Enforcement in the pharmaceutical sector in the EU

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**The views expressed are those of the speaker and do not necessarily reflect those of DG Competition or the European Commission*

Competition

Overview

1. Introduction
2. IPR-related abuse of dominance - the *AstraZeneca* Judgement
3. Recent pay-for-delay (EC) cases
    - Lundbeck
    - Fentanyl
    - Servier
    - debate on pay-for-delay: common misconceptions

Antitrust rules in pharma industry

1. General categories of antitrust rule enforcement:

   - Unilateral practices: special responsibility of dominant undertaking and competition that is not on the merits
   - Multilateral practices: agreements, coordinated behaviour

2. Special situation of the pharmaceutical sector:

   - highly regulated (market authorisation, pricing, reimbursement, IPR)
   - high investment into R&D compared to other sectors

   Yet, no exemption of the sector from competition scrutiny (evident from judgements of European courts)

3. Practices aimed at reducing competition

   - on price (e.g. delaying/blocking generic entry) or
   - on innovation (e.g. delaying/blocking entry of new innovative product)

   likely to attract scrutiny. => each case to be assessed on its own merits

IPR-related abuse of dominance – the *AstraZeneca* Judgements

The AstraZeneca Judgments

Commission Decision 2005

fining AZ €60 million for abusing its dominant position (Article 102 TFEU)

Market defined as PPI inhibitors (=proton pump inhibitors **treating various gastrointestinal diseases,** e.g. such as peptic ulcers)

Two abuses delaying generic entry:

- misrepresentations to patent offices
- misuse of regulatory procedures

Judgements of EU Courts

1 July 2010: General Court essentially upholds Commission Decision (reducing fine to €52 million)

6 December 2012: Court of Justice of EU upholds General Court judgment

The AstraZeneca judgments – misrepresentations to the patent office

COURT OF JUSTICE:

"…AZ's consistent and linear conduct, as summarised above, which was characterised by the notification to the patent offices of **highly misleading representations and by a manifest lack of transparency**,… and by which AZ deliberately **attempted to mislead the patent offices and judicial authorities** in order to keep for as long as possible its monopoly on the PPI market, **fell outside the scope of competition on the merits**." (para. 93, emphasis added)

"…the **assessment** of whether representations made to public authorities for the purposes of improperly obtaining exclusive rights are **misleading must be made in concreto** and may vary according to the specific circumstances of each case. It thus cannot be inferred from that [GC] judgment that any patent application made by such an undertaking which is rejected on the ground that it does not satisfy the patentability criteria automatically gives rise to liability under Article 82 EC." (Para.99 emphasis added)

The AstraZeneca Judgment – deregistration of reference products

Deregistration and withdrawal of capsules of 1st generation product from the market (replacement by tablets)

- Losec capsules were required reference product for generic market authorisation
- deregistration but not withdrawal/product switch constituted an abuse

Court of Justice:

- "…deregistration, without objective justification and after the expiry of the exclusive right to make use of the results of the pharmacological and toxicological tests and clinical trials…, of the MAs for Losec capsules…, by which AZ intended…, to hinder the introduction of generic products and parallel imports – does not come within the scope of competition on the merits." *(para 130, emphasis added)*
- "…As that court [GC] pointed out, the illegality of abusive conduct under Article 82 EC is unrelated to its compliance or non-compliance with other legal rules and, in the majority of cases, abuses of dominant positions consist of behaviour which is otherwise lawful under branches of law other than competition law." *(Para 132, emphasis added)*

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* — Opening of proceedings (2011)

U.S.: (not discussed)

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

U.K.: (not discussed)

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

Lundbeck decision (6/2013) - 1

Background:

- **Citalopram:** blockbuster antidepressant medicine and Lundbeck's best-selling product at the time.
- Lundbeck's **basic patent** for the citalopram molecule and **original processes** had **expired**. Thus, **market** was in principle **open** for generic competition.
- However, **remaining process patents** offered still limited protection.
- **Several generic companies** had made serious **preparations to enter**; **one** of them **had actually started** selling its own generic version of citalopram.

Lundbeck decision (6/2013) - 2

Facts:

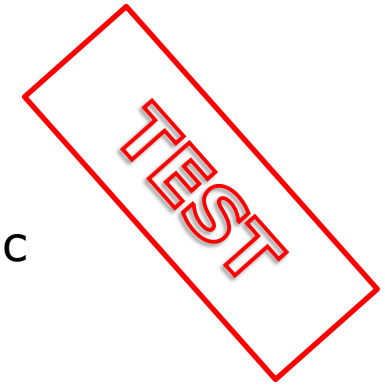
- **Generic** producers **agreed with Lundbeck** in 2002 **not to enter** the market **in return for substantial payments and other inducements** from Lundbeck amounting to tens of millions of euros, instead of competing.

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

- Internal documents refer to a "club" being formed and "a pile of $$$" to be shared among the participants.

Lundbeck decision (6/2013) - 3

Assessment took into account:



- **Potential competition** between Lundbeck and generic companies
- **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 decision (6/2013) - 4

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 decision (6/2013) - 5

Conclusion:

- **Restriction by object**; **Article 101(3) criteria were not met**
- However, 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

Fentanyl (12/2013) - 1

"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.

In 2005, Sandoz was preparing to sell its own generic version of fentanyl (having obtained MA, and produced packaging etc.). Fentanyl was no longer protected in the Netherlands.

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.

Fentanyl (12/2013) - 2

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.

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.
- 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 EEA 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, Servier gave a licence to a generic company for 7 markets in exchange for the "sacrifice" of other markets.
- **Likely effects** of the agreements on competition were **appreciable.**

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.

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 and by effect (Article 101)
- Abuse of Servier's dominant position (Article 102)
- Fines totalling: €427.7 million
- 8 appeals pending

Debate on pay-for-delay: common misconceptions

- US *per se* = EU *by object*
- Only cash payments are illegal
- Obligation to litigate to the bitter end
- Settlement with payments can be procompetitive
- Chilling effect on innovation

Thank you for your attention!