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Settlements and Anti-Competitive Behaviour: the Sector Inquiry One Year On

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Sector Inquiry Report, July 2009

- **"The Commission will apply increased scrutiny under EC antitrust law … First enforcement action is already underway"**

- **Main antitrust issues**
  - settlement agreements
  - unilateral strategies for delaying generic entry (the "toolkit")
    - patent thickets and lifecycle management
    - vexatious litigation
    - intervention in national procedures
    - negative marketing
  - defensive patent strategies (blocking patents)

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Since then …

- Servier investigation opened, July ‘09
- Further Lundbeck raids, Dec ‘09
- 1st round of settlement monitoring, Jan/July ’10
- AstraZeneca/Nycomed raids, Dec ‘10
- 2nd round of settlement monitoring, Jan ‘11

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Settlement Agreements

Sector Inquiry Report

- **Focus on 'reverse payment' settlements**
  - value transfer from originator to generic
  - delayed/restricted generic entry
- **Inspired by FTC enforcement in US**

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FTC position

- ***Schering-Plough* (2001 – 2006)**
  - "[If] the patent holder makes a substantial payment to the challenger as part of the deal, absent proof of other offsetting considerations, it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable compromise"

- **<u>Presumption</u> of illegality if**
  - substantial reverse payment
  - generic entry not immediate, and
  - no proven rationale for the payment other than delayed generic entry

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Actual US Law

- **Courts consistently reject FTC approach**
  - *Schering-Plough v. FTC* (11th Cir)
  - *In re Tamoxifen* (2nd Cir)
  - *In re Ciprofloxacin* (Fed. Cir.)
- **Settlements presumed lawful if**
  - generic entry not restricted outside patent term/scope
  - no evidence of sham litigation or fraud

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An EU law presumption?

- **Sector Inquiry Final Report, July '09**
  - "any assessment of whether a certain settlement could be *deemed* compatible or incompatible with EC competition law would require an in-depth analysis"
- **Dominik Schichels, Nov '09**
  - Commission "will not take the view *per se* that patent settlements are probably illegal"

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An EU law presumption? (II)

- **1st Monitoring Report, July '10**
  - categorization of patent settlements based on "two main criteria"
    - "limitation on the generic company's ability to market its own medicine"
    - "value transfer" from originator to generic
- **Dominik Schichels, Oct '10**
  - "we do not like to see a value transfer, as without it, the companies would likely have found a different date"

US Developments

- **FTC continues to pursue presumption of illegality - without success (so far)**
  - *FTC v. Watson* (Androgel) – dismissed
  - *FTC v. Cephalon* (Provigil) – ongoing because of allegations of restrictions outside patent scope

- ***In re Ciprofloxacin* (2nd Cir.) (*Arkansas Farmers*)**
  - CoA panel upheld *In re Tamoxifen* precedent but recommended *en banc* rehearing
  - CoA *en banc* again upheld precedent
  - Supreme Court appeal sought (outstanding)

1st Monitoring Report

- **Additional categories of suspect settlements**
  - settlements that contain "restrictions beyond the exclusionary zone of the patent" (time, geography, claim)
  - settlements where "patent holder knows [patent] does not meet patentability criteria"

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1st Monitoring Report (II)

- **Limitations on generic entry**
  - no-challenge agreements
  - non-compete agreements
  - licenses
- **Value transfers**
  - direct monetary transfer
  - side-deals
  - licenses

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Other Antitrust Issues

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AstraZeneca, 1 July 2010

- **Commission Decision** (June '05) **was 1st abuse of dominance case in pharma sector**
- **Addressed questions central to non-settlement issues in Sector Inquiry**
  - market definition and dominance in the pharma sector
  - key and novel theories of abuse
    - unlawfully obtaining IP rights (1st abuse)
    - misuse of IP rights/processes (2nd abuse)
- **General Court upheld and <u>extended</u> Commission Decision**

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Dominance

- **GC upholds separate PPI market (ATC 4)**
  - focus on actual prescribing practice rather than ATC classifications
  - no special treatment in light of extensive regulation
  - in fact healthcare systems reduce price competition and promote narrow markets
- **Dominance**
  - no special treatment for innovation markets
  - healthcare systems also promote dominance
- **Trend to 'molecule' markets and routine dominance?**

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1st Abuse: General Court

- **"Intentionally misleading" SPC applications**
  - information re date of 1st marketing authorization incorrect/incomplete
- **As a result of which**
  - AZ wrongly granted patent right extensions
  - market entry of generic PPIs delayed
  - AZ's dominance in PPIs prolonged
- **AZ also subsequent sought to enforce SPC rights in national courts**

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1st Abuse: General Court

- **Intention to mislead not necessary**
  - misleading nature of representations "must be assessed on the basis of objective factors"
  - AZ "could not reasonably be unaware" that submissions misleading
  - "intention nonetheless constitutes a relevant factor"

- **'Special responsibility' of dominant companies**
  - to avoid misleading authorities
  - to clarify ambiguity, and
  - to seek to correct errors

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Duty to clarify ambiguity

- **AZ argued**
  - underlying legislation ambiguous
  - submissions consistent with its interpretation
  - had obtained two supporting legal opinions

- **General Court found AZ had "refrained from disclosing"**
  - its interpretation of the legislation, and
  - the facts relevant if its interpretation was wrong

- **"Manifest lack of transparency"**

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Duty to correct errors

- **If a dominant undertaking "is granted an unlawful exclusive right as a result of an effort by it in a communication with public authorities**

- **Then it is required "at the very least, to inform the public authorities of this so as to enable them to rectify those errors"**

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Some questions

- **Does this apply to all IP applications?**
  - some authorities have duty to assess applications
- **How does this apply if the IP right creates a dominant position for the first time?**
  - cf *Rambus*
  - **nb** duty to correct errors
- **When does the duty to clarify arise?**
  - any ambiguity?

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Abusive litigation

- **GC upholds finding that litigating SPCs formed part of the 1st abuse**
- **AZ defended the SPCs granted to it in court**
  - made misleading submissions to the courts
  - pursued facts and arguments on which "it could not reasonably rely"
- **Cf *ITT Promedia***
  - litigation abusive if (i) manifestly unfounded and (ii) part of a plan to eliminate competition
  - note that AZ was a defendant in relevant litigation

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2nd Abuse: Commission Decision

- **AZ launches new formulation of Losec**
  - tablet rather than capsule
- **Deregisters capsule MAs**
  - in certain selected countries only
  - offers no objective justification (e.g. public health)
- **Entry by generics and parallel imports hampered (in affected states) as a result**

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2nd Abuse: General Court

- **AZ argued there was no abuse as**
  - legally entitled to withdraw MAs
  - no obligation to assist competitors by maintaining them
  - withdrawal objectively justified

- **General Court found**
  - existence of abuse unrelated to legality of action under other legal rules
  - purpose was “solely” to exclude competitors
  - no basis for withdrawal in competition on the merits
  - no objective justification

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No objective justification

- **AZ argued**
  - withdrawal of MAs objectively justified to avoid pharmacovigilance reporting obligations
- **General Court found**
  - AZ had not raised this argument before Commission
  - it was not credible as it was not mentioned in internal AZ documents
  - in any event, the obligations did not represent a sufficient burden to justify withdrawal

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2nd Abuse: Comments

- **Must the 'sole purpose' be to exclude competition?**
  - burden effectively shifted to AZ
  - GC questions sufficiency of objective justification
  - Commission refers to 'predominant purpose' in context of defensive patents
- **Importance of internal documents**
  - issues of purpose and intention often turn on internal documentation

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Closing Thoughts

- Enforcement focus remains settlements (for now)
- Legal analysis in settlement cases remains unclear
- First signs of enforcement on other issues potentially emerging
- AZ potentially significantly lightens the Commission's burden in bringing non-settlement cases

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Thank you!

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