Intellectual Property and Health Innovation
- Challenges for the Future -

28 April 2014
ATHENS
organized by
"The World Intellectual Property Organization"
and "The Hellenic Industrial Property Organization"

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Outline

- The AstraZeneca Judgment
- Patent settlements in the pharma sector
- Statistics: Sector Inquiry and 3rd Patent Settlement Monitoring
- Recent cases (EU/US):
  - Fentanyl decision (12/2013)
  - *Lundbeck* decision (6/2013)
  - *Perindopril (Servier)* Statement of Objections (7/2012)
  - US Supreme Court *Actavis* decision (6/2013)

Antitrust rules in pharma industry

Special situation of the pharmaceutical sector:

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

Yet this does not exempt the sector from competition scrutiny as evident from some judgements of European courts

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

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 or **unilateral conduct** by dominant companies

The AstraZeneca Judgment

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 the patent system
- misuse of regulatory procedures

Judgement of European Court of Justice

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 Judgment

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 Judgment

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)*

Pharma Sector Inquiry

opened in January 2008

main focus of the SI company behaviour in view of generic delay (ORI-GEN) & decline in innovation (ORI-ORI)

preliminary report in November 2008

- Practices in focus: patenting, litigation, agreements (including settlements), interventions, follow-on products

Conclusion of the Sector Inquiry in July 2009

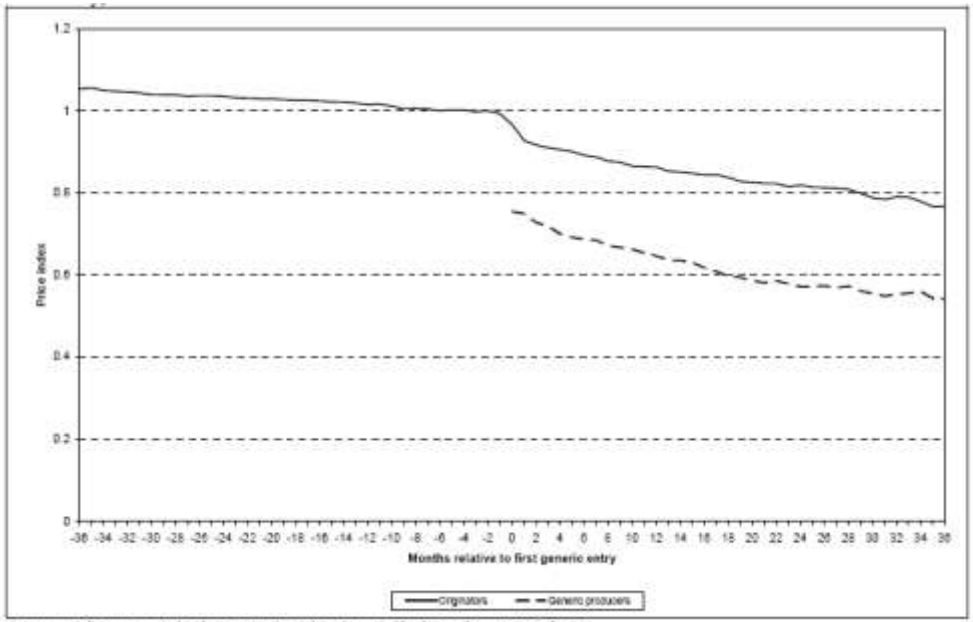
- Policy Recommendations
  - Enforcement of Competition Law
  - Improvement of the Regulatory Framework

Impact of generic entry

Industry context: The pharma sector

- Competition between originator and generic medicines results in lower prices and significant savings for consumers
- Originator companies aim at managing the end of the "life cycle" for their blockbuster products

Development of prices of medicines at generic entry



Source: Pharmaceutical Sector Inquiry (partially based on IMS data)

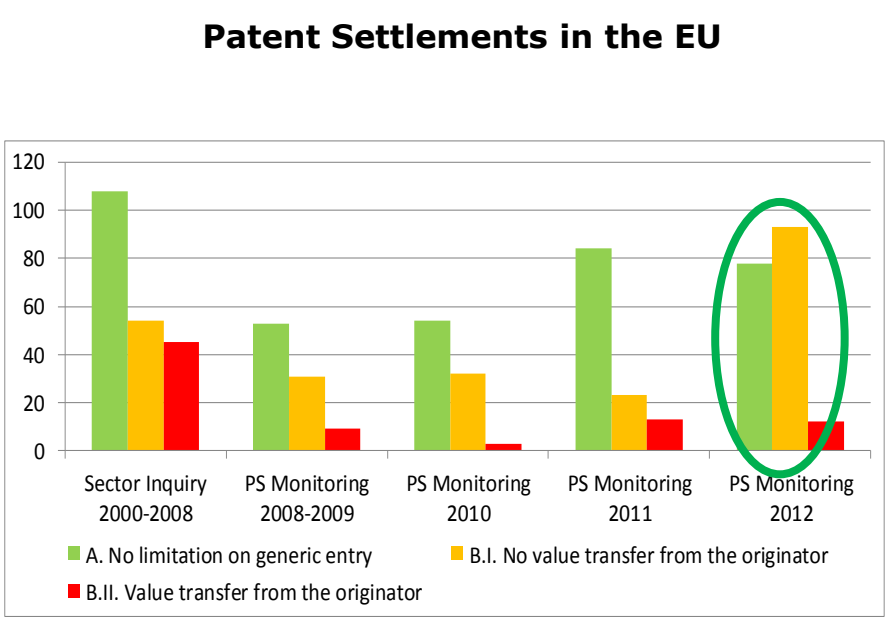
Pharma Patent Settlements

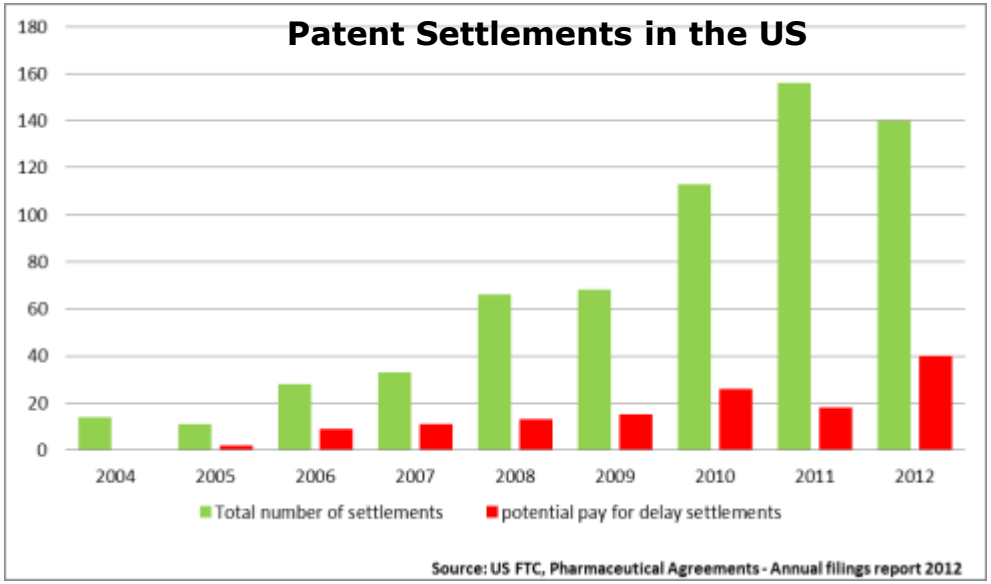
- Patent protection of great importance for innovation in pharma sector
  - Molecule patent: patent term (20 years) and Supplementary Protection Certificate (prolonging this patent up to 5 years)
  - Secondary patents: e.g., process patents and formulation patents providing more limited patent protection

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

- In EU, no exclusivity period for first generic challenger (in U.S., first generic challenger receives 180 days exclusivity).

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

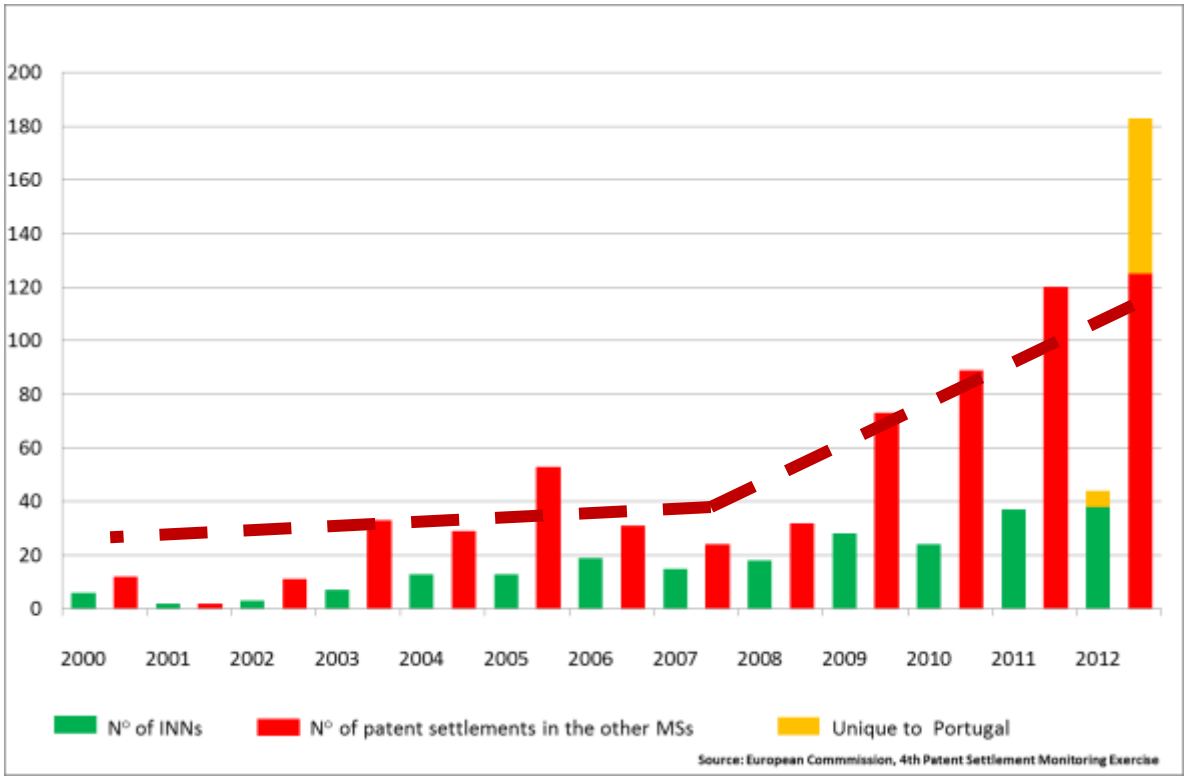




- **The vast majority of all settlements reported in the EU can be immediately classified as unproblematic.**
- **Potential antitrust scrutiny only concerns a small fringe of all settlements.**

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.

Recent cases

Commission enforcement

• Fentanyl	Decision (12/2013)
• *Lundbeck*	Decision (06/2013)
• *Perindopril (Servier)*	SO (07/2012)
• *Cephalon*	Opening of proceedings (2011)

U.S.

- Supreme Court: *Actavis* Judgment (06/2013)
- District Court of Massachusetts: *In re Nexium* (9/2013)

The Fentanyl case

Case

- 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

Procedure

- Statement of Objection issued on 30 January 2013
- Prohibition decision with fines adopted on 10 December 2013
- No appeal before the Court (see below)

Parties

Originator

HQ: United States
2012 turnover: € 52Bn

and its Dutch subsidiary

Janssen-Cilag B.V.

Generic

HQ: Switzerland
2012 turnover: € 44Bn

and its Dutch subsidiary

Sandoz B.V.
(at the time Hexal B.V., then Sandoz B.V.)

Product: Fentanyl

- A pain killer stronger than morphine
- Originally developed by J&J
- Used for chronic pain, i.e. cancer
- In the form of transdermal patches in this case

2 types of Fentanyl transdermal patches

Depot patch	Matrix patch ("next generation")
Product in a 'reservoir'	Product embedded in layers

Starting point: Novartis/Sandoz about to launch

Novartis/Sandoz was ready to launch its generic depot in summer 2005

- Fentanyl depot patch has never been protected by a patent in the Netherlands
- It had obtained a marketing authorization
- Packaging material had been produced
- Depot patch considered substitutable to new "matrix" patch by decision of the Dutch authority

Novartis/Sandoz's planned launch constituted a threat to J&J's sales and profits

- Loss of market share
- Lowering of prices at the time generic entry due to Dutch regulatory framework

Negotiations: Reasoning of the parties

Reasoning of J&J as shown by contemporaneous evidence of internal discussions:

- Novartis would abstain from entering the Dutch market in exchange for

" a part of [Johnson & Johnson's] cake"

- The aim of the deal was

"not to have a generic on the market and in that way to keep the high current price"

The Co-promotion agreement

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

For 17 months, Dutch patients had to pay an artificially high price – more than 30% higher

Conclusion and fines imposed

This agreement between the incumbent originator J&J and its close potential competitor constitutes a restriction of competition by object

The Commission adopted on 10 December 2013 a prohibition Decision imposing fines

	Undertaking	Fine
1.	Johnson & Johnson and Janssen-Cilag B.V., jointly and severally	€ 10 798 000
2.	Novartis AG and Sandoz B.V., jointly and severally	€ 5 493 000

Impact of the Decision

14 December 2013: Press release by Janssen-Cilag announcing it would not appeal and it is discussing compensation with health insurers in the Netherlands

Janssen announces that it will not appeal the European Commission decision relating to the co-promotion agreement the company made with Sandoz for the marketing of the DUROGESIC(r) matrix patch, which took place in The Netherlands only between 2005 through 2006.

"We accept accountability for our actions relating to this matter and acknowledge we did not act in line with the high expectations of our patients and stakeholders. We regret that because of this co-promotion agreement, health insurers did not benefit from lower generic prices during this period'', said Sonja Willems, Managing Director Janssen Benelux since 2012. Janssen is in contact with health insurers in The Netherlands to discuss this matter. At all times patients had full access to the fentanyl pain patch.

Janssen has guidelines and internal compliance efforts in place in order to prevent that this situation will repeat itself in the future.

Press release by Novartis and Sandoz announcing they would not appeal the decision and the fine

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
- Fines: Lundbeck ~ €90 million; generics ~ €50 million
- 6 appeals pending

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
  - Also: **patent acquisitions**
- **Article 102 TFEU: Comprehensive strategy** by *Servier* to prevent generic market entry when end of patent protection for *Servier's* perindopril was imminent.

=> **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. 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.

District Court *In re Nexium* (9/2013)

- **Direct proof of market power: supra-competitive price level** (cross-price elasticity only with generic Nexium).

- **No "monetary transaction" required** for value transfers.
  - AstraZeneca concluded **"no-authorized generic agreement"** with Ranbaxy (worth over $1,000,000,000)
  - AstraZeneca **forgave** Teva and Dr. Reddy **contingent liabilities** tied to **unrelated** to *Nexium* infringement suits

Thank you!

Website:

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