Max Planck Institute
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Are Patent Settlements Anti-Competitive?

The EU Perspective

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Introduction: What makes the EU situation different?

Uniform EU competition law and mostly centralized patent grant (EPO), but:

- **National law applies to**
  - (1) **substantive patent infringement**
  - (2) **procedures** regarding patent infringement
    - ➔ with bifurcation in Germany and Austria
  - (3) national **concept of a settlement agreement**
- **No patent linkage – no data exclusivity for first generics application**

  What are the **incentives for pay-for-delay settlements?**

  But: **National law** decides on whether an **application for marketing allowance** justifies **injunctive relief** in favour of the patent owner

Overview

- Development of the debate in the EU
- European Cases
- Economic incentives for pay-for-delay settlements
- European case-law so far
- Legal assessment of pay-for-delay settlements
- Conclusion

Development of the debate in the EU (1)

- **EU Pharma Sector Inquiry** (Report of 2 July 2009)
- **Commission investigations**
  - (1) ***Perindopril (Servier)*** – opened 2 July 2009; SoO 30 July 2012
  - (2) ***Lundbeck*** – opened 7 Jan 2010; SoO 25 July 2012; **decision 19 June 2013**
  - (3) ***Cephalon*** – opened 19 April 2011
  - (4) ***Fentanyl*** – opened 18 Dec 2011; SoO 31 Jan 2013
- **Review of Commission's Technology Transfer BER (2014)**
- **National developments (United Kingdom)**
  - **(1) Damage action:** ***Secr'y of State for Health v Servier*** (stayed Oct 2012)
  - (2) **OFT:** ***GSK (Seroxat)*** – SoO 24 Oct 2013

Development of the debate in the EU (2)

EU Pharma Sector Inquiry (Report of 2 July 2009)

Results: 2000-07: 700 cases of litigations

149 final decisions (patent owners lose in 62%)

207 settlements

47 cases of reverse payments (total of € 200 mio.) or other value transfer

+ some other cases of value transfer

3 Monitoring Reports: What do the numbers tell us?

➔ 2008/09: **9**/93 cases; 2010: **3**/89 cases; 2011: **13**/120 cases

Commission: Continued need for monitoring

Development of the debate in the EU (3)

EU Pharma Sector Inquiry (Report of 2 July 2009)

Do such agreements restrict competition?

Report, para 1573:

"Agreements that are designed to keep competitors out of the market **may also run afoul of EC competition law**. Settlement agreements that **limit generic entry and include a value transfer** from an originator company to one or more generic companies are an example of such **potentially anticompetitive agreements**, in particular where the **motive** of the agreement is the **sharing of profits via payments from originator to generic companies to the detriment of patients and public budgets**."

European cases (1)

The *Lundbeck* case:

Facts: Lundbeck produces **blockbuster anti-depressant** (citalopram) as its best-selling product; **product patent** had **expired**; but Lundbeck still held **process patents**. Agreement with **four generics producers** (2002); Lundbeck made substantial payments to the generics companies amounting to "tens of millions of euros"

Anti-competitive conduct: (1) **substantial payments**; (2) **purchase of generics** for the **purpose of destroying them**; (3) offer of guaranteed profits in a **distribution agreement**

Anti-competitive effect: **Exclusion of generics** from the market **without guarantee that they would enter the market in the future**

Fine: **€ 93.8 million** on **Lundbeck**; total of **€ 52.2 million** on **generic producers**

Lundbeck's action for annulment (T-472/13): **bona fide patent infringement settlement; patents are valid and infringed**

European cases (2)

The *Perindopril (Servier)* case:

Facts: Servier was **dominant** with a **cardio-vascular medicine** (perindopril); patent was **about to expire** in 2003; Servier applied for a **second-generation patent**; Servier sued generics producers for infringement and then entered into settlement agreements; payments of up to **GBP 10 million to generics companies for not entering the UK market**; **generics entered the market only in 2007** after the patent had been annulled in the UK (but it had previously been upheld by EPO Opposition Division)

Alleged anti-competitive conduct: (1) **acquisition of scarce technology** for the production of perindopril; (2) entering into **settlement agreements** with generics companies

Alleged anti-competitive effect: **Exclusion of generics** from the market

UK government's action: **GBP 220 million damage claim** because of excessive prices paid by the **National Health Service;** claim based on **Art. 102 TFEU** alleging that Servier had applied for the patent by providing misleading information to the EPO, and **Art. 101 TFEU**

European cases (3)

The *Cephalone* case:

Facts: Cephalon from the US sells **drug against sleeping disorders** (modafinil) under the Provigil brand. In 2005, Cephalon settles patent **infringement proceedings** in the **US** and the **UK** against **Teva** from Israel. Teva promises **not to sell in the EEA before October 2012**, which is **prior to the patent expiry.** Settlement includes side deals that seem to lead to a **value transfer to Teva**

The Cephalone/Teva case: In 2011, Teva seeks to acquire Cephalon. In October 2011, the Commission allows the merger under the **condition** that **Cephalon sells its own generic version of modafinil**

European cases (4)

The *Fentanyl* case:

Facts: **Johnson and Johnson** sells fentanyl, a most powerful **pain killer**. J&J's closest generic competitor is Sandoz, a subsidiary of **Novartis**. The **patent expired in 2005.** J&J's Dutch subsidiary and Novartis enter into a **"co-promotion agreement"** for the Netherlands which included **monthly payments to Sandoz** for not selling the generic product in the Netherlands. Sandoz abstained from entering the market from July 2005 until December 2006.

European cases (5)

The *GSK* case of the OFT:

Facts: GSK sells **paroxetine**, an important **anti-depressant,** under the **Seroxat** brand. The drug is GSK best-selling product. When three generics companies wanted to sell generics in the UK, they were **challenged by GSK for patent infringement**. In settlement agreements, GSK makes substantial payments to generics

Allegations of OFT: GSK violated **national and EU competition**; through both **anti-competitive agreements and abuse of market dominance**

European cases (6)

Comparison:

- From clear violations to problematic cases
  - ***Fentanyl:*** **exclusion of generics beyond patent expiry**
  - ***Servier:*** **Reverse payments** during patent term + **invalid patent and – maybe – bad faith**
  - ***Lundbeck:*** **Reverse payments** during patent term + **weak patent but – maybe – good faith**
  - ***Cephalon*** **and** ***GSK*****: Reverse payments** during patent term + **invalidity not specifically argued**
- Patent for originator drug provide much market power (dominance) in large markets
- Different forms of value transfer: **payments, licences, distribution agreements**
- Additional forms of abuse
  - ***Servier:*** **Abuse of patent filing procedures** (cf. *AstraZeneca*) + **acquisition of scarce technology**
  - ***Lundbeck:*** **Purchase of generics for destruction**

Economic incentives for pay-for-delay settlements (1)

Assumption: pay-for-delay less profitable/less likely in the EU than in the US

- **But: Lack of marketing exclusivity for generics**
  - does not prevent pay-for-delay settlements with **several** generics producers
  - does not prevent pay-for-delay settlements with **single** generics producers

- **Other features may limit access of generics to the market**
  - Particular **market power of the "first" generic product**
  - Availability of **marketing authorization** of the **originator company's own generics version**
  - **Drug regulation may delay market entry of generics** (decision on prescription drugs; price regulation)

Economic incentives for pay-for-delay settlements (2)

- **Lack of patent linkage in EU does not exclude other means of promoting litigation**
  - National patent linkages (Hungary) – in conflict with EU drug law
  - Filing for market allowance justifies injunctive relief (Austria)

- **Limits to solving the problem of "poor patent quality" by "raising the bar"**
  - **Information deficit of patent offices**

    Patent applicants are better informed on state of the art than patent examiners
  - **More intensive examination may be economically inefficient**
    - Many patent grants, but very few blockbuster drugs
    - Applications are made at a very early stage in time; only a very few patents make it to the market, and even fewer patents make it to blockbuster drugs
    - High probablitiy of invalidity of pharmaceutical patents as part of the system

European case-law

Problem: Only one Commission decision (*Lundbeck*) that is not publicly available

***Maize seed* (1982):** Settlement agreements are not exempted from Article 101 TFEU

***Bayer v Süllhöfer* (1988):**

A **non-challenge clause is not restrictive of competition** if it is included **in a settlement agreement** in the sense of Article 101(1) TFEU (para 14)

A **non-challenge clause in a licensing agreements** does **not restrict competition** in the sense of Article 101(1) TFEU if the licence does **not include an obligation to pay royalties** (para 16)

But: **Article 5(1)(b) Draft TTBER:**

Any restriction of the right to challenge the validity of the patent **will be considered a restriction that is excluded from the exemption** (no exemption of the right of the licensor to terminate the licence)

Draft TT Guidelines (para 227):

Non-challenge clauses in settlements can be **illegal** if the licensor **reasonably knows about the invalidity or induces the licensee to enter into settlement (eg, through payments)**

Legal assessment of pay-for-delay settlements

Article 101(1) TFEU:

- Settlement agreements are **not exempted as such**
- Settlements **without value transfer do not restrict competition**
- Settlements **with value transfer** are **restrictions by object**

  ➔ Any delay of market entry **reduces price competition**

  ➔ **Patent strength** and **knowledge of patent owner about validity do not matter** (patent validity is never certain)

Article 101(3) TFEU:

- **Efficiency defence** can be possible

  e.g.: Payment may help financially weak generic company to prepare for later marketing (but very unlikely, no interest of patent owner)

Conclusion

- EU situation **substantially differs from the US**
- But **absence of Hatch-Waxman does not mean that the EU has no problem**
- **Cases differ considerably**
- **Case-law still has to develop**
- **Any value transfer may suffice** for a violation
- Pay-for-delay should be **distinguished from other infringements**, such as abusive use of patent procedures
- **Strength of the patent should not matter** ➔ competition agencies will not decide on validity
- **Limited scope for an exemption** under Article 101(3) TFEU