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Reverse Payment Patent Settlements in Europe

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What's the issue?

Consider the following 3 hypothetical situations:

1. Company A pays Company B $30m not to sell satnavs in the UK = market allocation = hardcore restriction = cartel

2. Company A holds a patent over satnav technology and obtains an injunction against Company B to stop it from selling a satnav using the patented technology in the UK. It also receives damages of $30m for the loss arising from the amount of sales that have occurred = legal enforcement of a legal monopoly right

3. After raising court proceedings Company A settles with Company B. Company B concedes that his product breaches the Company A patent and agrees not to launch it in the UK. In addition Company A pays $50m to achieve a settlement = cartel as in 1? or enforcement of a legal monopoly as in 2?

Does it depend…

- On the strength of the patent? If so, how is this determined?
- On the remaining term of the patent?
- Whether there are other competitors on the market?
- Whether there are other restrictions?
- Does it make a difference whether Company A pays $30m to Company B or if Company B pays $30m to Company A?

The story for far…

- Sector Inquiry – 2008/9
- Perindopril (Servier) – 2009
  Decision 2014 – On appeal
- Citalopram (Lundbeck) – 2010
  Decision 2013 – On appeal
- Modafinil (Cephalon) – 2011
- Fentanyl (J&J) 2011
  Decision 2013 – No appeal
- Boeringer – 2011 – Case closed on Settlement
- National Proceedings

Sector Inquiry

Restrictions on generic entry

- No-challenge clauses
- Non-compete clause
- Licenses to the generic company
- Distribution or API supply deals

Value transfers from originator to generic company

- Lump sum payment
- Unrelated benefits such as early entry elsewhere or with another product

Led to an annual monitoring exercise of patent settlement agreements

- Category A: no restrictions on generic entry
- Category B.I: restriction on generic entry but no value transfer
- Category B.II: restriction on generic entry and value transfer

- Fifth monitoring report published 5 December 2014

Perindopril (Servier)

- Investigation opened in 2009
- Commission Decision issued in 2014 – fines of €427.7 million
- Article 102 (abuse of dominance) and Article 101 (restrictive agreements):
  - Commission alleges a comprehensive originator strategy to prevent market entry via patent and other acquisitions and settlements
  - Reverse payment settlements with a number of generics
  - Included no-challenge and non-compete provisions
  - Held to be a 'by object' restrictions

Questions

- Are the agreements 'by object' infringements? – cf *Cartes Bancaires*
- How much of a 'pattern' is needed to cross the Article 102 threshold?
- Should both Article 101 and Article 102 apply to same facts?
- What is the role of the strength of the patent?

Appeals Pending

Citalopram (Lundbeck)

- Investigation opened in 2010
- Commission Decision issued in 2013 – fines of €146 million
- Article 101 (restrictive agreements) infringements
  - Commission found substantial value transfers involving (i) lump sums (ii) purchase of stock for destruction (iii) offer of guaranteed profits through distribution system
  - Agreements concluded after certain patents had expired

- Main Factors taken into account in the Commission Decision
  - Lundbeck and generics were potential competitors
  - Generics agreed to limit independent efforts to enter
  - Value transfer substantially reduced generics' incentives to enter

Questions:

- When is a value transfer 'substantial'?
- When does a unilateral action become Article 101 infringement?
- How much patent protection is needed?
- To what extent do the means of exclusion matter?

Appeals pending

Modafinil (Cephalon)

- Investigation opened in 2011
- Settlement of parallel patent disputes in the UK and the US part of the agreement was not to sell modafinil in the EEA for a certain period and certain side agreements
- FTC challenged the settlement in the US
- Press release does not contain much information on the type of settlement: B.I or B.II

Case ongoing

Fentanyl (J&J)

- Investigation opened in 2011
- Commission Decision issued in 2013 – fines of €16million

- Article 101 (restrictive agreements) infringement
  - Not a settlement case: No patent and no regulatory reasons preventing a generic fentanyl entering the market
  - Co-promotion agreement between originator and the generic company which involved monthly payments to the generic company for as long as no generic product was launched in the market
  - Payment exceeded profits generic could make from own product
  - Very little if any co-promotion activities took place

Questions

- What are the monthly payments for?
- What would the position be absent the monthly payments?
- Do you need to have a potentially competing product?
- If so, how close to entry do you need to be?

No appeals

Boehringer

- Ongoing patent dispute about the breadth of patent applications leading to an alleged ‘blocking’ position:
- In addition to EPO and court action the generic company complained to the Commission. The European Commission opened investigation in 2007.
- Commission suggested that the parties reach a settlement that allowed the generic access to the market – “most efficient and speedy way” to ensure consumers could benefit from product.
- Resulted in the removal of the alleged blocking position and a license for two non-EU countries.

What next for Europe?

- European Commission Decisions appear influenced by FTC approach despite different regulatory regime (no Hatch-Waxman)
- Further infringement findings may follow
- Appeals to the General Court pending for Perindopril and Lundbeck cases.
- Possible progression to CJEU
- Creates high level of uncertainty until the final outcome of the issues
- Read across to other IP-intensive industries?
  - There is no Hatch-Waxman equivalent in Europe that makes the analysis pharma-specific

Competition Law v IP rights

- Some possible unintended consequences
  - Wide definition of ‘value transfer’ brings agreements otherwise covered by the VBE into the hardcore object restriction remit
  - Effect on other industries:
    - Nothing pharma-specific about the analysis
  - Effect on other types of arrangements
    - e.g. co-existence agreements for trade marks
  - Effect on litigation more generally:
    - UK Civil Procedure Rules require parties to consider alternatives to litigation
    - Aim to avoid litigation and settle before proceedings
    - Mediation attempts to obtain ‘win-win’ position
    - This may require both sides to get something.

Dealing with uncertainty

Category A Settlements: Generally unproblematic

- no restriction on generic entry
- no value transfers

Category B.I problematic only in exception circumstances

- Restrictions on entry but no value transfer
- PLUS proceedings/patent = sham
- OR restrictions beyond the patent scope

Category B.II problematic

- Restrictions on generic entry
- PLUS significant value transfer

When do I need to be careful?

Restrictions

- Exclusive purchase obligations
- Non-termination provisions
- Non challenge obligations
- Unilateral options for the IP rights holder
- Restrictions beyond patent scope
- Restrictions on quantities supplied
- Taking a licence or co-promoting instead of making own product (de facto restrictions)
- Co-existence agreements in different geographies (e.g. we respect the patent in Poland, German and Czech Republic but you won't enforce it against us in the UK, France and Spain).

Value Transfers

- Supply agreement (API or finished product)
- Initial lump sums
- Recurring monthly/quarterly payments
- Payments dependent on absence or maximum level of generic entry

John Schmidt

John is dual qualified in the UK and Germany. He has experience in dealing with competition authorities at both national and EU level and advising in major UK and EU competition investigations and antitrust litigation.

John has consistently been ranked as a leading competition law expert by Chambers UK and Legal 500 over the past ten years and in 2014 the team won the coveted The Lawyer Competition Team of the Year award.

Competition Team of Year 2014

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