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# Pharmaceutical Sector Inquiry Competition Law Issues

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# What is the Goal of the Inquiry?

*In particular, the inquiry will examine whether agreements between pharmaceutical companies, such as settlements in patent disputes, may infringe the EC Treaty's prohibition on restrictive business practices (Article 81). It will also look into whether companies may have created artificial barriers to entry, whether through the misuse of patent rights, vexatious litigation or other means, and whether such practices may infringe the EC Treaty's ban on abuses of dominant market positions (Article 82). ...The inquiry's findings will allow the Commission or national competition authorities to focus any future action on the most serious competition concerns, and to identify remedies to resolve the specific competition problems in individual cases.*

Press release – 16 January 2008.

# The Sector Inquiry is a Competition Law Exercise

- The legal authority for the Sector Inquiry is Regulation 1/2003 – the framework procedural regulation for application of EC competition law
- The Commission team that has conducted the inquiry is drawn from DG Competition
- The primary goal of the exercise is to provide a basis for action under competition rules
- The preliminary report should be read in the context of broader competition law developments under Article 82

## **Article 82 Guidance (Commission Communication 3/12/2008)**

**“The emphasis of the Commission’s enforcement activities is on . . . ensuring that undertakings that hold a dominant position do not exclude their rivals by other means than competing on the merits of the quality of products or services that they provide” (para. 6)**

**“The aim of the Commission’s competition policy in relation to exclusionary conduct is to ensure that dominant undertakings do not impede effective competition by foreclosing rivals in an anticompetitive way.” (para. 19)**

**“The Commission will normally intervene under Article 82 where, on the basis of cogent and convincing evidence, the allegedly abusive conduct is likely to lead to competitive foreclosure” (para. 20).**

# The “More Economic Approach” and the Pharmaceuticals Inquiry

- Abuse cases should be based on cogent and convincing evidence of likely competitive foreclosure
- Anticompetitive effects tolerated where
  - result of competition on the merits of the quality of products
  - “Objective justification” for conduct exists (e.g., health or safety)
- Lack of tolerance for technical or legalistic limits on Article 82 powers
- The purpose of the Preliminary Report is to gather “cogent and convincing evidence” that practices by dominant pharmaceutical companies “foreclose rivals in an anticompetitive way”

# The “Traditional” IP-Competition Law Interface

- The *existence* of IP rights is *normally* not affected by competition rules
  - This means that “the essential function of the right” should not normally be curtailed
- The *exercise* of IP rights can be abusive (or restrictive for purposes of Article 81)
  - *e.g.*, charging excessive prices for patented products, blocking parallel trade
- The essential function of the right may be curtailed only under “exceptional circumstances”
  - *e.g.*, refusal to license essential IP to protect dominant position in downstream market (*Magill, IMS, Microsoft*)

# The Traditional Approach offers Limited Scope for Intervention on the Issues Identified on the Report

- Infringement litigation is abusive only where “objectively baseless”
- Settlement of *bona fide* litigation traditionally viewed as non-restrictive
  - Not clear how payment could alter this classification
- Filing of patents (whether as part of “patent thicket” or “patent fence”) – equates to existence of right
  - assuming *good faith* basis for validity
- Article 82 tools limited to:
  - *Ex post* findings of bad faith filings/law suits
  - Mandatory license of blocking patents (if *IMS* criteria satisfied)

# Can the Article 82 Envelope be Stretched to Reach the “Problems” Identified in the Preliminary Report?

- Expansive interpretation of “exceptional circumstances”?
  - CFI judgement in *Microsoft* can be interpreted to support broader scope for exceptional circumstances exception
    - would apply to any conduct that limits development of products that differ “with respect to parameters which consumers consider important” (para, 656).
  - Closer reading of judgment may not support this interpretation
  - This approach would also not support Commission where relevant difference of rival product is limited to price



# Can the Article 82 Envelope be Stretched to Reach the “Problems” Identified in the Preliminary Report?

- Examine the “essential function of the right” on a patent-specific basis?
  - Note this observation in the Preliminary Report  
“Adequate and efficient patent protection is an essential prerequisite for future innovation. It allows companies to recoup investment costs and yield an adequate profit for the risks associated with the innovative process.” (para. 4).
  - It may be argued that the “essential function” of the patent right is to allow the patentee an adequate profit where it has made significant investments in a particular innovative technology
  - This would mean that
    - where the patentee has not invested heavily in the protected technology *or*
    - where the protected technology does not reflect the innovative efforts of the patentee *or*
    - where the technology is not innovative at allthe filing of the patent or the enforcement of the patent is not protected as part of the essential function of the right

# Problems with Stretching the “Essential function” concept

- From legal perspective, this reading of “essential function” can find some support in ECJ precedents on other forms of IP (eg *Hag II* on trademarks)
  - but is inconsistent with previous cases on patents and copyright (including *Magill* and *Microsoft*)
- From policy perspective, issue whether function of encouraging investment and allowing return should be dealt with at level of “IP system” or of individual IP rights
- From practical perspective real question as to whether Commission or other enforcement authorities can efficiently assess whether IP rights reflect investment and innovation in a specific case