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Patent Settlement Agreements

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The Issues

- **Pay for delay/reverse payment settlements**
- **Sham settlements**
  - exceed patent scope
  - based on facially invalid patents
  - involve fraudulently obtained patents

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Reverse Payments

- **US Appeal Court split has emerged**
  - long running FTC campaign
  - US Appeal Courts consistently reject FTC position
  - until July 2012 3rd Circuit upholds FTC position

- **EU enforcement moving forward**
  - SOs issued in *Servier* and *Lundbeck* cases, July 2012
  - annual patent monitoring reports continue
  - UK investigation ongoing (*GSK/Generics UK*)

US Developments

The FTC's concern

"As a matter of economics, it will generally be most profitable if the brand and the generic firm avoid the possibility of competition and share the resulting monopoly profits"

Michael Kades, FTC

"it is one thing to take advantage of a monopoly that naturally arises from a patent, but another thing altogether to bolster the patent's effectiveness in inhibiting competitors by paying the only potential competitor $40 million per year to stay out of the market."

In re Cardizem (6th Cir)

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The FTC test

- "[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"

  Schering-Plough (FTC, 2003)

The FTC test

- **Settlement <u>presumed</u> unlawful if**
  - there is a substantial reverse payment
  - generic entry is not immediate, and
  - no proven motive for the payment other than delayed generic entry

US Courts to July 2012

- **Consistently reject FTC approach**
  - *Schering-Plough v FTC* (11th Cir. 2003)
  - *In re Ciprofloxacin* (Fed. Cir. 2008)
  - *Arkansas Carpenters* (2nd Cir. 2010. *cert. denied*)
  - *FTC v Watson* (11th Cir. 2012)
- **Settlements lawful within patent scope**
- **Antitrust issues may arise if**
  - entry delayed beyond patent scope (*In re Cardizem*)
  - sham litigation or fraudulent patent
  - entry delayed without settlement (*Andrx Pharms*)

Reasoning

- *Prima facie* valid patent gives right to exclude
- Settlements are in the public interest
- No settlement may have been possible absent reverse payment
- 'You can't pay them all off' (no a/c effect)
- Value transfers difficult to identify
- Antitrust trial not the appropriate forum for assessing patent validity

In re K-Dur (3rd Cir. 2012)

- **Court adopts FTC presumption of illegality for reverse payment settlements**
- **Facts identical to *Schering-Plough* (11th Cir. 2003)**
- **Reasoning**
  - 'scope of patent' test
    - leads to "effectively conclusive" presumption of legality
    - not appropriate in non-infringement litigation
    - inconsistent with Hatch-Waxman Act
    - 73% of generic challenges under H-W successful
    - patents limited exception to general rule
    - other settlement options available

EU Developments

EU Sector Inquiry Report (2009)

- **"as 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"**

Subsequent Action

- **Annual Settlement Monitoring Reports, July 2010, 2011 and 2012**

- **Statements of Objection issued in July 2012**
  - *Servier* (perindopril)
  - *Lundbeck* (citalopram)

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A Presumption of Illegality?

- **It really matters**
  - reverse payments difficult to justify vs presumption
  - cases difficult to make without a presumption
- **EU law supportive**
  - no presumption of legality for settlements (*Bayer v Sülhöfer*)
  - readiness to second guess IP litigation (*Toltecs-Dorcet*)
  - deferential attitude of EU courts
- **<u>But</u> some cases will remain easy either way**
  - generic entry restricted outside patent scope
  - shams and fraud

3rd EU Monitoring Report

- **Two main criteria for classifying settlements**
  - limitation on the generic company's ability to market its own medicine
  - a value transfer from the originator to the generic company
- **Limitation broadly defined**
  - includes: no challenge clauses, non-compete clauses, royalty bearing licenses and distribution agreements
- **Value transfer broadly defined**
  - cash, distribution agreements, “side deals”

The Good News

- **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 Schnichels, Nov '09**
  - Commission "will not take the view *per se* that patent settlements are probably illegal"

The Bad News

- **Dominik Schnichels, Oct '10**
  - "we do not like to see a value transfer, as without it, the companies would likely have found a different date"
- **Commissioner Almunia, Oct '11**
  - "Paying a competitor to stay out of the market is a restriction of competition that the Commission will not tolerate"
- **Commission refuses to publicly state analysis adopted in *Servier* and *Lundbeck* SOs**

The cases

- ***Servier* (perindopril)**
  - UK court "the sort of patent which can give the patent system a bad name" and "very plainly" invalid
- ***Lundbeck* (citalopram)**
  - gap between initial patent expiry and follow-on patent
- ***Boehringer***
  - not a reverse payment case (blocking patent seemingly obtained by misrepresentation)
  - but Commission case closure w/o fine following a settlement

Final remarks

- **Settlements may raise issues if**
  - generic entry not immediate and value transfer made to generic, or
  - based on sham patent or litigation, or
  - exceed patent scope (time, product, geography)

- **High risk in settlement context**
  - limits on generic entry outside the patent's scope
  - internal documents questioning patent validity
  - cash payments to generic
  - side deals with no commercial rationale

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Thank you for listening

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