The DG Competition Pharmaceutical Sector Inquiry Patents and Competition

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Outline

- Presentation of the report of the sector inquiry
  - Background of the inquiry
  - I. Competition between originator and generic companies:
    - Claims re the tool-box used by the originator companies
  - II. Competition between originator companies
  - III. Comments on the regulatory framework
- Comments/criticisms on the report

Background observations

- « Dawn raids » in Jan. 2008
- Sector inquiry (art. 17(1) Reg. 1/2003)
  - The COM might request the undertakings « to supply the information » and « may carry out any inspection necessary » for giving effect to art. 81/82
    - Selection of 43 originator companies and 27 generic companies (80% of turnover) - period between 2000 and 2007
  - No individual case of wrongdoing/ no guidance as to compatibility of practices with competition rules
- Commission's observations (15 Jan. 2008):
  - Delayed market entry of generic medicines
    - Average time to entry = 12 months (only 4 months for most valuable medicines) - Variations between countries (UK v. ES)
  - Decline of innovation: less new originator medicines enter the market (decrease between 1990 and 2007)

Impact of inquiry

- Release of the preliminary report on 28 Nov. 2008:
  - Public consultation (till end January 09)
- Final report on 8 July 2009
- COM report: was it purely factual?
  - >< press release of Commission: « delaying tactics »
  - Neutrality? Fair treatment?
  - Risk of perception of bias (even if no real bias)
    - Starting point = « dawn raids » (prosecution rather than inquiry)
- Further individual actions against abusive conduct of originator companies?

Preliminary report (28 Nov. 2008)

- Consultation of interested parties:
  - Consumer groups, generic companies and health insurance sector: generic medicines too slow to be on the market - decline in innovation
  - Originator companies, law firms, patent attorneys: delays to generic entry not due to originator companies' behavior - no evidence that companies' practics hinder innovation
  - EPO: interface between patent and competition: should be defined with reference to ECJ case law - against a scrutiny of the intent of patent applicants
- Agreement on the need of COM/EU patent + unified patent litigation system

Final report (8 July 2009)

- Market structure:
  - High R&D: 17 % of the originator companies turnover (see p. 7-8 Ex. Summary)
  - The consumer is not the decision maker (but doctors)
  - Regulation of prices (including through reimbursement)
  - Actors are not price sensitive
- Generics entry
  - Generics = 70 % of sales; > 7 months after patent expiry
  - When entry: 26% lower; two years after: 40% less than originator price

I. Competition between originator and generic companies

Cumulative use of various tools (notion of tool-box):

1. Patent strategies (re filing)
2. Patent litigation (including EPO opposition)
3. Settlement agreements
4. Interventions before authorities
5. Life cycle strategies for follow-on products

1. Patent strategies

- Aim at extending the breadth and duration of patents
  - Protection of various aspects of the product through secondary patents
    - Primary patents: on the active substances
    - Secondary patents on different dosage forms, production process, new formulations
  - Issue of follow-on patents and incremental innovation
- Building of « patent clusters »
  - Multiplication of secondary patents (up to 1300 patents for a blockbuster medicine; filings come quite late at the end of the patent duration)
    - This creates uncertainty for generic companies
  - Use of divisional patent applications: split of an original patent application (the examination of the divisional patent application continues even if the parent application is withdrawn or revoked)
    - Creates legal uncertainty

2. Patent litigation (see p. 11-12)

- Nearly 700 cases per year (patent litigation)
- Mostly on secondary patents
- Generic companies win > 60 % of the cases
- Average duration of cases to reach final outcome: 2,8 years
- Interim injunctions granted in 112 cases: average duration = 18 months

Patent opposition

- Opposition rate is higher: 8% (comp with average about 5%)
- Mostly on secondary patents
- Generic companies win 60 % of opposition cases (thus claim of weak patents)
- Nearly 80 % of procedures before the EPO take more than 2 years; therefore: delay

3. Patent settlements

- More than 200 settlements
  - No limitation of generic entry: 108
  - Limitation of generic entry: 99
    - No value transfer: 54
    - Value transfer: 45

4. Interventions - regulatory bodies

- Claims before national authorities that generic products are not equivalent, less effective, less safe, of inferior quality or protected by patent
  - Litigation against decisions of national bodies
- Interventions at different levels:
  - Marketing authorisation (delay of about 4 months)
  - Pricing
  - Reimbursement

5. Life cycle strategies for follow-on products

- Second generation (or follow-on) products for 40 % of the medecines (new formulation, etc.)
  - Intensive use of marketing and promotion strategies in order to switch patients to the second generation product before generic entry

II. Competition between originator companies

- 1. Patent strategy: defensive patenting (patent for limiting the freedom of operation of others)
  - On compounds that would be of interest to a direct competitor
  - Often, overlap between products/R&D poles and patents of competing originator companies
- 2. Patent litigation:
  - 40 % of originator companies are involved in litigation with another originator company
  - 2/3 of cases are settled (licence agreement is concluded)
    - More than half the agreements concern marketing and commercialisation

III. Comments on the regulatory framework

- 1. The European patent system: originator and generic companies support:
  - The creation of a Community/EU Patent
  - The creation of a unified and specialised patent judiciary in Europe
    - 700 cases, risks of conflicting judgments (reported in more than 11 % of total)
- 2. Marketing authorisation
  - Bottlenecks on the procedure (and thus delays, administrative burden, etc.)
    - No international harmonisation of MA

Regulatory changes: patent system

At intergovernmental level:

- 1973 European Patent Convention (EPC: 34 States):
  - Single application in Munich at the European Patent Office (EPO), but bundle of national patents
  - Centralized grant, but national enforcement

At EU level:

- Draft Community Patent Regulation
  - Single filing procedure (before the EPO) and EU-wide patent
- Draft Treaty on the litigation system and Recommendation from the Commission to the Council to authorise the Commission to open negotiations for the adoption of an Agreement creating a Unified Patent Litigation System
  - Reduction in costs + reduction of divergences between the decisions of Member States
- Harmonization Directives (divergences of existing law):
  - Biotech inventions Directive (1998)

Regulatory changes: marketing authorisation and pricing

- Marketing authorisation
  - MA if the medicine is safe, effective and of good quality
  - Administrative costs
  - Discrepancies in the assessment criteria
  - Risk of disclosure of information to competitors
  - « Patent linkage » when regulatory bodies consider if the product infringes some patent
- Pricing and reimbursement
  - Delays and uncertainties due to the fragmentation of the national decision-making process, health technology assessment, demands re equivalence between originator and generic product

Some criticisms (patent side)

- Patent is under particular scrutiny - but the rest?
- Misunderstandings (examples):
  - amendments of patents in opposition = a success of the opponent: it depends whether the amended patent is a barrier
  - majority of litigated patents were revoked (>< percentage between 29,5 and 37 %)
- Reference years (2000-2007) for the inquiry: how to take into account that the Bolar exception allowing pre-patent-expiry development was only supposed to be transposed by 31 Oct. 2005?

Some criticisms (patent side)

- Methodological issues: how to best count patents?
- The distinction between primary and secondary patents
  - Patents on the molecules/new ingredients v. patents on subsequent, incremental inventions? The latter ones should be subject to higher scrutiny?
  - Goal of patents = to promote inventions built on inventions
    - The follow-on innovation can come from third parties (>< owner of patent on primary patent) - Final report is cautious see p. 5 Ex. summary
- No analysis of other factors that could have lead to fewer innovation (scientific complexities, high attrition rate in late stage due to regulatory risk aversion, etc.)

Some criticisms (patent side)

- No serious analysis of causation:
  - Inconsistencies: number of patents per country is higher for countries with shorter delay for generic entry (for ex. UK) and lower for countries with long delay (ES)
- What is the relevance of intention in patent filing and patent litigation?
  - Is the subjective intent of the applicant in acquiring patent rights (protect or block?) relevant?
  - Issue of the use of quotations in retrieved e-mails: is intention enough to establish abuse? How could « intention to exclude » be illicit when you have a legal right to exclude?

Patent regulatory response

- Change of EPO implementing rules re divisional application: effective on 1 April 2010:
  - No more up to the date of patent expiry
  - Must now be filed within 24 months from either the issuance of the first communication of the Examining Division or the issuance of a lack of unity objection
- To fight abusive / last minute divisional applications (that keep at bay EPO examiners and competitors)