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The Commission's Pharmaceutical Sector Inquiry - What's Next?

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Outline

- Findings of the Sector Inquiry
- Competition law and the pharmaceutical sector
  - Market specifics
  - Overview of enforcement actions in the sector
  - Selected practices, in particular patent settlements

  - *Nota bene*: not covered parallel trade

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The Sector Inquiry

- January 2008 - July 2009 (publication of Final Report)
- Focus on competition between originators and generics / amongst originators

Main Findings of the Final Report

a) Originator practices aimed at generics and other originators

- Particular analysis of the following practices affecting ORI-GEN competition
  - Patenting
  - Litigation
  - Agreements, in particular patent settlements
  - Interventions before regulatory authorities and denigration
  - Follow-on products
- Possible effect: undue delay of generic entry

b) Reported shortcomings of the regulatory framework (e.g. patents, marketing autorisation, pricing & reimbursement)

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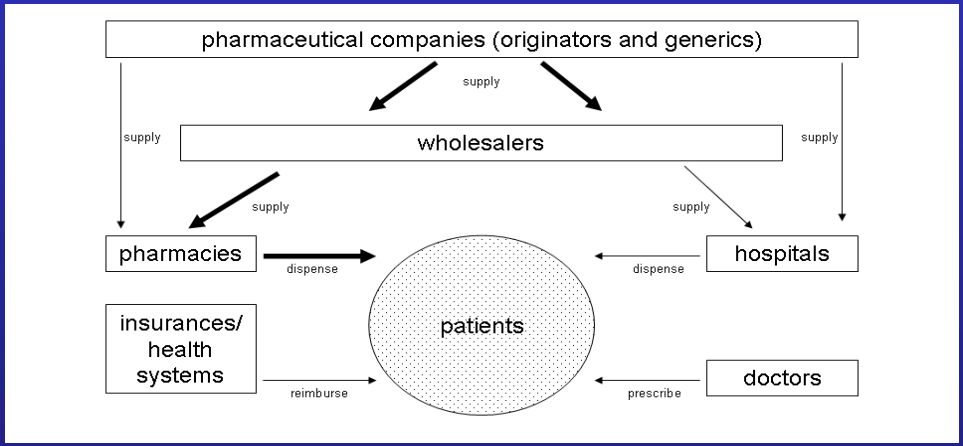
Policy Recommendations

- Competition law enforcement
- Competition advocacy
  - EU patent & judiciary (breakthrough achieved during SE Presidency)
  - Marketing authorisation
  - Pricing & reimbursement
    - VP Tajani announced a review of P&R legislation (Transparency Directive)
    - Improvements in certain Member States, such as Spain

Market Characteristics

- **The Players**
  - Supply side: originators, generics, parallel traders
  - Demand side: wholesalers, pharmacists, doctors, hospitals, health authorities/insurers, patients



- **Cost Structure (annual costs only)**

	Marketing	Manufacturin	R&D	Administratio	Distribution	Other costs
Originators	**21%**	**21%**	**18%**	**7%**	**1%**	**2%**
Generics	**13%**	**51%**	**7%**	**6%**	**3%**	**1%**

Market Specifics

Exclusive rights determine life-cycle of innovative products

- Generating turnover at prices well above marginal costs until loss of exclusivity as incentive/reward for invention in view of high R&D costs
- Patents 20Y (and up to 5Y SPC), functions include:
  - market exclusivity (primary aim), but also
  - tradable asset as production input (licensing, assignment)
  - safeguarding own freedom to operate
  - defensive function (can be a means to preempt rivals' freedom to operate)
- Data exclusivity rules (currently 6 or 10Y depending on MS, 8+2+1Y as of 2013 throughout EU): protection of data that GENs need for abriged MA
- Average effective protection period: 10.5Y in 2000, 14+Y in 2007

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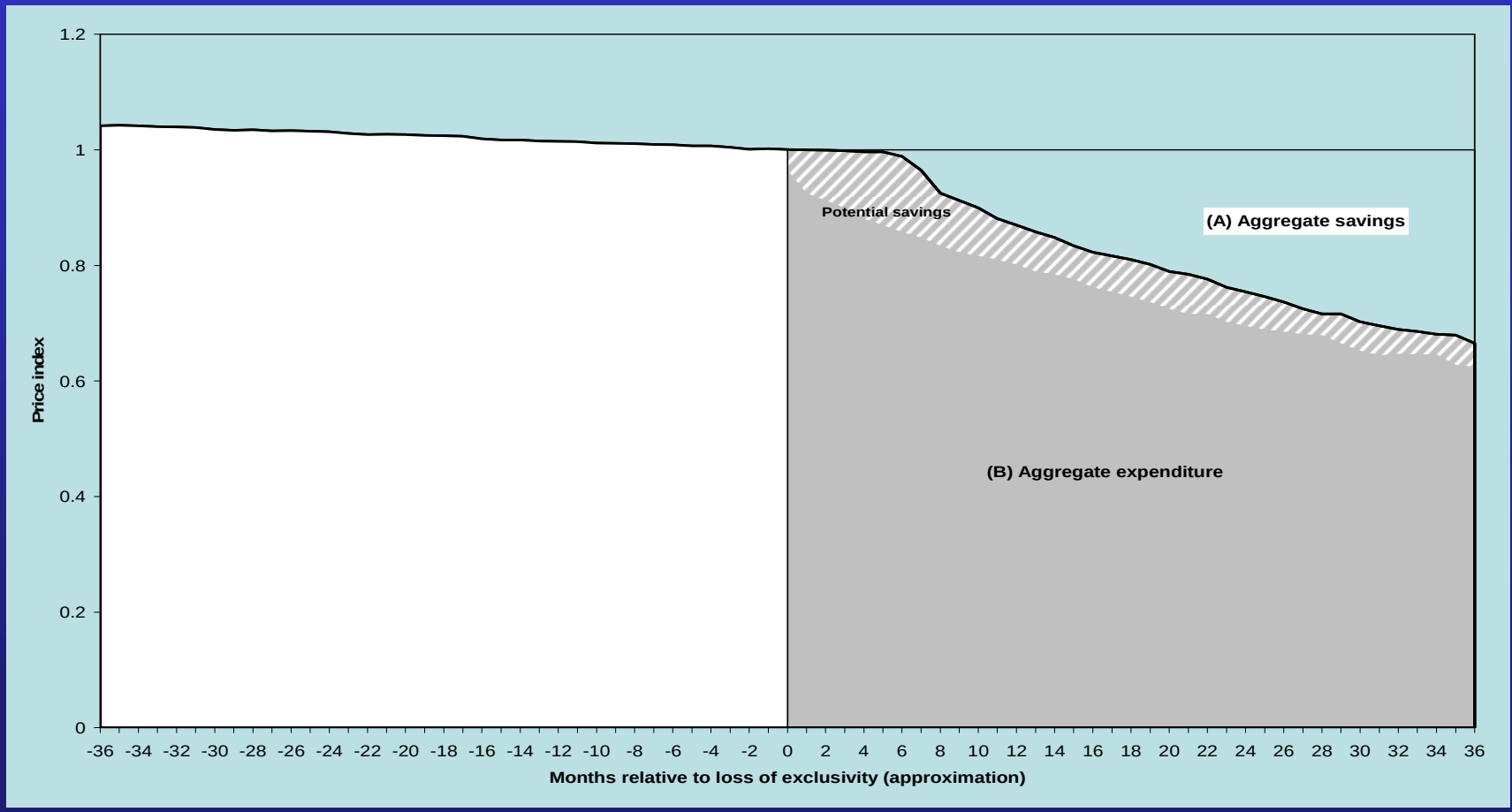
Market Specifics

Generic entry matters: prices, volumes, savings



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Market specifics

Relationship of IPRs and competition law

- A tension? Patent rights & co are exclusionary rights
- Both patent law and competition law have as their objective to increase consumer welfare; in the long term, this is possible mainly by dynamic competition = complementarity
- Yet, no immunity from competition law when the objective is transgressed

Limitations to anti-trust interventions

- Balancing act – anti-trust intervention should take into account impact on incentives to innovate
- No substituting for the patent office
- Exceptional circumstances (e.g. refusal to supply/licence case law)

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Enforcement Activities and Pipeline Cases

Commission

- **AstraZeneca decision** – misuse of regulatory procedures, misrepresentations to patent offices to extend de facto and de iure market exclusivity of omeprazole
- **Servier and Lundbeck cases**– formal openings of Commission proceedings: agreements between an originator company and a number of generic companies possibly delaying generic entry, unilateral conduct by the originator

NCAs

- **Gaviscon** – OFT's SO addressed to Reckitt Benckiser: product switch and delisting of first generation product to prevent generic entry
- **NAPP case** - OFT decision imposing fines for price differentiation between hospitals and retail outlets to capture first prescriptions
- **Schering Plough / Arrow Génériques case** – interim measures granted by FR competition authorities against SP's campaign systematically denigrating Arrow's generic product
- **GSK case Italy** – refusal to grant a licence

Selected practices: focus on patent settlements

- Generally patent settlement are an efficient way of resolving patent disputes (resources, legal certainty for the parties)
- *Inter partes* instead of *erga omnes* effects (i.e. in patent invalidity actions)
- Contractual obligations may span from mere non-assertion, non-challenge to different forms of restrictions on the generic challenger
- Value flows in both directions possible

Patent settlements and the Sector Inquiry

- Accompanied by claims that patent settlements with reverse payments are specific to the US due to the regulatory differences (Hatch-Waxman Act)
- Confirmed existence not only of patent settlements (207) but also of patent settlements with reverse payments
- One of the instruments that can induce generic delays
- Monitoring of patent settlements (1st exercise launched in January 2010, report underway)

Theory of harm for settlements with reverse payments

- Interest of the originator company: to safeguard market exclusivity by removing a challenge to the validity or enforceability of its patent(s) by a specific generic competitor and thus maintain high prices for the product
- Interest of the generic company: to substitute the incertitude of patent litigation with a compensation for the agreement to desist from activities necesary for a possible viable generic entry
- Interest of the consumers: not represented during negotiations, but « paying the bill » as potential of generic entry is removed

Legal framework for patent settlements

- Windsurfing, C-193/83: *"It must be stated that such a [non-challenge] clause clearly does not fall within the specific subject-matter of the patent, which cannot be interpreted as also affording protection against actions brought in order to challenge the patent's validity, in view of the fact that it is in the public interest to eliminate any obstacle to economic activity which may arise where a patent was granted in error."*
- Süllhöfer, C-65/86: *"[i]n its prohibition of certain "agreements" between undertakings, Article 85(1) [now 101(1) TFEU] makes no distinction between agreements whose purpose is to put an end to litigation and those concluded with other aims in mind*."
- BAT, C-35/83 (trade mark law): *"[delimitation] agreements are [not] excluded from the application of Article 85 [now 101 TFEU] of the Treaty if they also have the aim of dividing up the market or restricting competition in other ways. As the court has already stated in its judgment [the Consten and Grundig case], the Community system of competition ' does not allow the improper use of rights under any national trade mark law in order to frustrate the Community' s law on cartels."*

Typology of patent settlements possibly raising concerns

- Settlement merely a pretext for a restrictive agreement, no genuine patent dispute (sham patent)
- Settlement parameters go beyond the exclusionary zone of the patent right (*ratione temporis, materiae*) which is the subject matter of the dispute, and thus of the settlement
- Patent settlements with reverse payments typified by:
  - Non-challenge/non-assertion clause
  - Limitations on generic entry
  - Payment to the generic challenger

Thank you for your attention!

Questions?