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.”
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
Sector Inquiry into Pharmaceuticals in the EU

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
Impact of generic entry

Development of average price with and without generic entry

- Markets with entry
- Markets without entry (moving average)
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
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.”
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
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

75% success ratio for the generic opponent

25% defeat ratio for the generic opponent

Number of procedures

- Patent revoked
- Patent amended
- Patent upheld
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

In total more than € 200 million were paid from originator companies to generic companies
Sector Inquiry into Pharmaceuticals in the EU

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

ORIGINATOR COMPANIES

Interventions

Interventions

Interventions

Application by generic companies

Marketing authorisation

Pricing

Reimbursement
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].”
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“
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.
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
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
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”
Next steps

- Final Report expected before summer break 2009

- Preliminary Report is available at:
  