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# Settlement Agreements State of Play in EU Antitrust Law

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## Overview of the EU landscape

- The origin
- Definition
- The issue
- Classification of patent settlement agreements
- Patent settlement monitoring
- Pending cases

## The origin: the 2008/2009 Sector Inquiry

- *“The Commission's pharmaceutical sector inquiry points to significant shortcomings in the pharmaceutical sector. Patent settlements are an area of concern, not least if there are situations where an originator company pays off a generic competitor in return for delayed market entry. We need to monitor this type of agreement in order to better understand why, by whom and under which conditions they are concluded. The monitoring will also provide us with the possibility to act should this become necessary. Since completing the sector inquiry, the Commission has launched a number of new antitrust investigations and we will continue to do so should this be necessary.”*
  - Commissioner Kroes, January 2010

## Chronology of events

- 8 July 2009: Commission Communication concluding the Pharmaceutical Sector Inquiry
- 8 July 2009: first opening of proceedings concerning a patent settlement
- July 2010: 1st Report on the Monitoring of Patent Settlements
- July 2011: 2nd Report on the Monitoring of Patent Settlements
- July 2012: 3rd Report on the Monitoring of Patent Settlements
- July 2012: first Statement of Objections in a patent settlement investigation

## A flavour of the debate

*“I regard these as major cases because they raise an important issue. Strong competition from generic competitors reduces costs for patients and health-care systems. It also keeps pressure on manufacturers of brand-name products to evolve, innovate, and become more efficient.*

*In a period when public finances are strained and many households struggle to get going, we must be particularly vigilant on the respect of competition rules.*

*But these cases are not only about access to cheaper generic medicines. They are also about the interplay of competition and intellectual property rights.*

*We know that patents are essential to encourage the development of new treatments. But the protection they offer is not boundless and unconditional; this is not how we understand the patent system.*

*In a nutshell, the question is whether holders can use their financial power to shelter their patents from lawful challenges. The incumbent producer, who holds a monopoly over the product, can afford to offer generic challengers more than they would have gained from selling the product.*

*This behaviour may be similar to that of two competitors who agree to set prices and volumes or share their markets and this should not be immune from competition scrutiny.*

*Our on-going investigations will help to draw a line to prevent patent-system abuses in the industry. But obviously, we will listen carefully to the arguments made in each case before taking our decisions.”*

Commissioner Almunia at the IBA, Sydney, March 2013

## EU definition of patent settlement agreements

- Commercial agreements to settle patent-related disputes
  - Patent infringements
  - Patent validity
- Concluded in the context of non-adjudicated
  - Patent disputes
  - Opposition procedures
  - Litigation
- With a view to ending the disagreement

## The issue from the EU's perspective

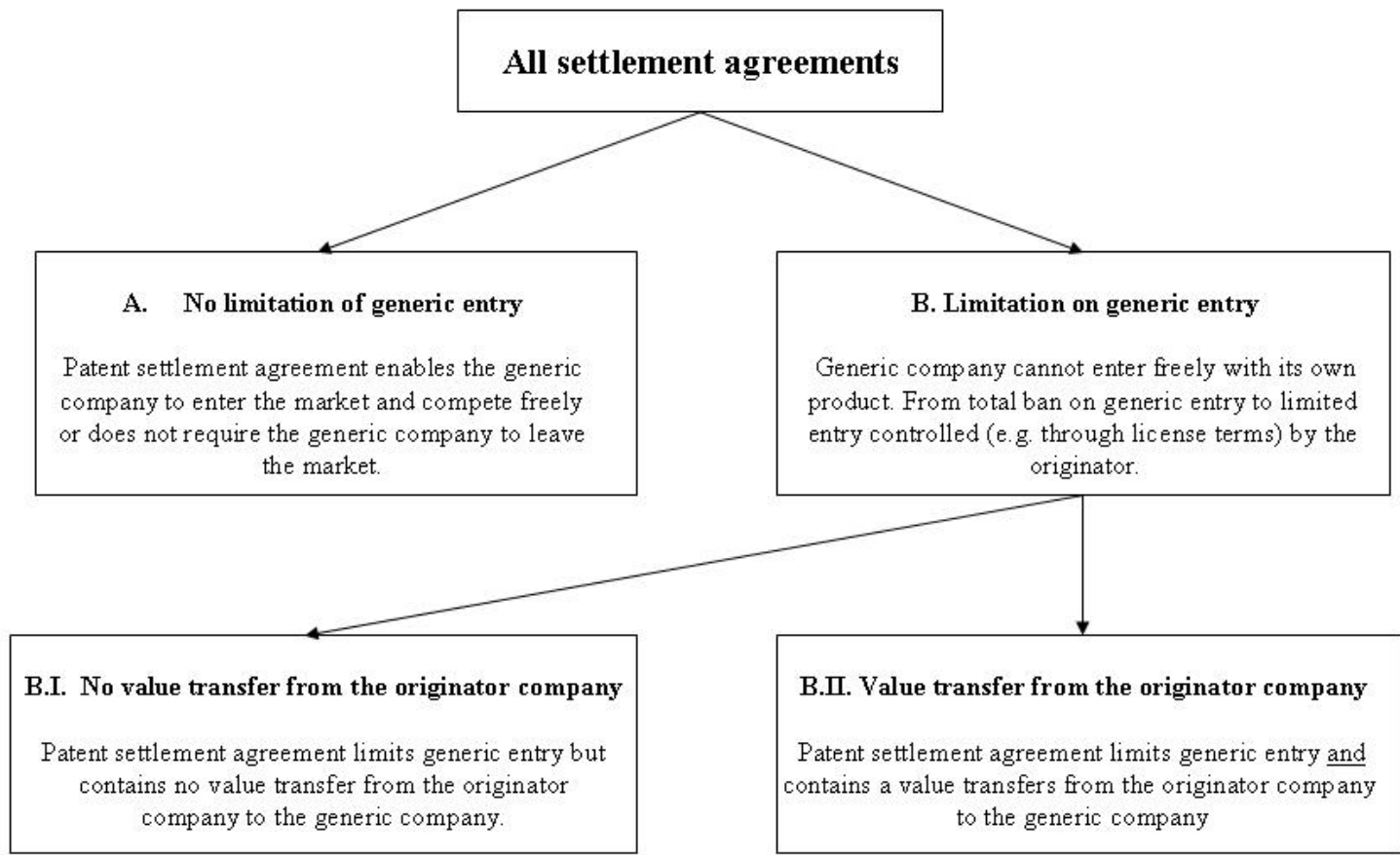
- Pro
  - Legitimate way of ending private disagreements
  - Discontinue dispute/litigation because too costly, time-consuming and/or risky as regards its outcome
  - Can save courts and/or patent offices etc time and effort
- Con
  - Delay of generic entry in return for value transfer
  - Restrictions beyond patent's geographic scope, period of protection or exclusionary scope
  - Patent holder knows patent does not meet patentability criteria – e.g. granted based on provision of incorrect, misleading, or incomplete information
- Draft revised guidelines on technology transfer
  - *“licensor provides an inducement, financially or otherwise, for the licensee to accept more restrictive settlement terms than would otherwise have been accepted based on the merits of the licensor's technology”*

## EU classification of settlement agreements

- Guiding principles:
  - Does agreement limit generic company's ability to market own medicine?
  - Does agreement foresee value transfer from originator to generic company?
- Examples of limitations:
  - No-challenge clause
  - Non-compete clause
  - Originator licenses generic company (with some except.) or appoints generic company as distributor
  - Generic company agrees to source API from originator
- Examples of value transfers
  - Monetary transfer (incl. for payment of generic stock)
  - Distribution agreement
  - "Side-deal" (e.g. enter market before patent expiry or allow market entry with other product marketed by originator)
  - License generic company to enter market
  - BUT: check also net amount of transfer and any justification



# Sector Inquiry Classification Tree



## Patent settlement monitoring

- Each year since January 2010
- Information requests to selected number of originator and generic companies asking for copies of relevant patent settlement over past year - no additional background information requested
- In case a specific settlement raises additional questions, more targeted request for information may follow.
- Commission analyses the agreements and publishes short report providing a statistical overview.
- Will be repeated annually “*for as long as the Commission considers that there is a potential problem*”.

## The trend as per the EC's monitoring

- Substantial increase in settlements overall: 120 in 2011 compared to 24 per year in the period Jan 2000-June 2008
- The proportion of potentially problematic settlements has stabilised at a low level of 10-11% - compared to 21% in the findings of the Sector Inquiry

# PENDING CASES

## CITALOPRAM

- Settlement agreement between Lundbeck and 4 generic competitors re its citalopram antidepressant
- Proceedings opened in 2010, SO issued in July 2012
- Generic manufacturer agreed to abstain from entering the market after certain of Lundbeck's patents had expired
- Three types of value transfer at issue:
  - direct payments
  - purchases of generic citalopram stock for destruction
  - guaranteed profits in distribution agreement

## PERINDOPRIL

- Settlement agreement between Servier and 5 generic competitors re its perindopril cardio-vascular product
- Proceedings opened in 2009, SO issued in July 2012
- Servier is alleged to have induced its generic challengers to conclude settlements when its patents were about to expire
- Value transfer at issue: direct payments
- Coupled with patent acquisitions that could potentially shut out competitors from the market (abusive conduct)

## MODAFINIL

- Settlement agreement between Cephalon and Teva re its modafinil product for treatment of certain sleeping disorders
- Proceedings opened in April 2011
- Believed to relate to direct payment and side deals in return for delayed generic entry
- Cfr also U.S.