Danish Competition Law Society

Pay-for-Delay Agreements in Pharma

January 2015

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European Commission

Recent pay-for-delay cases

European Commission:

- 39.226 *Lundbeck* — Decision (06/2013)
- 39.685 *Fentanyl* — Decision (12/2013)
- 39.612 *Perindopril (Servier)* — Decision (07/2014)
- 39.686 *Cephalon* (not discussed) — Opening of proceedings (2011)

U.S.:

- Supreme Court: *Actavis* Opinion (06/2013)

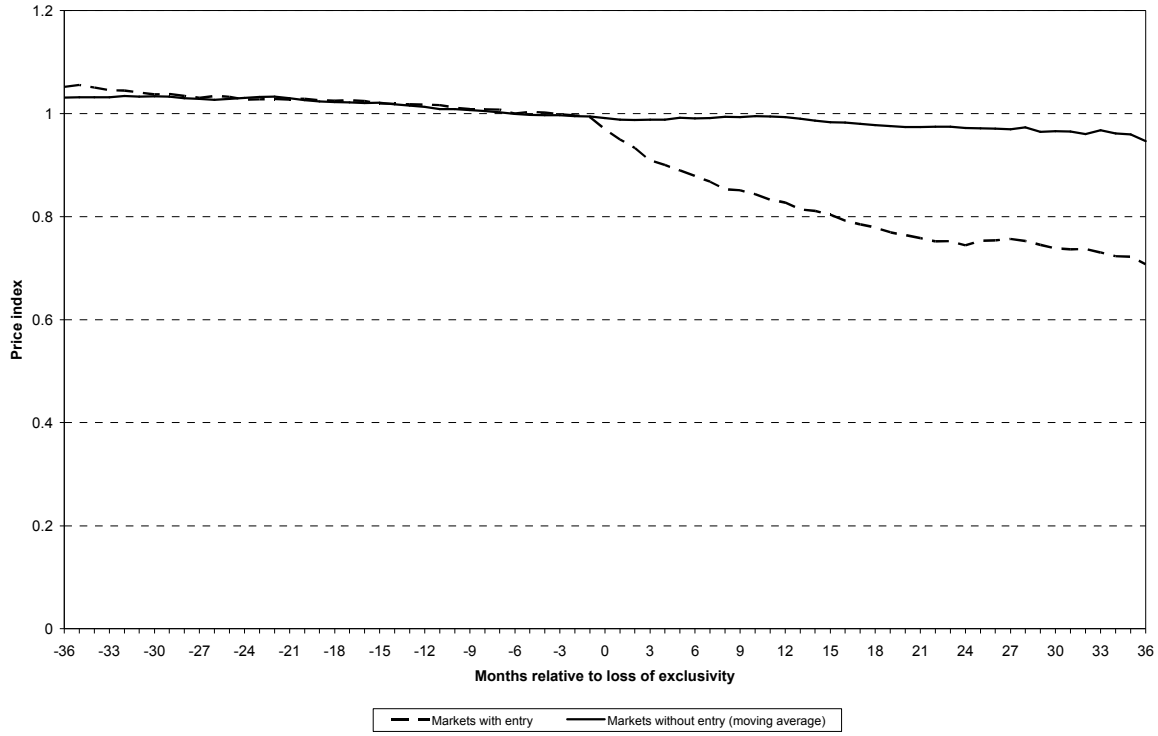
U.K.: (not discussed)

- CE/9531-11 *Paroxetine* — SO (CE/9531-11) and SSO

Outline

- **Market dynamics of generic entry**
- **Why „pay-for-delay“?**
- **Fentanyl Decision: pay-for-delay without patent context**
- **Patents / patent settlement monitoring**
- **Patent related pay-for-delay cases (EU/US): Lundbeck, Servier and Actavis**

Market characteristics of generic entry (based on 2009 Sector Inquiry)



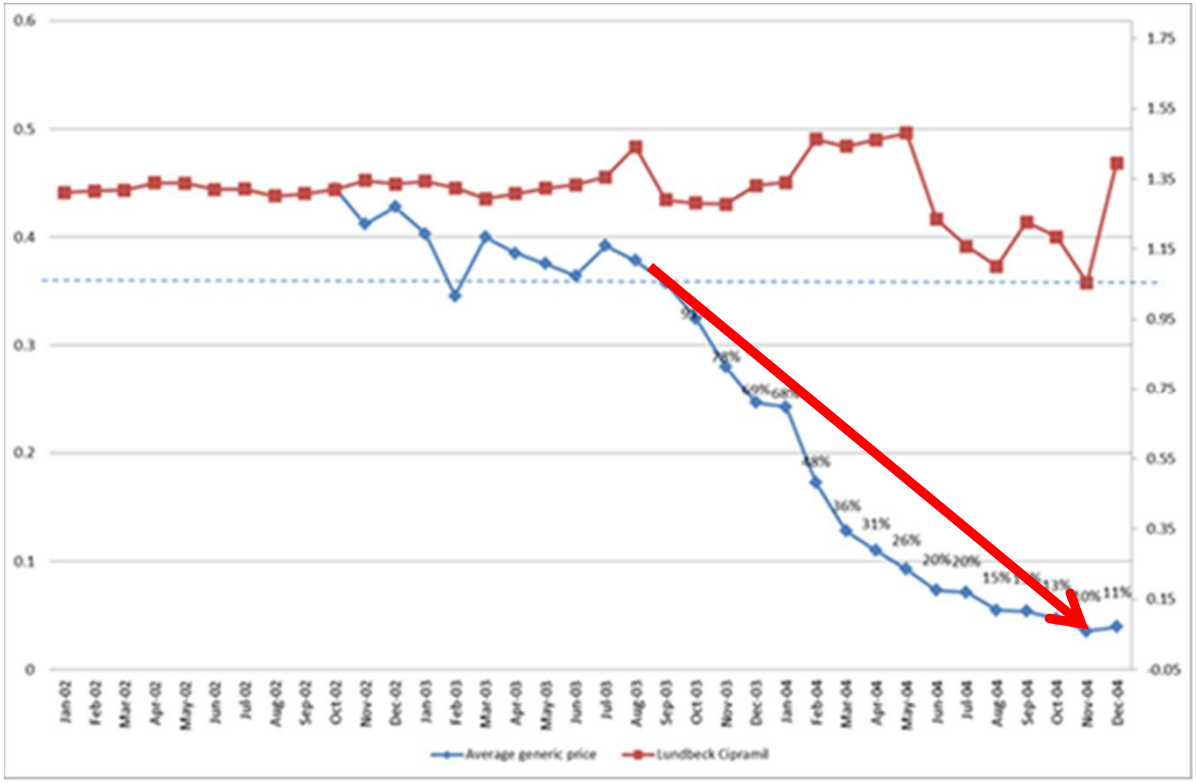
Prices with vs without generic entry

1st year:
- price: -25%; MS: 35%

2nd year:
- price: -40%; MS: 45%

Lundbeck: market impact of generic citalopram, e.g., UK

- Generic price from Sept. 2003 to Nov. 2004: 90% price decline (UK). (Market exclusion agreements: Jan. 2002 – June./Oct./Dec. 2003)



Red line: Lundbeck

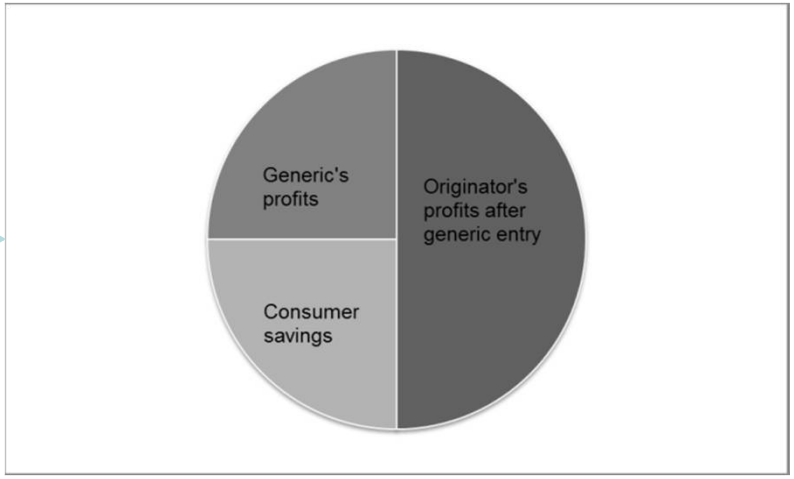
Blue line: weighted average generic citalopram prices per DDD in the UK (GBP) 2002-2005. (Decision, ¶212)

Why pay-for-delay?

Competition with generic entry:

- generics erode prices and gain market shares resulting in consumer savings.

Before generic entry



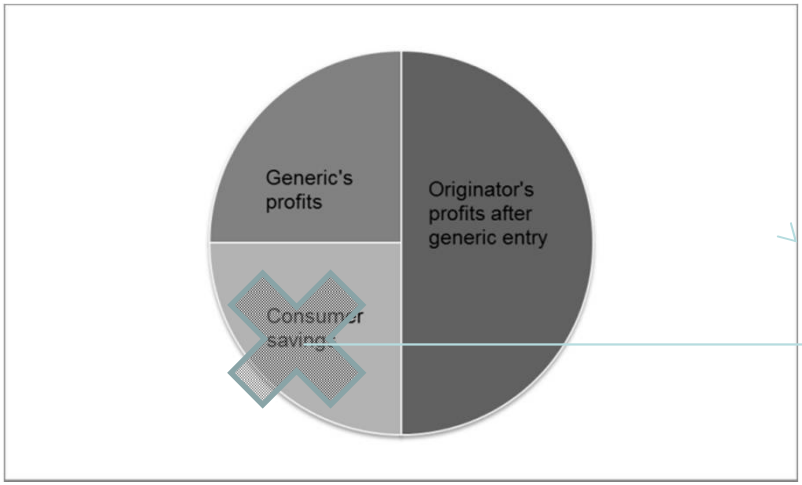
After generic entry

Why pay-for-delay? cont'd

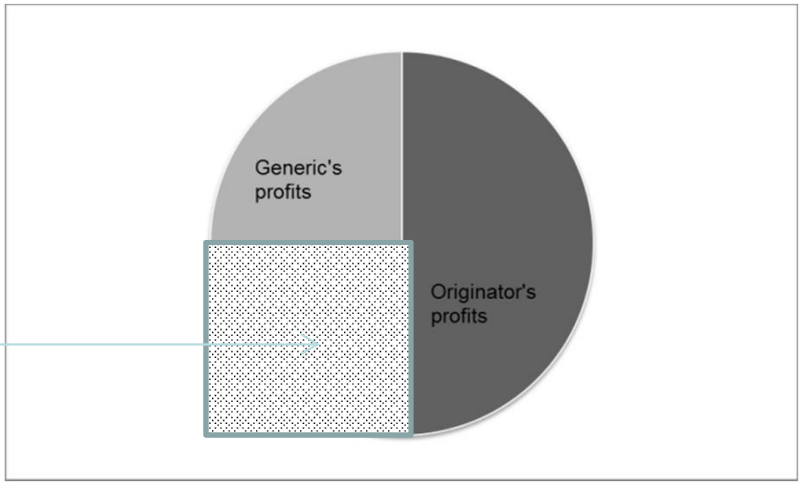
-> The originator continues to earn monopoly rents.

-> The potential consumer gains are shared between the originator and the generic.

-> The originator is better off. Also the generic is better off.



With generic entry



With an exclusion payment agreement preventing generic entry

-> The one who loses is the consumer.

Fentanyl (Case 39.685; 12/2013)

Nota bene: Not a Patent Settlement case

E.g. cases *Servier* and *Actavis*

Another form of "pay-for-delay" agreement

Article 101 TFEU "by object" case

Fentanyl (12/2013)

"Co-promotion" agreement between Johnson & Johnson (Janssen-Cilag) and Sandoz (Novartis) to delay the market entry of a generic version of the strong pain-killer fentanyl in the Netherlands. Fentanyl was no longer protected in the Netherlands. (Therefore: no patent dispute.)

In 2005, Sandoz was preparing to sell its own generic version of fentanyl (having obtained MA, and produced packaging etc.).

Sandoz received monthly payments for as long as there was no generic on the market (i.e. 17 months). The payments exceeded Sandoz' profit expectations in case of generic entry. Hardly any promotion services.

Fentanyl (12/2013)

Internal documents:

- Sandoz abstained from entering the Dutch market in exchange for "*a part of [the] cake*".
- Cooperation to avoid generic entry so as "*to keep the high current price*".

Parties terminated their agreement after 17 months in December 2006, when 3rd party generic entry was imminent.

Conclusion: Restriction by object; fines: €16 million. **No appeal.**

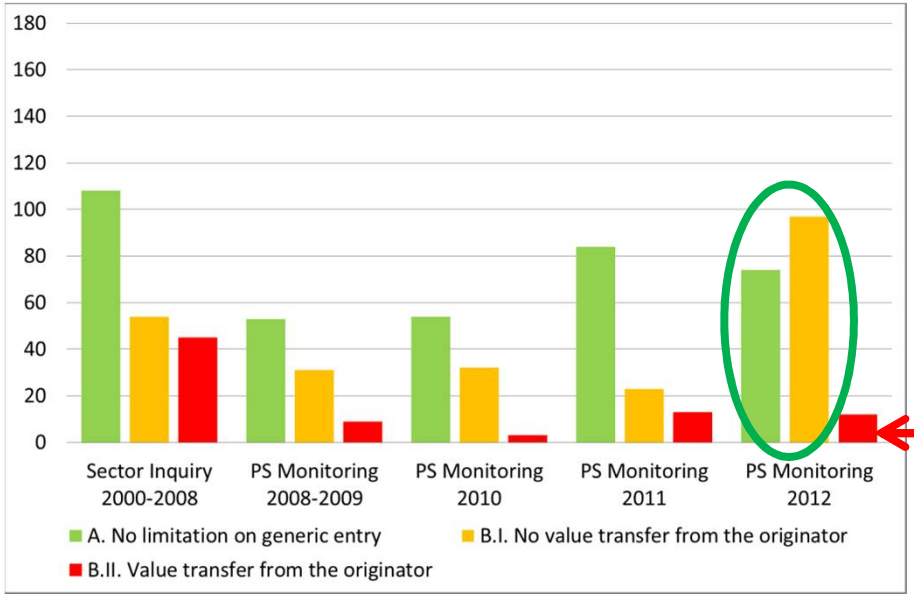
Press-release 14 December 2013 by Janssen: "We accept accountability for our actions … We regret that … health insurers did not benefit from lower generic prices during this period'.'

Pharma patent settlements - introduction

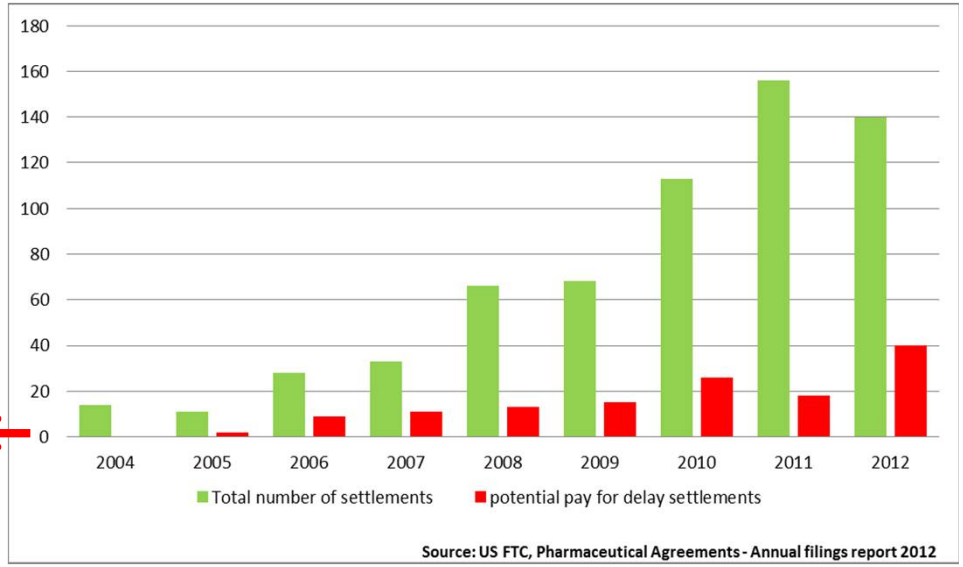
- Patent protection of great importance for innovation in pharma sector („dynamic competition")
  - Molecule patent (including original processes): patent term (20 years) and Supplementary Protection Certificate (prolonging this patent term up to 5 years)
  - Secondary patents: protect, for instance, processes or formulations (and provide more limited protection) (Lundbeck / Servier)
- After molecule patent expiry, and loss of Data Protection/Market Exclusivity, the market is in principle open for generic entry. However, patent disputes regarding remaining patents may arise leading to settlements.

Monitoring: Patent settlements *vs* reverse payment settlements over time

Patent Settlements in the EU

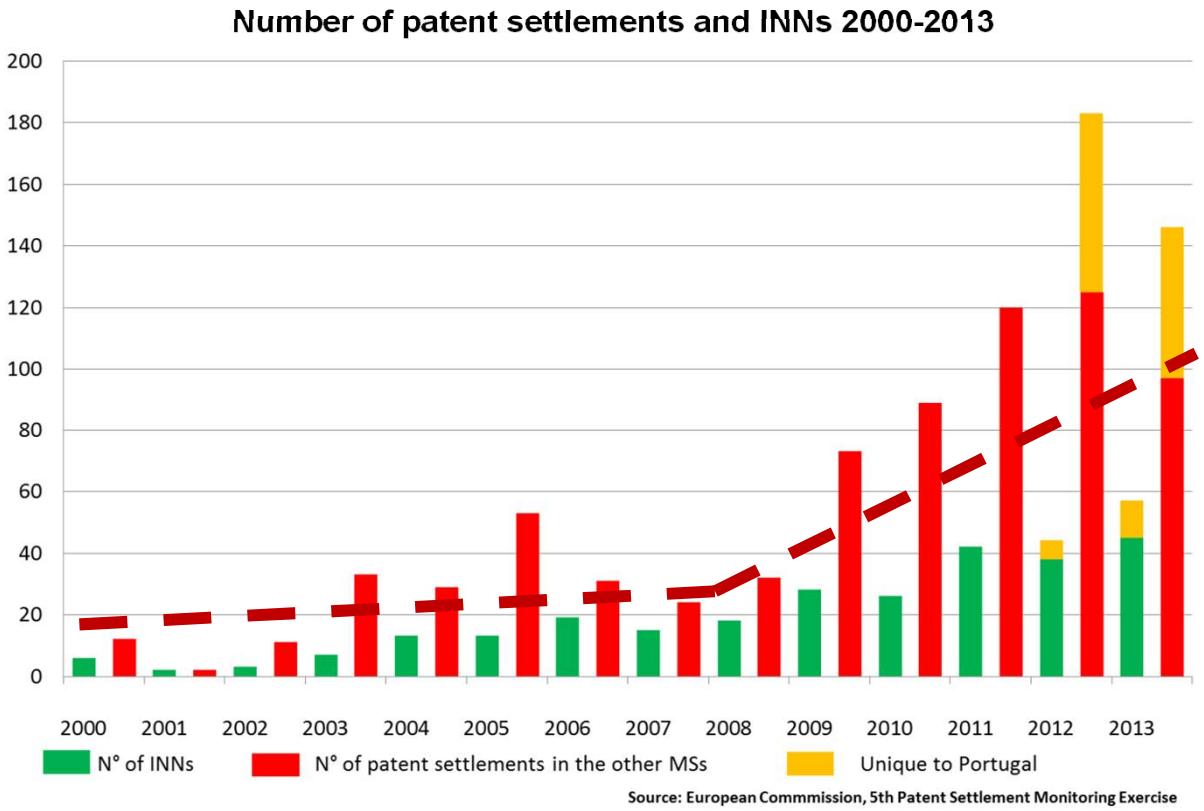


Patent Settlements in the US



- **The vast majority of all settlements reported in the EU can be immediately classified as unproblematic.**
- **Potential antitrust scrutiny only concerns a small fringe of all settlements.**

Monitoring: Patent settlements from 2000-2013



Pharma companies settle more and more – the Commission's enforcement clearly does not prevent the settlements from taking place.

*"while a **patent holder has the right to oppose possible infringement** of its patent, **patent law does not provide for a right to pay actual or potential competitors to stay out of the market** or to refrain from challenging a patent prior to entering the market. The means used by patent holders to defend their rights matter. …*

*In particular, **payments** made by patent **holders to generic challengers** … **to stop or delay their independent efforts to enter** the market **may** well, in certain specific circumstances, **fall afoul of Union competition law**" (*Lundbeck Decision, ¶641)

Pay-for-delay cases with a patent context

European Commission:

• 39.226 *Lundbeck* (6/2013)	No settlements, but agreements concluded in the context of a patent dispute (Art. 101)
• 39.612 *Servier* (7/2014)	Patent settlements and unilateral conduct to exclude generics (Art. 101 and 102)

U.S. Supreme Court

• *Actavis* Opinion (6/2013)	Patent settlements

Lundbeck: Article 101(1) „by object" / the parties

Four generic groups

- Merck KGaA / Generics [UK]
- Arrow (Resolution)
- Alpharma (Xellia / Zoetis / A.L. Industrier)
- Ranbaxy

Lundbeck / the product

- **Citalopram** (brand name: Cipramil) is a **selective serotonin reuptake inhibitor (SSRI) antidepressant**, Lundbeck's **"golden egg" and blockbuster** at the time, on which it largely depended.

- SSRIs/SNRIs are **second generation** antidepressants launched in the 1990ies, leading to strong growth of the antidepressant market.

- Escitalopram is Lundbeck's second generation product.

Lundbeck's strategy against generic citalopram

- Patenting processes to manufacture citalopram

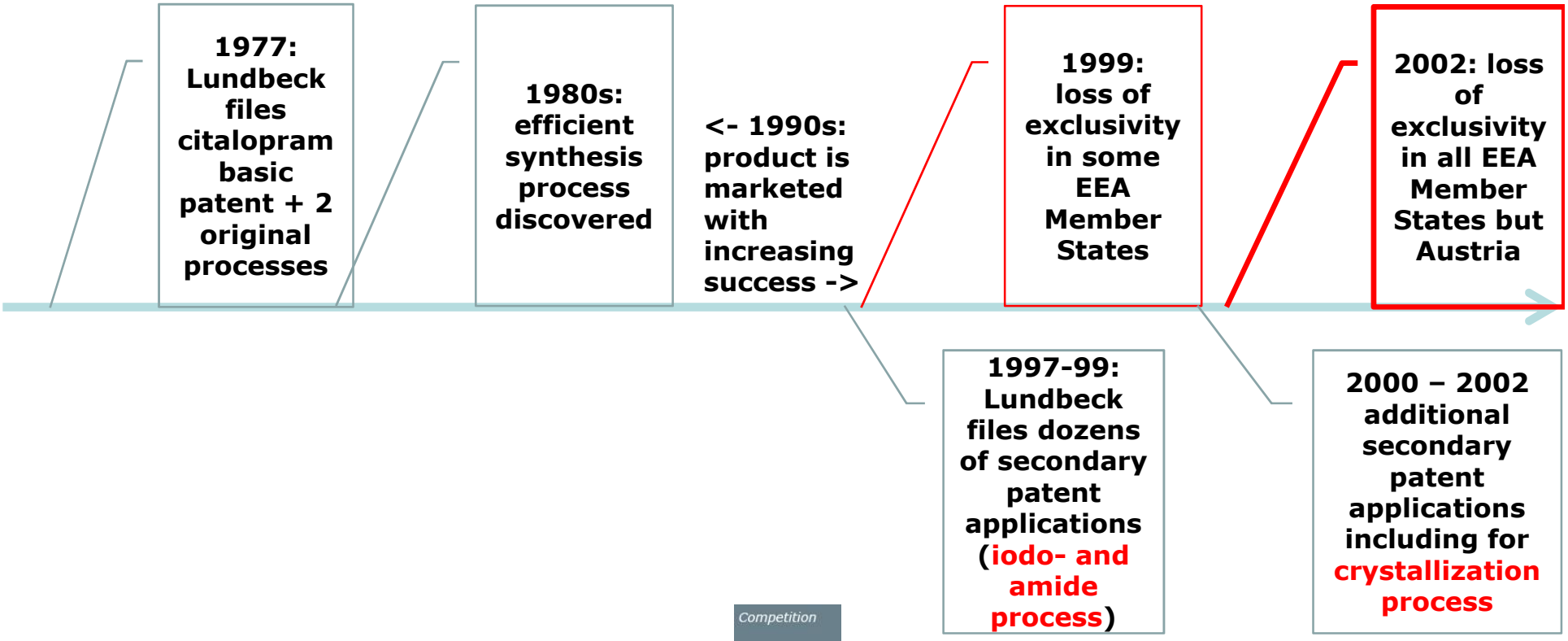
- Persuading generic suppliers to stop their efforts to enter the citalopram market

- Creating a window of opportunity for escitalopram

(Further strategies are summerized in Chapter 6 of the Decision)

Lundbeck's patent strategy

"*From 1997 we patented some 30 different citalopram processes…. In addition, we have some use patents…*" (¶145) However, Lundbeck's compound patent including the two original processes had expired: its patents no longer covered all possible ways to produce citalopram.



Lundbeck / potential competition

Did the potential infringement of Lundbeck's process patents / patent applications prevent potential competition?

Lundbeck: "*It would be naïve to think that it is **not** possible for producers of generic copies to produce Cipramil without breaking our patent.*"(Nov. 02, ¶150)

Lundbeck acknowledged that proof of process patent infringement is *"very difficult".* (¶745)

Regarding the crystallization patent, Lundbeck (internally) estimated invalidation risk at 60%. (¶157)

Lagap settlement allowing entry to avoid a "*humiliating defeat".* (¶160)

Lundbeck / potential competition cont'd

"***Lundbeck considered*** *at the time that* **"*[g]*eneric competition is foreseen** on markets **where the product patent has expired**" … [i.e. as of **1999 or January 2002**] … [T]*here is abundant evidence that* ***the dynamic competitive process*** *for generic citalopram entry* ***had started with full force*** *before the agreements were concluded…* ***only few*** *… generic companies* [in fact **those with whom Lundbeck concluded the agreements**] *were …* ***able to compete for being*** **"in pole position"** *for generic entry. Merck called the time period shortly before conclusion of the agreements "*the **race** against" … [*Arrow and Alpharma*]*. This dynamic race with* ***changing positions of*** **"front runner[s]"** ***stopped…***" as a result of the agreements. (¶622)

Lundbeck / four infringements overview

Lundbeck entered into **six agreements** with **four groups of generic companies at a crucial time for generic competition for a duration of between 10 and 22 months**. **In total**, Lundbeck transferred a value of around **EUR 66.8 million**:

- **Merck**: +/- **EUR 31.4 million**
  - EUR 19.4 million for the **United Kingdom** agreement (24/1/2002-1/11/2003)
  - EUR 12 million for the **EEA** agreement (22/10/2002-22/10/2003);

- **Arrow**: +/- **EUR 11 million**
  - EUR 10.4 million for the **United Kingdom** agreement (24/1/2002-20/10/2003)
  - EUR 684.000 for the **Denmark** agreement (3/6/2002-1/4/2003);

- **Alpharma**: +/- **EUR 11.7 million** for the **EEA** agreement (22/2/02-30/6/2003);

- **Ranbaxy**: +/- **EUR 12.7 million** for the **EEA** agreement (16/6/02-31/12/2003).

Lundbeck / overview cont'd

- **Nature of value transfers**: Lundbeck paid **lump sums**, **purchased generics' stock** for the sole purpose of destroying it, and offered **guaranteed profits in a distribution agreement**.

What did the generics offer in return?

- **Generic** producers **agreed with Lundbeck** in 2002 **not to enter** the market with citalopram **in return for those value transfers.**

Lundbeck / legal test

Assessment took into account:

- **Potential competition:** That Lundbeck and generic companies were at least potential competitors
- **Commitment** of the generic company **to limit** its **independent efforts to enter** the market
- **Value transfers** that substantially **reduced the incentives** of the generic company to pursue its **independent efforts to enter** EU markets

Lundbeck / legal test cont'd

Assessment - other factors:

- That the value transfers **took into consideration** the **turnover or profit expected** by the generic in case of entry;

- That Lundbeck could **not have obtained the same limitations** on entry **through enforcement** of its process patents;

- That the agreement contained **no commitment from Lundbeck to refrain from infringement proceedings** if entry post-expiry of the agreement.

Lundbeck / Example: Merck (GUK) agreements

Two Agreements between Lundbeck and Merck/Generiks [UK]

1. Covering the United Kingdom, from 24 January 2002 until 1 November 2003 (twice extended and terminated in October 2003, when Lundbeck settled the Lagap litigation); value transfer ~ EUR 19.4 million;

2. Covering the EEA excluding the United Kingdom from 22 October 2002 until 22 October 2003; value transfer ~ EUR 12 million.

… here discussed together; the Decision assesses the two agreements separately, but finds one single infringement of Article 101(1) TFEU.

Lundbeck / Merck (GUK) / Assessment

1. Lundbeck and Merck (GUK) were **at least potential competitors** (or the "economic and legal context")

Facts (Note: loss of exclusivity is January 2002)

At the time the agreements were concluded, Lundbeck's citalopram was the only citalopram being sold in the UK (with 2001 sales amounting to [50-130]* million (¶738)). In Sweden, Merck (GUK) had already entered through NM Pharma.

March 2001: Following Lundbeck's visit of Natco, Merck (GUK) concluded: "*Lundbeck left* [Natco] *after 45 minutes not knowing anything about Natco… and the quality of their material, which is excellent…"* (fn 1347)

Lundbeck / Merck (GUK) cont'd

5 July 2001: UK publication of Lundbeck's crystallization patent.

13 Sept. 2001: Lundbeck: *"…you must be patent infringing, we will sue you to hell…"* to which Merck (GUK) replied *"good luck* […] *…this does not affect us launching".* (¶748)

Internally, Merck (GUK) concluded: *"Raw material Natco (Indian). This is non-infringing.*" (being based on the original process) (¶¶748, 754)
Merck (GUK): Natco supply was "*not a problem*" (¶747)

28 Sept. 2001: Merck (GUK) considered two options ("*Met twice with Lundbeck in the UK to achieve a deal*"):

In the first scenario, "*current plans*", launch, earn profits of "…*£9m*[illion]" in year 1.

In the second scenario, "*Plan 2*", Merck (GUK) would be supplied by Lundbeck with the goal "…*to achieve the same profit figure*". (¶748)

Lundbeck / Merck (GUK) cont'd

12 Oct. 2001: Merck (GUK): *"…it is now time to move forward in readiness for the legal action from Lundbeck."* (¶749)

24 Oct. 2001: Merck (GUK) stated: "*we intend to attack* [Lundbeck] *by all possible means*". (¶749)

15 Nov. 2001: Merck (GUK) started "clearing the way procedure", internally observing: *"none of the published patent applications … constitute a problem*". (¶754)

11 Dec. 2001: Lundbeck meets Merck (GUK). Merck (GUK) resumes: "*Lundbeck do*[es] *not want a generic on the market. However, they could compensate us for the profit we would have made etc."* (¶780)

5 Jan. 2002: Lundbeck's compound patent expired in the UK / EEA (ex. Austria)

9 Jan. 2002: Merck (GUK) obtains UK marketing authorization

24 Jan. 2002: UK Agreement

Lundbeck / Merck (GUK) cont'd

1-4 Aug. 2003: Merck (GUK) launches in the UK: Lundbeck's *"final offer* [for [the second] extension] *wasn't good enough!!*"(¶755)

5 Aug. 2003: Lundbeck tripled its initial offer for the extension, and Merck (GUK) withdraws from the UK market. (¶755)

Oct. 2003: Following Lagap settlement, termination.

<u>EEA Agreement</u>

25 Feb 2002: Merck (GUK): Lundbeck's *"patent is considered to be weak*" (¶754)

21 May 2002: NM Pharma enters with Merck (GUK)'s Natco citalopram in Sweden and enjoys 5 months of "encouraging" sales until… (¶837)

Lundbeck / Merck (GUK) cont'd

22 Oct 2002: Conclusion of the EEA Agreement (excluding the UK)

23 Oct 2002: Merck (GUK): "*We are 100% confident that our evidence will show that we do not infringe any of their IP"* (¶754)

Conclusion on potential competition…

Lundbeck and Merck (GUK) were at least potential competitors, irrespective of the possibility of infringement of Lundbeck's process patents (¶761)

… similar conclusion for the EEA Agreement… (¶839)

Lundbeck / Merck (GUK) / Assessment

2. Commitments in the Agreements

2.1 Commitments accepted by Merck (GUK) (or "the content of its provisions, its objectives"):

- For the UK:
  - not to launch citalopram products based on Natco's API ("*subject to payment*")
  - to "*deliver up*" its Natco citalopram products in stock and on order to Lundbeck
  - not to license its United Kingdom marketing authorisations for Natco citalopram products to any other generic supplier
  - to "*exclusively purchase*" finished citalopram products from Lundbeck (distribution agreement)

Term: one year (24 Jan. 2002 – 31. Jan. 2003), two extensions until 30 July 2003 and 6 January 2004, respectively; early termination effective 1 Nov. 2003.

Lundbeck / Merck (GUK) / Assessment cont'd

Commitments cont'd

- For the EEA (excluding the UK):
  - to cease the sale and supply of citalopram in the territory
  - to use all reasonable efforts to ensure that Natco ceases to supply citalopram in the territory ("*it is expressly … agreed that Lundbeck shall not to be required to make any payments… in the event that Natco supplies*")
  - No other counterperformance

  Term: 22 October 2002 for one year

2.2 Commitments accepted by Lundbeck: value transfers as inducements (booked as "*cost*" to gain "*time*")

Lundbeck / Merck (GUK) / Assessment cont'd

Commitments cont'd

- For the UK: ~ EUR 19.4 million
  - GBP 3 million for **Natco stock** (roughly GBP 2 million was profit for Merck (GUK), which Lundbeck destroyed
  - GBP 9.65 million **guaranteed profits for distribution** of packs of 28 20 mg Cipramil tablets (first year: GBP 5 million in **monthly instalments**; extensions: first: 400.000/month; second: 750.000/month)

- For the EEA (excluding the UK):
  - **EUR 12 million** in twelve **monthly instalments**
  - **"*in consideration of*":** ("*lucrative*") **inducement** for Merck (GUK) to accept the commitments (and no indication of any legitimate reasons)

Lundbeck / Merck (GUK) / Assessment cont'd

Additional elements of analysis:

- The value transfers roughly corresponded to the profits Merck (GUK) expected to make in case of independent entry;
- Out-of scope commitments: covering all citalopram;
- Lundbeck gave no commitment to refrain from infringement proceedings after expiry of agreements.

- Intentions of the parties

Intentions / Lundbeck

Summarized in Lundbeck's strategy document "*Generic citalopram update 22 11 02*":

*"**It is like a poker game***

- ***We have been dealt a mediocre hand** – no aces, a couple of queens and some small uneven cards*
- ***But we have a large pile of $$$ at our side***
- ***We call it – "the art of playing a loosing hand slowly**"*

Our strategy

- *Our objective : To create a window of opportunity for the Cipralex switch …*

***Three main tactics**:*

- *Influencing the authorities*
- *Patent defence, mainly process patents*
- ***Deal making***". (Decision, ¶131, highlighting added)

Lundbeck's intentions

- Lundbeck Business Development document with the title *"Generic citalopram update 22 11 2002*":

  *"**Deal making***
  - *We have made a number of deals; although it is tricky*
    - *They fantasize of the value of the generics*
    - *It is **illegal to block competition***
    - ***Worthless taking out one of two or three players***
  - ***However some of our deals have been very valuable**."*

(Decision, ¶191 , highlighting added)

Lundbeck decision / overall conclusion

- **In total, four single and continuous infringements; restrictions by object; Article 101(3) criteria were not met**

- Although by object restriction, analysis of concrete situation in the UK market: one year after generic entry, price drop of 90%

- Fines: Lundbeck ~ €90 million; generics ~ €50 million

- 6 appeals pending; EFPIA intervention

Perindopril (Servier) (7/2014) - 1

Facts

- Perindopril was a **best-selling** anti-hypertension medicine (cardio-vascular).
- In **2003**, the **perindopril patent expired**. While certain **secondary patents** were still in force, generic producers intensively prepared for entry seeking access to patent-free products and/or challenging remaining patents.
- **From 2004 onwards**, Servier implemented a **strategy to exclude generic competitors and delay the entry** of cheaper generic perindopril medicines. Evidence showed that Servier used its "***pile of cash***" to buy generic competitors out of perindopril.
- No antihypertensive medicines other than **generic versions of perindopril were able to constrain Servier**'s sales and prices.

Perindopril (Servier) (7/2014) - 2

Article 101 TFEU:

- **Between 2005 and 2007**, virtually each time a generic company came close to entering the market, Servier settled the competitive challenge with the generic. Servier concluded **five agreements** with different generic companies with the **object of hindering generic perindopril entry** in EU markets:
  - **Generic companies abstained from entering** the market with generic perindopril and from further challenging Servier's patents.
  - **Servier paid substantial amounts** to generic companies amounting to several tens of millions of euros. In one case, Sevier gave a licence to a generic company for 7 markets in exchange for the "sacrifice" of other markets.

Perindopril (Servier) (7/2014) - 3

Article 102 TFEU:

- **Dominance on single molecule market perindopril.**
- **Comprehensive strategy by *Servier* to prevent generic market entry** when end of patent protection for *Servier's* perindopril was imminent:
  - In 2004, before concluding settlement agreements with generic competitors, Servier acquired an advanced non-infringing process technology that was developed for generic entry (to "strengthen the defence mechanism"). There were very few sources of non-protected technology.
  - 2005-2007: five reverse payment deals (see Article 101).

Servier prevented price drops up to 90% (e.g., in the UK). Internally, it commented "***great success = 4 years won***".

Perindopril (Servier) (7/2014) - 4

Conclusion

- Reverse payment deals: restrictions by object (Article 101)
- Abuse of Servier's dominant position (Article 102)
- Fines totalling: €427.7 million
- 8 Appeals pending

Supreme Court *Actavis* decision (6/2013) - 1

Facts

- Solvay: 2000 new drug approval for formulation of testosterone (Androgel). 2003 grant of formulation patent (valid until 2020).
- 2003: Paragraph IV challenges by Actavis, Paddock and Par, i.e. certification that patent invalid or not infringed.
- 2006 settlement: generic entry allowed by 2015 (thus 5 years before patent expiry).

Supreme Court *Actavis* decision (6/2013) - 2

- Solvay agreed to pay:
  - USD 19-30 million annually, for nine years, to Actavis; USD 12 million in total to Paddock; USD 60 million in total to Par.
  - Co-promotion agreement. Parties alleged compensation "for other services". However, the FTC contended that these other services had little value.
- 2012: Court of Appeals of 11th Circuit (*Watson (Actavis)*)
  - Potential scope of the patent test
- 2012: In *K-dur*, Court of Appeals of 3rd Circuit
  - Quick look rule of reason analysis: reverse payment

Supreme Court *Actavis* decision (6/2013) - 3

Application of "rule of reason" to reverse payment settlements "*consistent with this opinion*":

1. **On patents:** The fact that restrictions of generic entry might fall within the **scope of the exclusionary potential of a patent is irrelevant**.

   "*The patent here may or may not be valid, and may or may not be infringed*."

Supreme Court *Actavis* decision (6/2013) - 4

2. **Payment** may provide strong evidence that the patentee **seeks to induce** the generic challenger to abandon competition. Also, the size of the payment is a strong indication of **market power of the originator**.

3. **Absent justification**, the antitrust laws are likely to forbid such arrangement.

Convergence: Supreme Court's test similar to *Lundbeck*. However, justifications are examined under Article 101(3) TFEU.

Thank you!

Website:

http://ec.europa.eu/competition/sectors/pharmaceuticals/overview_en.html#