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The EU Sector Inquiry: Implications for Patent Litigation and Settlements

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Issues from the Preliminary Report

- **Market definition**
- **Vexatious litigation**
- **Settlement agreements**

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Market definition

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The traditional approach

- **ATC Level 3**
  - *Astra/Zeneca* (1999)
  - *Pfizer/Pharmacia* (2003)

- **Narrower market definitions possible**
  - *AstraZeneca – Losec* (2005)
  - but only after a detailed analysis

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A trend to 'molecule' markets?

- **Preliminary Report finds**
  - generic entry leads to an average 20% to 25% price drop, and
  - sales volumes increase
- **Recent merger cases assess competition at the 'molecule' level**
  - *Teva/Barr* (Dec 2008)
  - *Sanofi-Avetis/Zentiva* (Jan 2009)

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Vexatious Litigation

ITT Promedia

- **Litigation may be an abuse of dominance**
  - if it is "manifestly unfounded" (i.e. cannot reasonably be considered an attempt to establish the rights of the undertaking);
  - and forms part of a plan to eliminate competition.
- **A high standard**

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Will there be cases?

- **Preliminary Report**
  - "Our strategy is clear. We want to send a signal (by applying for interim injunctions **well knowing that we will not be granted a ban**) that we do not accept early [generic] entry"

- ***Servier v. Apotex*** (UK CoA, 2007)
  - Servier's patent a "**try-on**", not only invalid but "**very plainly so**"
  - "**the sort of patent which can give the patent system a bad name**"

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Settlement Agreements

The Preliminary Report

- **Does not aim to provide legal guidance, but ...**

- **"[A]s is shown by the enforcement action of the USA competition authorities, in particular the [FTC], it might also be argued that settlements contain arrangements that could fall within the scope of competition rules."**

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The original FTC position

- ***Schering-Plough*** **(2001 – 2006)**
  - "[If] the patent holder makes a substantial payment to the challenger as part of the [settlement] 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"

- **So, a settlement agreement is unlawful if:**
  - it involves a substantial 'reverse payment'
  - generic entry is delayed, and
  - there is no proof of any motive for the payment other than delayed generic entry

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The DoJ position

- **Strongly rejects the original FTC approach**
- **Amicus Curiae brief in *Schering-Plough***
  - "the public policy favoring settlements, and the statutory right of patentees to exclude competition within the scope of their patents, would potentially be frustrated by a rule of law that subjected patent settlements involving reverse payment to automatic or near-automatic invalidation."
  - "an appropriate legal standard should take into account the relative likelihood of success of the parties' claims, viewed ex ante."

The US Courts

- **Consistently rejected original FTC line**
  - *Schering-Plough v. FTC* (11th Cir)
  - *In re Tamoxifen* (2nd Cir)
  - *In re Ciprofloxacin* (Fed. Cir.)
- **Much less interventionist approach**
  - settlement agreements which do not delay generic entry beyond the term (or scope) of patent exclusivity do not infringe antitrust law (absent sham litigation or fraud)

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Rationale(s) of the US Courts

- Public interest in settlements
- FTC's counterfactual "untenable"
- Difficulties in attributing payments
- Legal presumption of patent validity
- Limited anti-competitive effect

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The apparent exception

- ***In re Cardizem*** (6th Cir)
  - reverse payment settlement found *per se* unlawful
  - but
    - settlement covered non-infringing products, and
    - prevented third party generic companies from launching generic products
- **Distinguished in *In re Ciprofloxacin* (and in *In re Cardizem* itself)**

The new FTC approach(es)

- ***FTC v. Cephalon* (2008)**
  - does not follow *Schering-Plough* analysis
  - originator accused of "monopolization"
    - as a result of a "course of conduct" including four reverse payment settlements
  - generic companies not pursued (so far)

- ***FTC v. Watson et al.* (2009)**
  - originator and generics pursued
  - accused of monopolization and anti-competitive agreements
  - details of FTC case not yet clear

Comments on Settlement Issues

- **Settlements potentially 'low hanging fruit'**
  - could be pursued under Article 81 (*cf* FTC in *Schering-Plough* and *Watson*)
  - no need to establish dominance

- **<u>But</u>**
  - criticisms of FTC position in *Schering-Plough* seem compelling
  - the analysis of the US Courts should be preferred

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Conclusions

- **Market definition**
  - narrower markets would increase risk for patent holders
  - but likely to be resistance
- **Vexatious litigation**
  - probably business as usual (avoid shams)
- **Settlement agreements**
  - tempting cases for the Commission to pursue
  - so keep restrictions within patent scope and duration
  - and be wary of reverse payments (for now)