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

## Outline

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§ Which was the bigger problem: company practices or regulation?

§ Where do we stand today on the regulatory front?

§ Examples of company practices that may come under antitrust scrutiny going forward

§ Patent settlement agreements

§ Input foreclosure

§ Vexatious patenting

§ Vexatious litigation

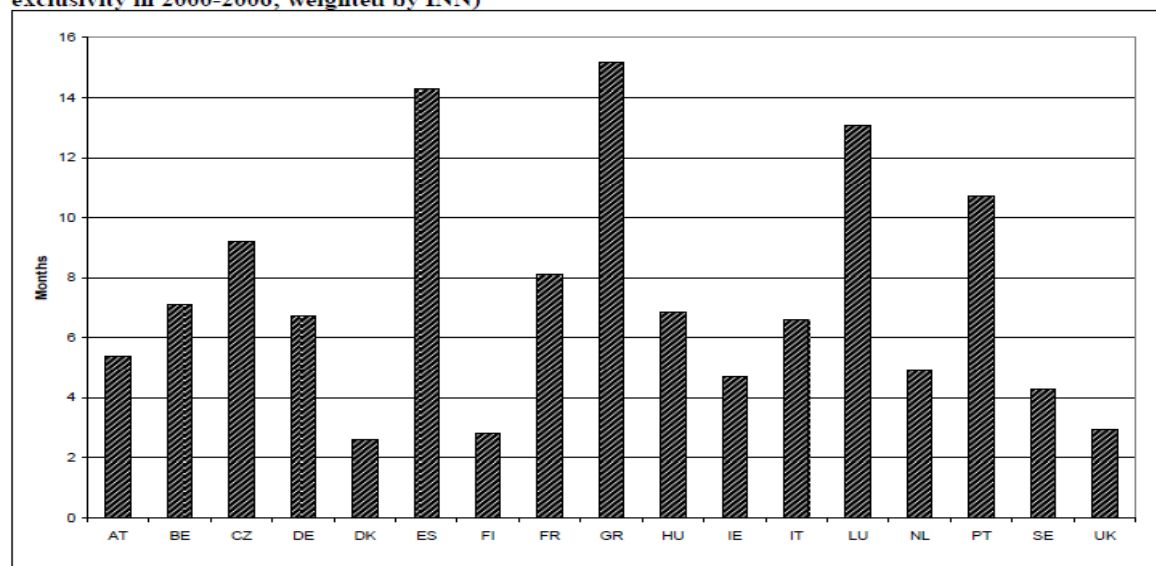
§ Conclusion

Which was the bigger problem:  
company practices or regulation?

## Company practices versus national regulation (1)

- § Sector inquiry focused on company practices
- § But national regulatory frameworks also affect the market
  - § What else can explain the disparities between countries, below?

**Figure 14: Average time to entry following loss of exclusivity, by country (sample: E75 list; loss of exclusivity in 2000-2006; weighted by INN)**



Source: Pharmaceutical Sector Inquiry (partially based on IMS data).

## Company practices versus national regulation (2)

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- § Preliminary report was criticised for having failed to examine regulation as a factor in delaying generic entry and in the fall in new medicines reaching the market
  
- § Final Report went long way to remedying this omission
  - § It concluded that regulation goes to heart of question of why generic entry is delayed, significantly in certain Member States
  - § No explicit conclusions on impact of regulatory factors in relation to decline in new medicines reaching market – though implicit conclusion was again that regulatory factors are at heart of issue

## Statistical analysis in Final Report regarding generic entry (1)

### § Analysis based on:

- § data obtained from companies and from IMS Health
- § selection, in 3 Member States (FR, DE and UK) of 75 top-selling INNs that faced loss of exclusivity between 2000 and 2007

### § Main findings

1. Value of market at time of loss of exclusivity “is important driver of generic entry” (Final Report, ¶ 189)
2. “A number of regulatory variables play an important role” (Final Report, ¶ 190)

### § No parallel analysis of impact of regulation on new medicines reaching the market

## Statistical analysis in Final Report regarding generic entry (2)

- § Some regulatory factors that the Commission examined and found had an effect on generic entry
  - § INN prescription by doctors and mandatory generic substitution by pharmacists
    - § “Having a compulsory substitution policy increases, all other things being equal, share of generic drugs by 12% - 25%” (Final Report, p. 573)
  - § Imposition of mandatory discounts or price caps on generic
    - § “The presence of a price cap policy decreases, all things being equal, the share of generic drugs by about 15%” (Final Report, p. 574)
    - § “in the longer run the price cap becomes a focal point for the generic companies, i.e. the producers align their pricing to this focal point and even though they could potentially undercut this price they stick to it instead” (Final Report, p. 575)

## Where do we stand today?

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- § Regulatory issues are recognised as important for competition in the sector
- § But the Commission does not have the legal power to legislate in a number of relevant areas and in other areas proposals are yet to be adopted
- § Much of the positive impact that the sector inquiry could have by improving the regulatory framework is still awaited
- § Perhaps inquiry could have done more to investigate impact of regulatory framework on number of new medicines reaching the market – could have contributed to an increase in innovation (dynamic competition)



Examples of company practices that may come under antitrust scrutiny going forward

## Patent settlement agreements (1)

- § Sector Inquiry gave only limited indication of which settlement agreements are most likely to attract antitrust scrutiny:
  - § “Settlement agreements that limit generic entry and include a value transfer from an originator company to one or more generic companies are an example of such potentially anticompetitive agreements, in particular where the motive of the agreement is the sharing of profits via payments from originator to generic companies to the detriment of patients and public health budgets” (Final Report, ¶ 1573)
- § Critique
  - § Settling litigation is normally a positive step
  - § Strange that agreements granting license allowing generic to enter market prior to patent expiry are viewed as a potential restriction on generic entry due to fact that generic recognises validity of patent
  - § US concerns about patent settlements do not easily translate to EU given regulatory differences (no Hatch-Waxman)

## Patent settlement agreements (2)

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§ Patent settlements are the one area covered by sector inquiry with broad implications for whole industry

§ Article 101 TFEU applies to all – not just dominant companies

§ Also problem for generic companies entering into settlements

§ How to approach patent settlements today?

§ No guidance in Sector Inquiry as to what is / is not acceptable

§ No mechanism to seek clarity on proposed settlements

§ Guidance unlikely to be provided in monitoring report on patent settlements

§ A case by case analysis has to be undertaken for each settlement

## Input foreclosure (1)

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- § In order to launch a generic product, a generic company needs to have access to the Active Pharmaceutical Ingredient (API) for the medicine
  
- § Generic company can choose either to produce an API itself or to purchase it from third party
  
- § A number of companies specialise in producing APIs which they sell to both originator and generic companies

## Input foreclosure (2)

- § Sector Inquiry looked at whether between 2000 and 2007 generic companies had suffered from any discontinuation of supply by an API producer either
  - § following its acquisition by originator company or
  - § due to agreement (e.g. patent settlement or licence) between originator company and API producer
  
- § Very little evidence in Final Report that either phenomenon occurred during 2000-2007 period
  - § Only 4 originator companies acquired an API producer
  - § Only 2 originator companies concluded settlement agreements which subsequently led an API producer to cease to supply generic companies

## Input foreclosure (3)

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§ Question mark remains over whether such conduct could constitute breach of Article 102 TFEU

§ Final Report notes two decisions of the Italian NCA

§ However, look at paragraph 517 of Sanofi / Zentiva merger decision:

§ “moderate entry barriers for existing API suppliers, the frequent use of dual sourcing for APIs, the current spare capacity in the API-industry and increasing competition from producers in China and India makes any vertical foreclosure strategy unlikely to succeed.”

## Vexatious patenting

§ Sector Inquiry identified defensive patents as one of reasons for decline in number of new medicines reaching market

§ “defensive patenting strategies that mainly focus on excluding competitors without pursuing innovative efforts and/or refusal to grant a license on unused patents will remain under scrutiny in particular in situations where innovation was effectively blocked” (Final Report, ¶1571)

### § Implications

§ Only an issue for dominant companies

§ Minimal guidance given in Final Report – though definition of “defensive patenting” appears quite narrow

§ How big issue is this in reality?

## Vexatious litigation (1)

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### § Sector Inquiry accepts right to litigate:

§ “It should be noted from the outset that enforcing patent rights in court is legitimate and constitutes a fundamental right guaranteed by the European Convention of Human Rights. However, the inquiry's findings show that, like in any other industry, litigation can also be an efficient means of creating obstacles in particular for smaller companies. In certain instances originator companies may consider litigation not so much on its merits, but rather as a signal to deter generic entrants.” (¶¶ 548-549 Final Report)

§ However, no indication as to what these “certain instances” might be

### § Critique

§ Patents have been granted by a patent office, so should be presumed valid

§ Absence of guidance in Final Report is significant problem



## Vexatious litigation (2)

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§ Contrast relevant – and to date only – EU law precedent:

§ ITT Promedia (Case T-111/96) says that litigation may only be abusive in exceptional circumstances, where:

- § “it cannot reasonably be considered as attempt to establish its rights and can therefore only serve to harass opposite party”; and
- § “is conceived in framework of plan whose goal is to eliminate competition”

§ Implications?

- § This is only an issue for dominant companies
- § Given current case law, should there be any change in company practice?

Conclusion

## Conclusions

§ When asked in the early 1970s by Henry Kissinger about the impact of French Revolution, Zhou Enlai, then Premier of China, famously responded “it is too soon to say.”



§ The same can be said about the impact of sector inquiry