EU Pharmaceutical Sector Inquiry and Antitrust Enforcement

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

Findings of the Sector Inquiry (SI)

- Background
- Main findings (Final Report July 2009):
  - Competition between originator and generic companies
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  - Comments on the regulatory framework
- Policy recommendations and antitrust enforcement
Background

- Observations leading to the launch of the SI
  - Delay of generic entry
  - Decline in innovation
- SI investigated underlying causes
  - Focus on company behaviour
  - Importance of the regulatory framework
  - Method: In-depth analysis of 219 INNs representing nearly 50% (value) of prescription market 2000-2007
  - SI underlines need for effective patent system to maintain incentives for innovation
- Procedure
  - Launch on 15 January 2008
  - Information requests to all stakeholders
  - Preliminary report on 28 November 2008
  - 2 months of public consultation
  - Final Report on 8 July 2009
Competition between originator and generic companies

- Market characteristics of generic entry
- Originator companies’ practices ("tool-box")
Market characteristics of generic entry

- Price drop: generic price 25% lower than originator price prior to LoE (40% lower after two years)
- Average time to generic entry: almost 8 months (weighted by value)

Development of overall average price with and without generic entry:
Practices ("tool-box") of originator companies

- Patent strategies
- Patent disputes and litigation / EPO opposition
- Patent settlement agreements
- Interventions before authorities
Patent strategies

• Importance of patent rights and their efficient enforcement for the pharmaceutical industry.
• Patent clusters: Patent strategies aimed at extending the breadth and duration of protection

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.”
Patent disputes and litigation (698 litigation cases)

- Increase of patent litigation cases (2000-2007)
- Average duration to reach final outcome: 2.8 years
- Interim injunctions granted in almost half of cases (112 of 255 cases); average duration 18 months
- Generic companies won 62% of patent litigation cases reaching final judgment

Final outcome of EPO opposition proceedings

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

All settlement agreements

A. No limitation on generic entry

B. Limitation on generic entry

B.I. No value transfer from the originator company

B.II. Value transfer from the originator company
Originator companies „intervene“ before national authorities raising alleged patent infringement and safety issues („patent linkage“)
Competition between originator companies

• Patent strategies: defensive patenting
• Potential patent conflicts
Patent strategies: defensive patenting

- Importance of patent rights and of their efficient enforcement for the pharmaceutical industry.
- Defensive patent strategies: patents foreseen not to be used for innovation but primarily to block the development of competing products.

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.”
Estimation of potential patent “conflicts”:

• Potential overlaps
  - In 1100 instances overlap between competing originators’ products/R&D poles and patents
  - 20% of license requests refused

• Patent litigation
  - 40% of originator companies involved in patent litigation, 2/3 of cases settled.

• Opposition
  - High success rate of oppositions
Policy recommendations of the Final Report and antitrust enforcement:

- Patents
- Marketing Authorisation
- Pricing and Reimbursement
- Antitrust enforcement
SI Pharmaceuticals – Policy Recommendations

Patents
- Full support for a Community patent & specialised patent judiciary
  - First results: break through under Swedish presidency
- Improvement of EPO procedures (“raising the bar”)
  - First results: limitation of voluntary divisional applications

Marketing Authorisation
- Address patent linkage
- Enforce existing legal framework to respect deadlines and reduce discrepancies

Pricing and reimbursement
- Limit adverse effects of unjustified third party submissions
- Enforce deadlines
- Member States to consider mechanisms that facilitate generic entry
  - First results: Transparency Directive to be revisited
  - First results: Spain (automatic pricing for generics)
Relationship between IPRs and antitrust law
- Perceived tension (exclusive rights) but
- same objective: promote innovation and consumer welfare
- IPRs indispensable for dynamic competition but
- not immune from competition law intervention

Limitations to antitrust interventions
- No substituting for the patent office
- Need to take into account impact on incentives to innovate
- Exceptional circumstances (e.g. refusal to supply/licence case-law)

Enforcement actions following the SI:
- Perindopril and Citalopram cases
- Patent settlement monitoring (1/2010): focus on settlements which restrict generic entry and foresee a value transfer
AstraZeneca decision (under appeal)

• Fined €60 million for abusing its dominant position (Article 102 TEUF)
• Market defined as PPI inhibitors
• Two abuses delaying generic entry:
  » Misrepresentations to the patent system
  » Misuse of regulatory procedures
  » Lack of clarity of rules was not accepted as objective justification
Patent settlements (1)

• Generally an efficient way of resolving patent disputes (resources, legal certainty)
  
  \textit{Inter partes} instead of \textit{erga omnes} effects

• So far, no explicit EU case law on antitrust analysis of patent settlements but some indications in case-law

• SI confirmed existence of patent settlements in Europe, also settlements with reverse payments

• One of instruments that can contribute to delays in generic entry
Patent settlements (2)

- **Concerns:**
  - Sharing of monopoly rents between originator and generic, patients/health insurers not present at negotiation
  - Buying of “insurance” against risk of invalidation

- **Settlements possibly raising competition concerns:**
  - Sham patents
  - Restrictions beyond the exclusionary zone of the contested patent
  - Not allowing unlimited and immediate generic entry and including a net value transfer from the originator to the generic company

- Parties need to explain any value transfer; failure to do so may be an indication of a competition concern
Thank you for your attention!