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Intellectual Property Law & Policy

Session 7.B
DG Comp Pharma Inquiry: The Implications for Innovation
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Is competition law the wrong prescription for the pharmaceutical sector?

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When can the Commission launch a sector inquiry?

> *"Where…circumstances suggest that competition may be restricted or distorted within the common market, the Commission may conduct its inquiry into a particular sector of the economy…" [Regulation 1/2003, Article 17(1)]*

Why did it launch an inquiry of the pharmaceutical sector? [15 January 2008]

> *"fewer new pharmaceuticals are being brought to market"*
>
> *"the entry of generic pharmaceuticals sometimes seems to be delayed"*
>
> *"Few things make more of a difference [to the lives of individuals] than [pharmaceuticals]"*
>
> *"Medicines cost us all a lot of money – we spent around 200 billion euros each year on pharmaceuticals"*

How did it carry out the inquiry?

> *Unannounced "dawn" raids – "The kind of information the Commission will be examining…may also be easily withheld, concealed or destroyed. That is why we decided that inspections were necessary."*
>
> *Extensive questionnaires (not made public)*

What did the preliminary report say? [28 November 2008, 426 pages]

> *"originator companies have designed and implemented strategies (a 'tool-box' of instruments)…[which] may have the effect of delaying or blocking [generic] entry"*
> - *"filing for up to 1,300 patents EU-wide in relation to a single medicine"*
> - *"engaging in disputes with generic companies leading to nearly 700 cases of reported patent litigation"*

- *"concluding settlement agreements with generic companies"*
- *"intervening in national procedures for the approval of generic companies"*

"generic entry in many instances occurs later than could be expected…the practices under investigation contribute to this"

"savings from generic entry could have been about €3 billion more…if generic entry had taken place without delay" [NB over period 2000-2007]

"originator companies develop and practice defensive patenting strategies primarily in order to block the development of new competing products"

"stakeholders made a significant number of comments on the regulatory framework, highlighting perceived difficulties and shortcomings"
- *"need for a single Community patent"*
- *"creation of a unified and specialized patent judiciary in Europe"*
- *"bottlenecks in the procedures for approval and marketing of medicines (including pricing and reimbursement status)"*

What did the submissions say? [31 January 2009, 70 submissions, 802 pages]

- Generally critical, save for payers and generics

Associations of sickness funds, consumers and related organisations
- 8 submissions, 54 pages
- Generally supportive of Commission
- Emphasis on regulatory improvement

Generic companies and associations of generic companies
- 9 submissions, 168 pages
- Generally supportive of Commission
- Settlement agreements are not problematic
- Emphasis on litigation and regulatory problems

Government bodies
- 3 submissions, 24 pages
- Generally correcting and providing further information
- Mystery of the "toned-down" EPO submission

Individual citizens and academics
- 4 submissions, 25 pages
- All critical (some more than others)

Law firms, economic consultants, patent attorneys and their associations
- 11 submissions, 118 pages
- Generally critical, although one highly supportive

Originator companies and associations of originator companies

- 24 submissions, 369 pages
- All critical (more or less bluntly)
- Some support for regulatory analysis

Other business associations and federations

- 11 submissions, 44 pages
- Generally critical

To what extent can competition law address the issues identified by the Commission?

- Very limited scope
- Most of practices are unilateral acts which do not require dominance, so fall outside competition scrutiny

To what extent should competition law address the issues identified by the Commission?

- Should be very limited scope
- Competition law is supposed to be economic, not moralising
- Could catch some cases on the edges, but that does not resolve sectoral issues
- Solution, if necessary, must be in regulatory improvements