Seventh United Nations Conference to review the UN Set on Competition Policy

Wednesday 8th July 2015

Round table on Role of Competition in the Pharmaceutical Sector and its benefits for Consumers

The EU perspective: competition issues in the pharmaceutical sector

DG Competition
European Commission

The views expressed are purely personal and do not represent an official position of the European Commission or UNCTAD.

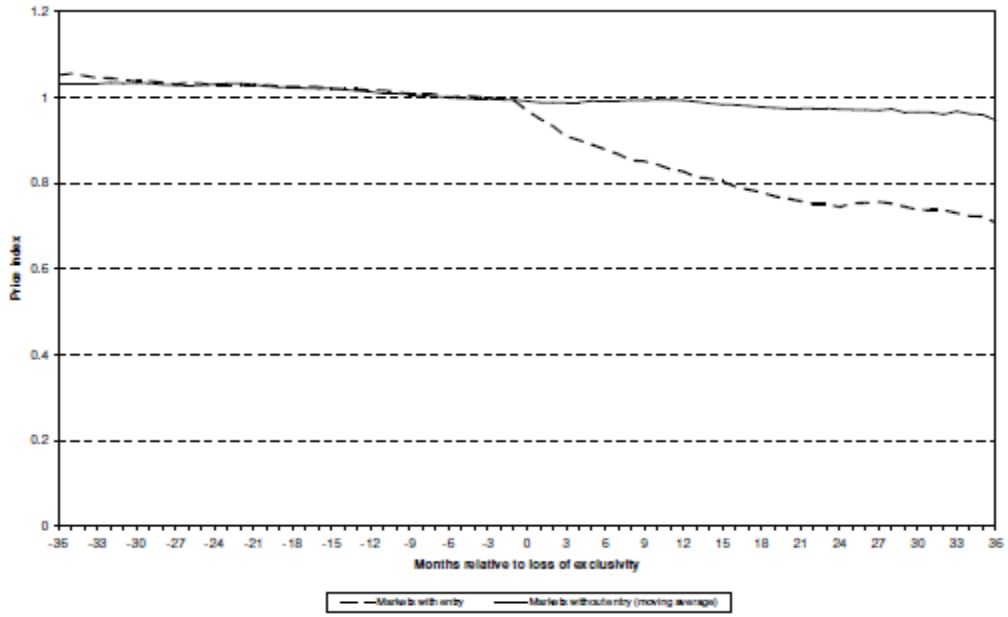
I. Pharma Sector Inquiry (2008-7/2009)

- Pharma industry: 430 €/annum/patient for prescription drugs
- Launch (1/2008) to investigate underlying causes for:
  - Delayed market entry of generic medicines
    > 1st Section: Competition between Originator and Generic Companies
  - Less market entry of new originator medicines
    > 2nd Section: Competition between Originator Companies **Methodology: In depth analysis of 219 medicines**
  - Observations on regulatory framework (patent system; marketing authorisation and pricing and reimbursement)
- Final Report after 18 months (7/2009; 600 pages; following Preliminary Report and Hearing)

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

I.1. SI Pharmaceuticals – Originator/Generics 1

1. Market characteristics of generic entry



Prices with vs without generic entry

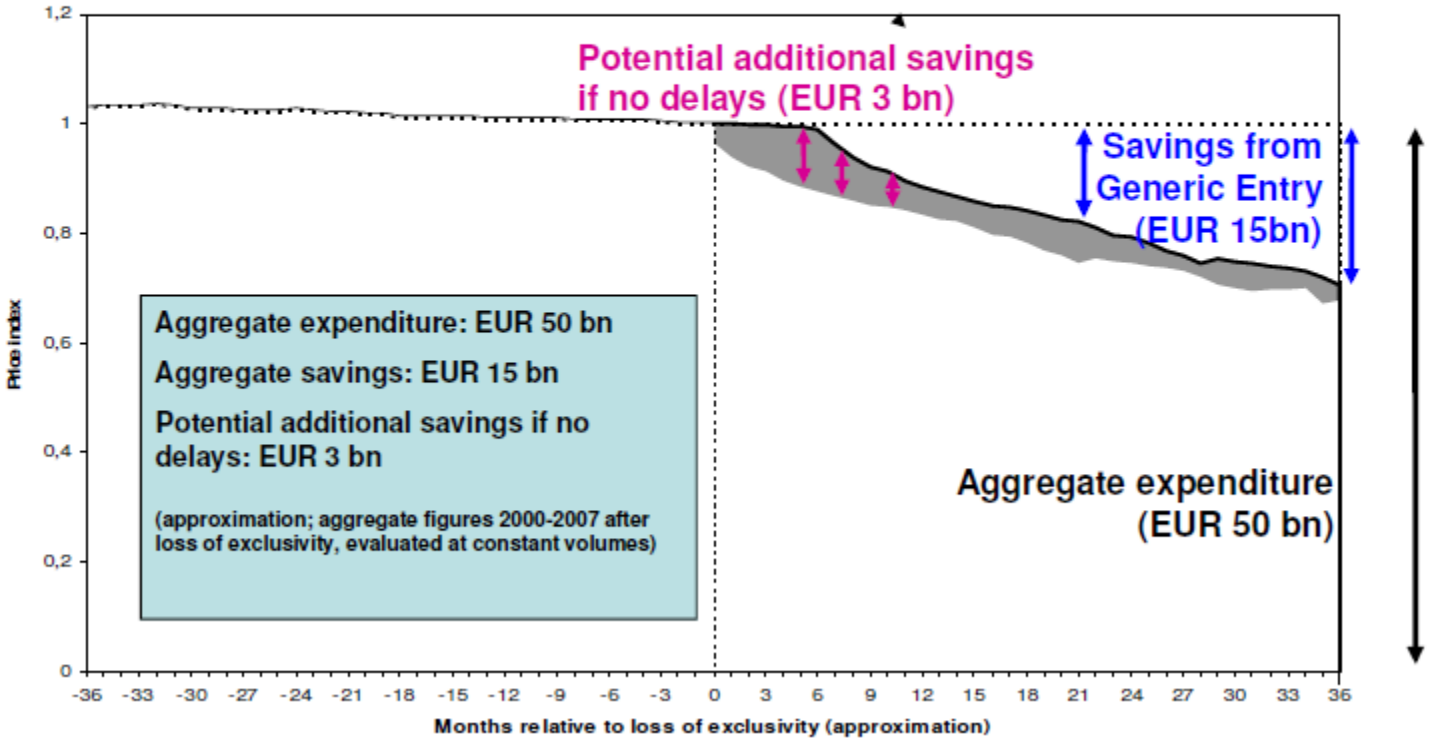
1st year:
- price: -25%; MS: 35%

2nd year:
- price: -40%; MS: 45%

European Commission

Average time to generic entry after Loss of Exclusivity: 7 months

- Sample of 50 billion € (17 MS; limited product number; 8 years)
- Actual savings of € 15bn; potential additional savings € 3bn



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2. Practices of Originator companies

a. Patent strategies

b. Patent disputes and litigation / EPO opposition

c. Settlement agreements

d. Interventions before authorities

e. Life cycle strategies for follow-on products

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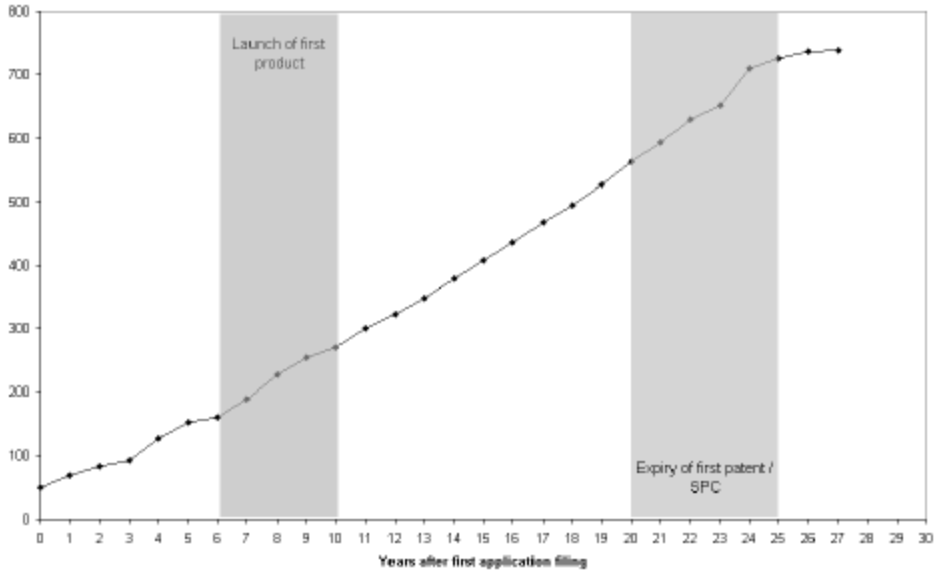
a. Patent strategies: patent clusters

The Sector Inquiry does not put into question the importance of patent rights and of their efficient enforcement in the pharmaceutical industry.



"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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b. Patent disputes and litigation / EPO opposition

(1) Litigation

- Average duration to reach final outcome: 2.8 years
- Interim injunctions; average duration 18 months
- Generic companies won 62% of patent litigation cases

(2) Opposition / appeal procedures EPO

- Almost 80% of procedures before the EPO took more than 2 years
- 60% of opposition cases led to rejection of the patent; 15% scope of patent reduced; 25% defeat of generic

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c. Pharma patent settlements - introduction

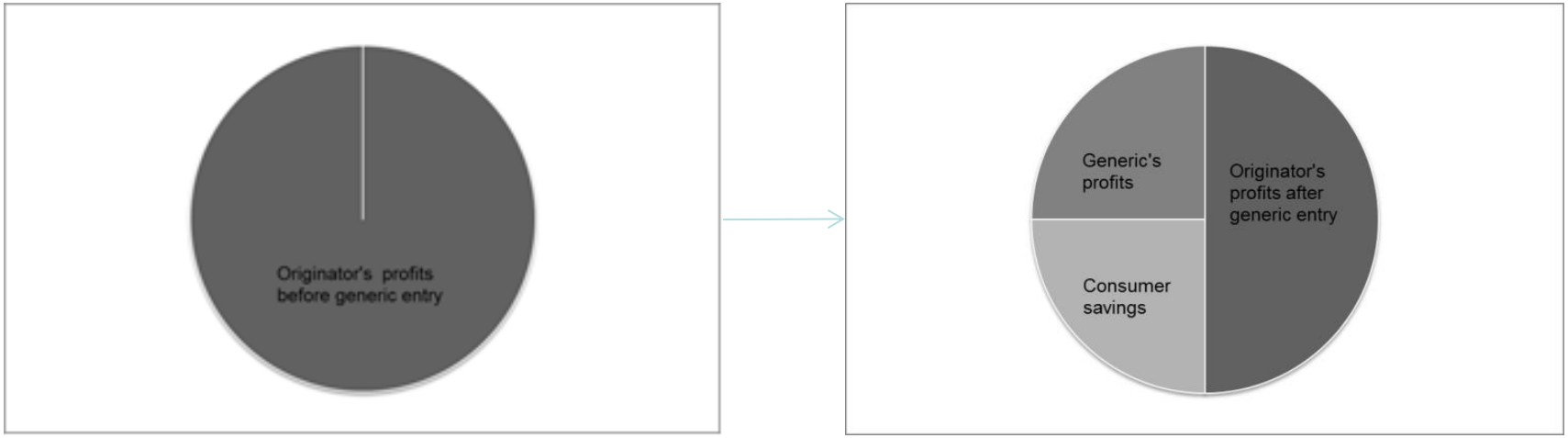
- Patent protection of great importance for innovation in pharma sector
  - Molecule patent: patent term (20 years) and Supplementary Protection Certificate (prolonging this patent up to 5 years)
  - Secondary patents: protect, for instance, processes or formulations (and provide more limited patent protection)

- After molecule patent expiry, market in principle open for generic entry. However, patent disputes regarding remaining patents may arise leading to settlements.

- In EU, no exclusivity period for first generic challenger (in U.S., first generic challenger receives 180 days exclusivity).

Why do some patent settlement agreements raise concerns?

Generics erode prices and gain market shares resulting in consumer savings.



Before generic entry **After generic entry**

EU cases with a patent context:

- 39.226 *Lundbeck* (6/2013) — No settlements, but agreements concluded in the context of a patent dispute (Art. 101)
- 39.612 *Servier* (7/2014) — Patent settlements and unilateral conduct to exclude generics (Art. 101 and 102)

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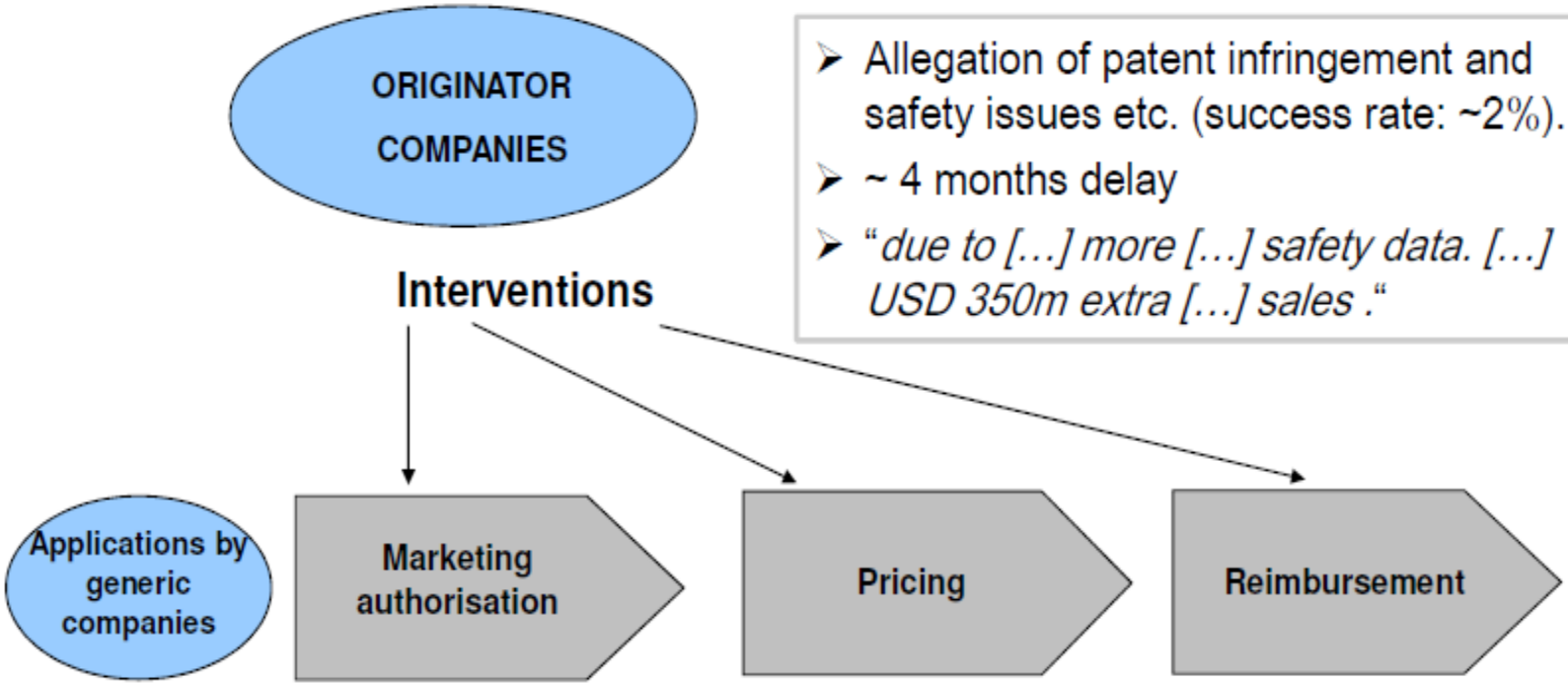
d. Interventions with Regulatory Bodies



- Allegation of patent infringement and safety issues etc. (success rate: ~2%).
- ~ 4 months delay
- "*due to […] more […] safety data. […] USD 350m extra […] sales .*"

II. Commission Decision 37.507/Astra Zeneca

- **Dominance on market** defined as proton-pump inhibitors (PPIs) (excluding H2 blockers)
- AZ committed **two abuses** (from 1993-2000) hindering market access for generics and preventing parallel imports of the PPI Losec (omeprazole):
  - By providing **misleading information** to patent offices and courts resulting in or to obtain supplementary protection certificates ("SPC abuse")
  - By misusing regulatory procedures through **selectively deregistering Losec capsule marketing authorizations** in Denmark, Norway and Sweden ("deregistration abuse") (while replacing these with tablets leading to loss of reference MA)
- Fined AZ in total €60 million (€30 million per abuse)

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e. Life cycle strategies for follow-on products

- Originator companies launched **second generation (follow-on) products** for 40% of the medicines in our sample.

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

- Originator companies made intensive use of marketing and promotion strategies and other instruments in order to **switch** patients to the second generation product **before generic entry**.

  "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]."

Conclusions

Special situation of the pharmaceutical sector:

- highly regulated (market authorisation, pricing, reimbursement, IPR)
- high investment into R&D compared to other sectors

Yet, no exemption of the sector from competition scrutiny (evident from judgements of European courts)

Practices aimed at reducing competition:

- on price (e.g. delaying/blocking generic entry) or
- on innovation (e.g. delaying/blocking entry of new innovative product)

likely to attract scrutiny. => each case to be assessed on its own merits

Thank you!

Website:

http://ec.europa.eu/competition/sectors/pharmaceuticals/overview_en.html#