Latest Developments in EU Competition Law in the Pharmaceutical Sector

Pharma Law Convention 2014

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"The views expressed are purely those of the writer and may not in any circumstances be regarded as stating an official position of the European Commission."

Outline

1. Introduction
2. IPR-related abuse of dominance - the *AstraZeneca* Judgement
3. Pay for delay

- Patent settlements:
  - Recent cases (Lundbeck, Servier, Actavis)
  - Patent Settlement Monitoring Exercise
- Co-promotion agreements (J&J Novartis)

Introduction: 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, as well as US courts)

=> Rather: each case to be assessed on its own merits

Introduction: Antitrust rules in pharma industry

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 catch attention of Commission

Agreements (Article 101 TFEU) or unilateral conduct by dominant companies (Article 102 TFEU)

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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

First Abuse

Submission of misleading information to the patent office:

Submission of wrong/misleading information in order to obtain prolonged exclusivity (SPC) – **duty of transparency for dominant companies**

GENERAL COURT:" *The submission to the public authorities of misleading information liable to lead them into error and therefore to make possible the grant of an exclusive right to which an undertaking is not entitled, or to which it is entitled for a shorter period, constitutes a practice falling outside the scope of competition on the merits (…). Such conduct is not in keeping with the special responsibility of an undertaking in a dominant position* (…)." (para 355)

The AstraZeneca Judgments

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

Second Abuse

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)*

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Patent Settlements in the Pharmaceutical Sector

Introduction: pharma patent settlements

- Patent protection of great importance for innovation in pharma sector
  - Molecule patent: patent term (20 years) and Supplementary Protection Certificate (prolonging this patent up to 5 years)
  - Secondary patents: e.g., process patents and formulation patents providing more limited patent protection

- After molecule patent expiry, market in principle open for generic entry. However, patent disputes regarding remaining patents may arise leading to settlements.

Reverse payment settlements:

Settlements = generally positive for society

However: potential problematic scenarios, where settling parties but not the consumer (patients and/or health funds) profit from the agreement:

- Settlements entailing a delay of generic entry in exchange for a value transfer from originator to generic (pay-for-delay = monopoly rent sharing)
- Settlements entailing restrictions beyond exclusionary zone of the patent concerned (going beyond geographic, time or material scope of the patent)

Incentives for reverse payment settlements in the EU (no exclusivity period for first generic challenger) compared to the U.S. (first generic challenger receives 180 days exclusivity)?

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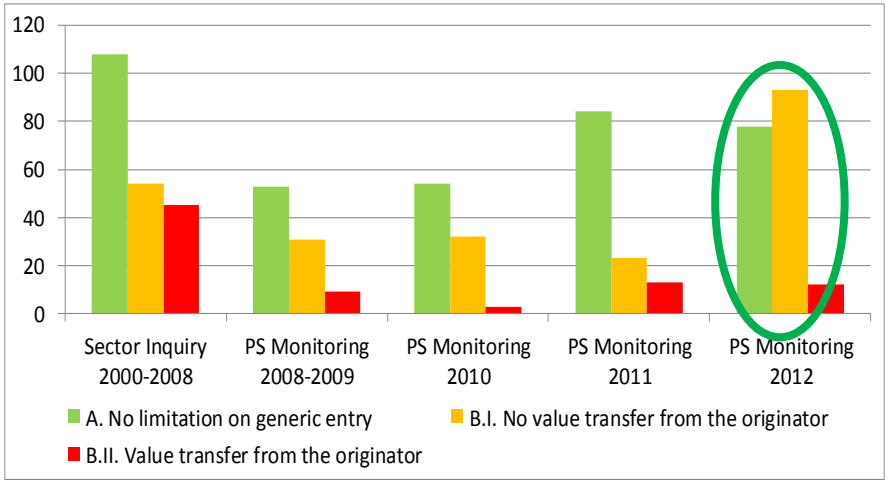
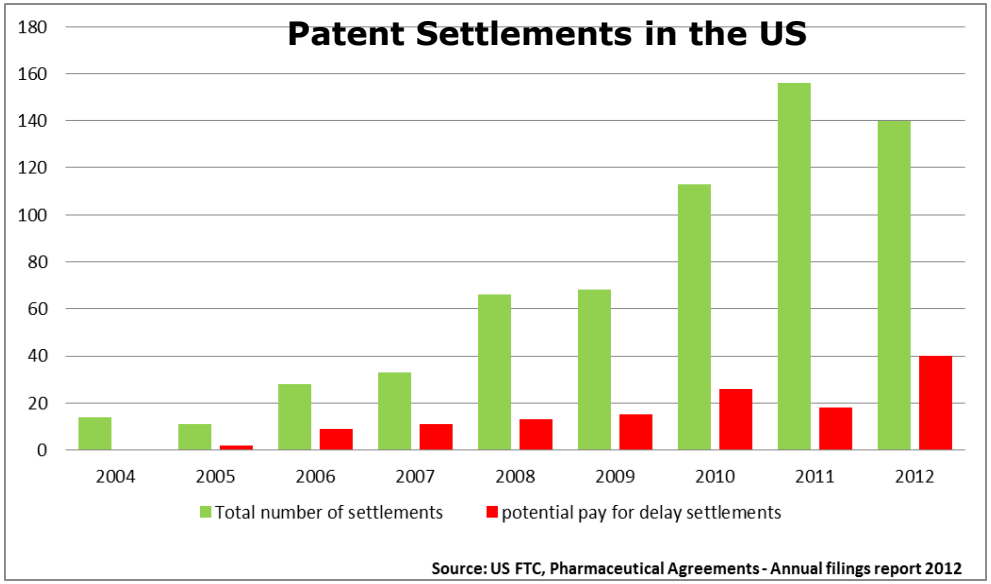
Follow up to Sector Inquiry – Patent Settlement Monitoring

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





- **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.**

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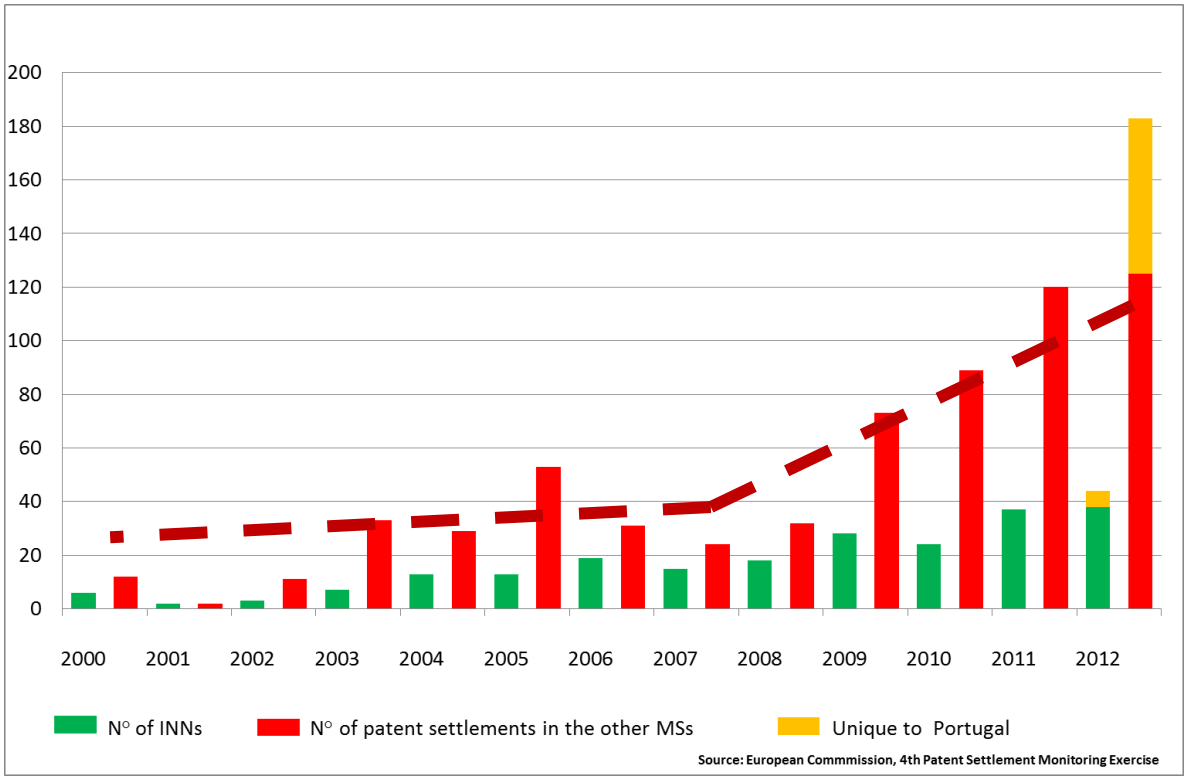
Monitoring: Patent settlements from 2000-2012

Number of patent settlements and INNs 2000-2012



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

Patent Settlement Cases

Recent cases

Commission enforcement

- 39.226 *Lundbeck* — Decision (06/2013)
- 39.612 *Perindopril (Servier)* — SO (07/2012)
- 39.686 *Cephalon* — Opening of proceedings (2011)

U.S.

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

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.

Perindopril (Servier) (SO; 7/2012)

Commission's preliminary view:

- **Article 101 TFEU: Agreements** between *Servier* and generic competitors may have hindered the entry of generic **perindopril** (cardio-vascular medicine) in EEA markets
  - **Generic** companies **abstained from entering the market** with generic perindopril and from further challenging the *Servier's* patents
  - **Substantial payments** from Servier to generic companies
- **Article 102 TFEU: Comprehensive strategy** by *Servier* to prevent generic market entry when end of patent protection for *Servier's* perindopril was imminent: patent acquisitions and settlements

=> **consumer harm**: delay of generic entry + prices remained high

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

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) - 2

2. **Payment** may provide strong evidence that the patentee **seeks to induce** the generic challenger to abandon competition.

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.

Co-promotion Case

Fentanyl (J&J Novartis)

- Article 101 TFEU "by object" case
- Agreement between J&J and its close, even closest, potential competitor Novartis/Sandoz that it would **not come into the market** with generic fentanyl in the Netherlands **in exchange for monthly payments**

Entered into force on 11 July 2005, when Sandoz was expected to launch in August 2005

- In force as long as no entry of any generic
- Monthly payments by J&J > Expected profits of Novartis/Sandoz
- Vague and limited co-promotion services

After one year, as no generic entry had taken place, extended by an addendum

- Terminated when an independent generic was about to launch
- No co-promotion activities whatsoever

=> **consumer harm**: delay of generic entry + prices remained high

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Thank you!

Website:

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