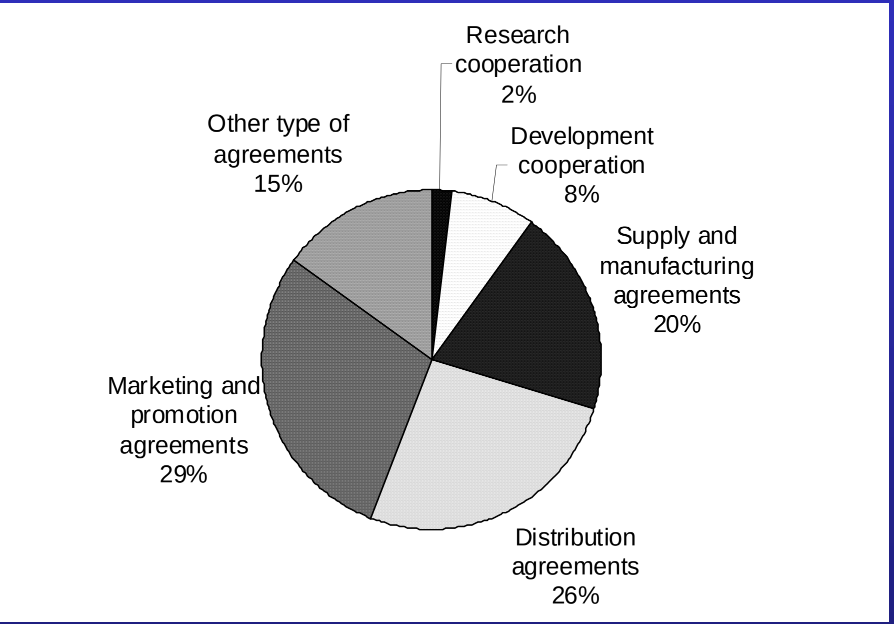


- Almost 40% of respondent originator companies were involved in patent litigation with another originator company
- Two thirds of litigations between originator companies were settled, the majority of these settlements contained a licence agreement.

Competition between originator companies

Agreements between originator companies

- More than 1450 agreements were concluded between originator companies
- More than 50% of agreements concerned marketing and commercialisation
- A particularly high number of agreements concerned Italy, Spain, Germany and Portugal



3rd focus

Comments on

the regulatory framework

- European patent system
- Marketing Authorisation
- Pricing and Reimbursement

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 420m EUR

- Generic companies (and to some extent originator companies) call upon the EPO to:
  - ensure the high quality of granted patents
  - effectively counter patent strategies that may cause unnecessary delays

Comments on the regulatory framework

Marketing Authorisation

- Companies, industry association 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

Next steps

- Public consultation until 31 January 2009
- Final Report expected for spring 2009
- Preliminary Report is available at:

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

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