Research Project

Patent Settlements within the Complex Institutional Framework of the Pharmaceutical Sector

Talk of Severin Frank (Doctoral Student)

Department of Economic Policy
Philipps-University Marburg

Introduction

Patents and Antitrust (1)

- Patents should incentivize innovation
- However: We have a basic tradeoff between innovation incentives and competition regarding consumer welfare
- The question is: Should a patent holder be allowed to do everything with its patent?
- => To put it more specific:

  Which types of behavior are within the exclusionary scope of the patent?

Introduction

Patents and Antitrust (2)

What are patent settlements?

$\Rightarrow$ They resolve a patent dispute

$\Rightarrow$ They may fix an entry date

$\Rightarrow$ They may involve value transfers

- Particular: focus of my research: Patent Settlements in the Pharmaceutical Sector between Originator and Generic Firms.

Introduction

Joaquín Almunia

(Vice President of the European Commission responsible for Competition Policy)

Speech: European and global perspectives for competition policy 21/03/2013

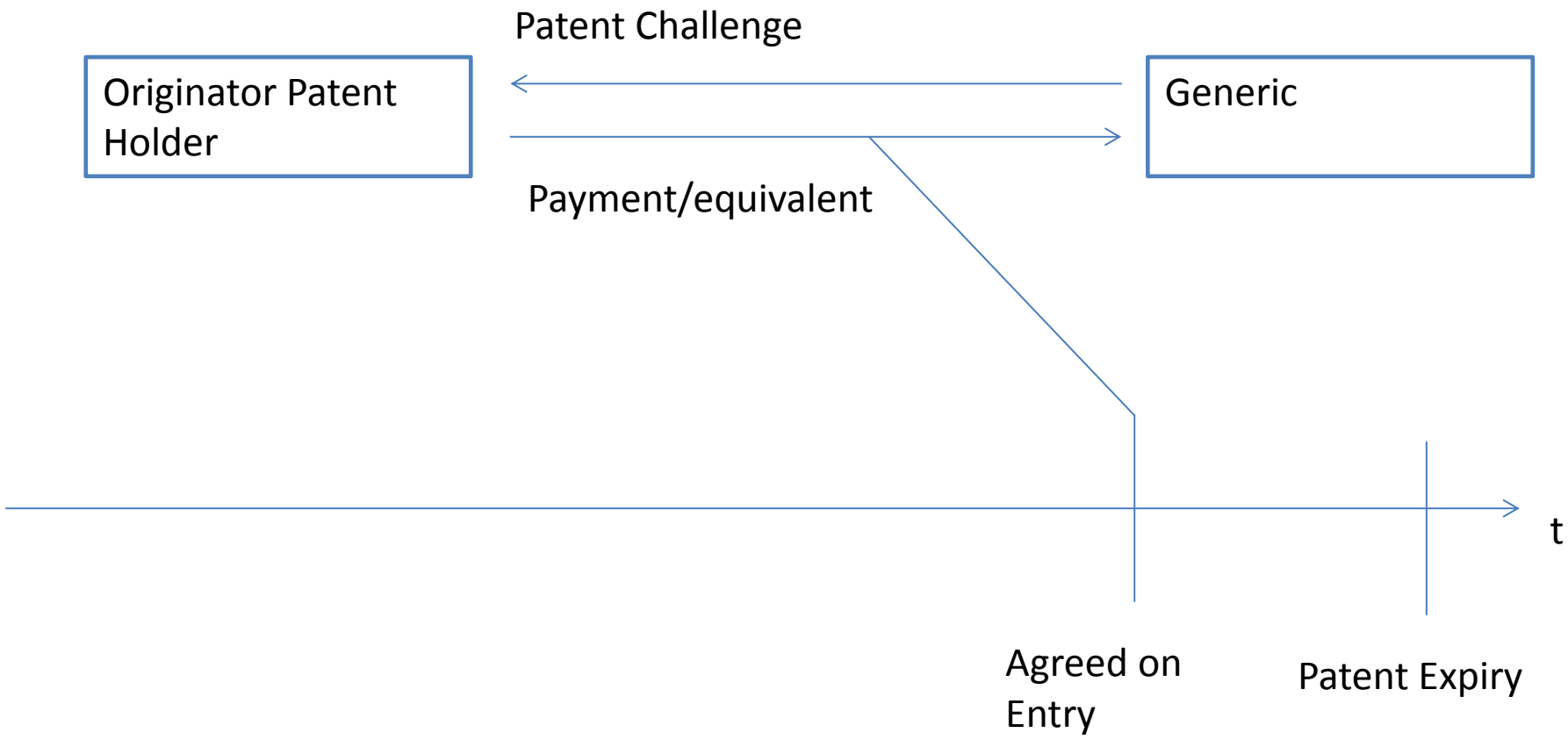
"We know that patents are essential to encourage the development of new treatments. But the protection they offer is not boundless and unconditional; this is not how we understand the patent system.

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."

Background: Pay for delay agreements

Pay for delay Structure (also known as Reverse Payments) (1)



Background: Pay for delay agreements

Pay for delay Structure (2)

Basic idea: Originators pay for preventing patent challenges! (the patent challenge can be prevented ex ante and ex post).

Is this a Problem?

YES

In case of an extension of the patent grant via the patent settlement clearly anticompetitive => cartel agreement => no dispute

NOT SO CLEAR

In case of generic entry before patent expiry problematic only if weak/invalid patents are assumed (Why should this be the case?)

Background: Pay for delay agreements

Weak Patents (1)

However:

Empirics show that patents are often rejected/adjusted in courts or by the patent offices.

E.g. Data of the the EC suggests that generics were successful in approx. 60% of secondary patent oppositions

$\Rightarrow$ THEREFORE there is a chance that the patent is invalid

Background: Pay for delay agreements

Weak Patents (2)

As the validity of patents is decided by courts (lengthy process), also the **mere chance of invalidity** (prospect of lower prices due to earlier generic entry for consumers) is significant => Weak Patent Argument!

But: How can we assess this likelihood of patent invalidity?

Answer: One can look at the terms of the patent settlement.

- Value Transfer
- Entry Date

Background: Pay for delay agreements

The Assessment of Patent Settlements

In Europe patent settlements are assessed as horizontal agreements under Art. 101 TFEU (Sec 1 Sherman Act in US) which however can be exempted by Art 101 (3) TFEU.

Patent Settlements can entail efficiency advantages such as

- Saving of litigation costs
- Earlier generic market access
- Reduction of uncertainty
- Correction of not sufficient patent length granted by patent offices

THEREFORE: Careful assessment needed. EC and US authorities agree on that

US Experience

The role of Regulation (1)

The Pharmaceutical Sector is highly regulated.

Why is regulation important? Example U.S. Hatch-Waxman Act

The Hatch-Waxman Act (1984) regulates generic entry into the market and aimed at facilitating generic access

Patent opposition and drug approval are an integrated process

E.g.

- 180 day rule => mitigates free rider problem for generics and encourages challenges, facilitates patent settlements

US Experience

The role of Regulation (2)

Result of HWA

- Strong position especially of first generic challenger
- Upcoming pay for delay agreements undermining the original aims of HWA
- Competition Authorities took action
- Recently: Supported by Supreme Court in Actavis Decision

EU Experience

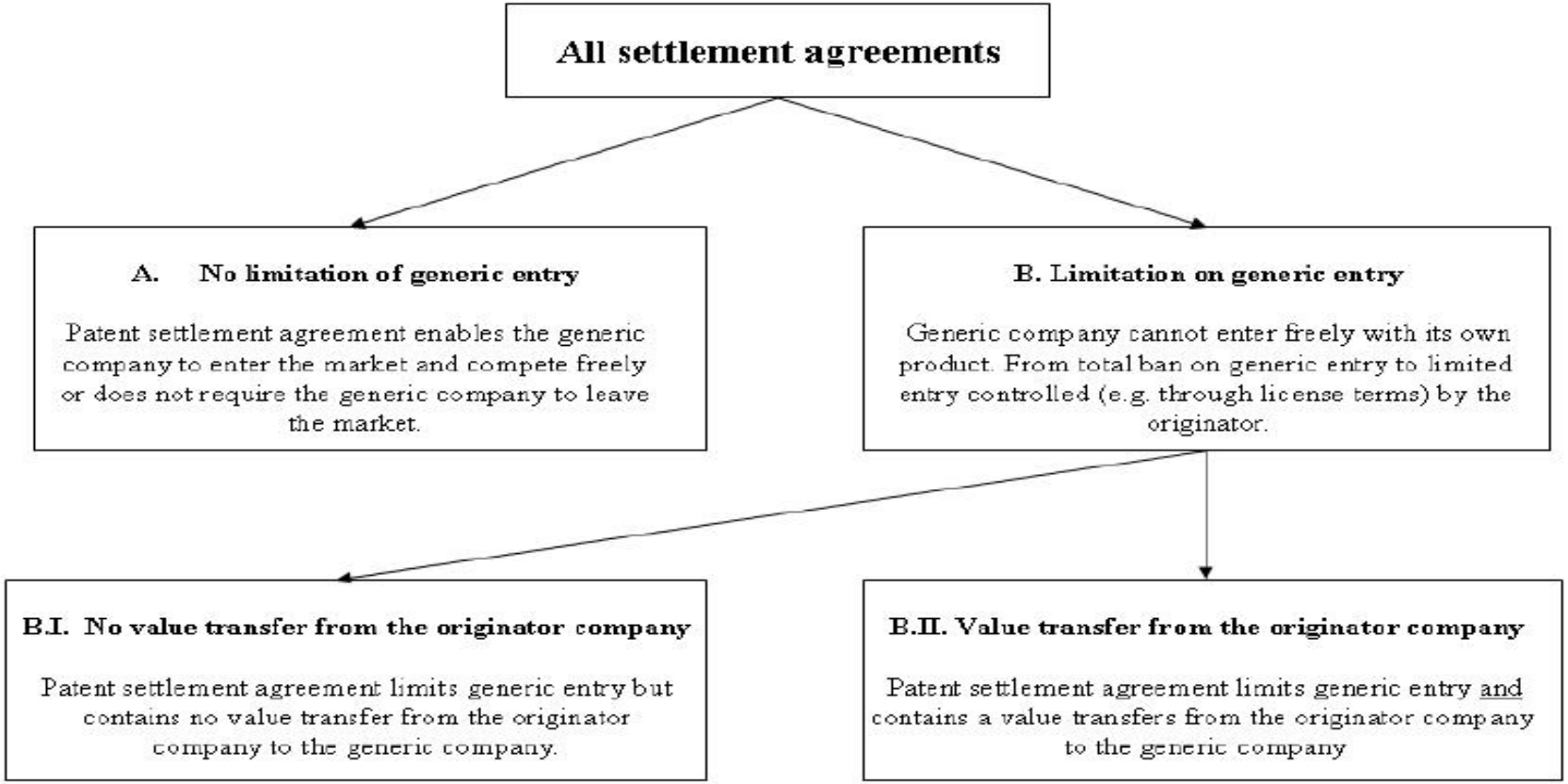
Patent Settlements in Europe

Generally similar problem in EU but different regulatory framework in the pharmaceutical sector.

EU conducted a Pharma Sector Inquiry and Monitoring of Patent Settlements

Moreover the EU competition rules were recently adapted with effect of May 1 2014 to include the assessment of patent settlements

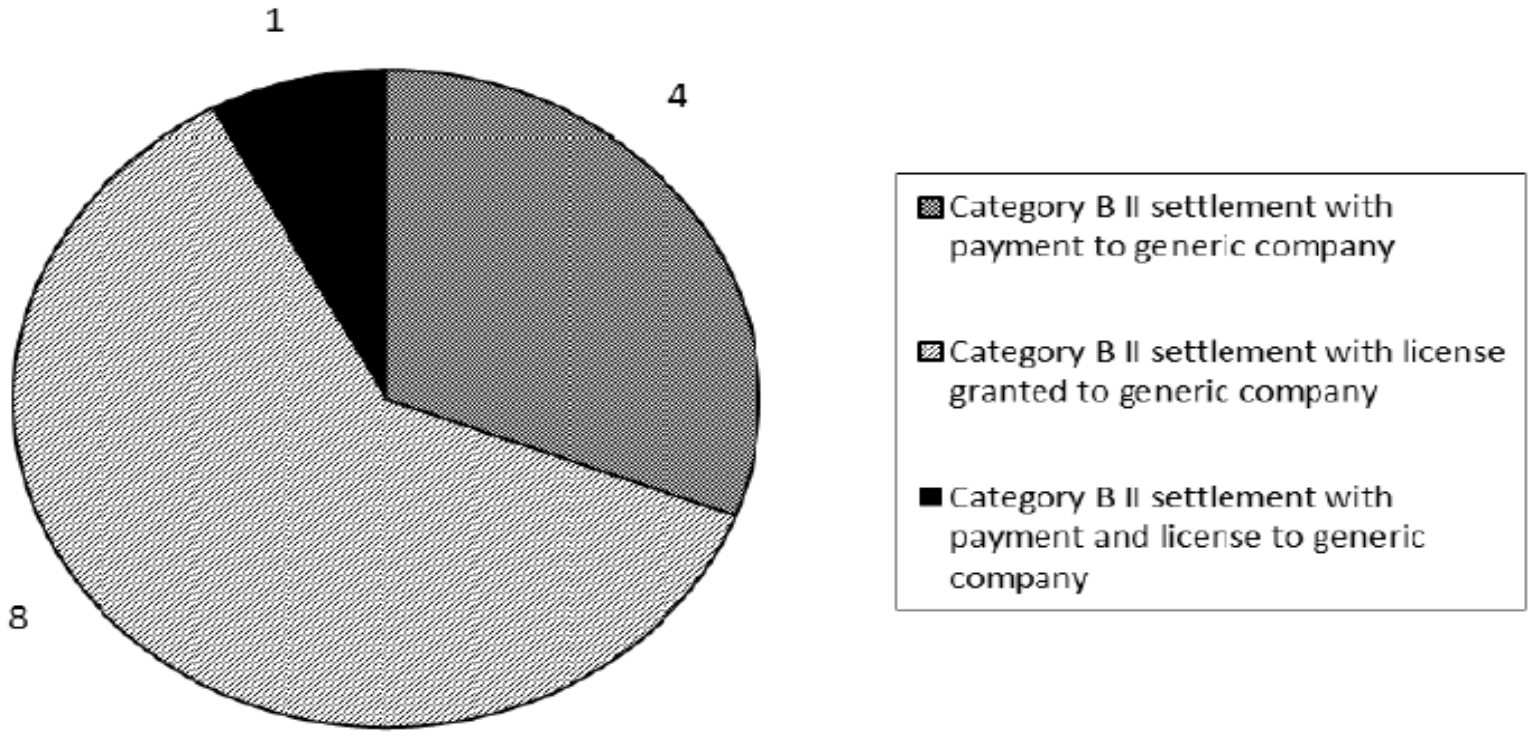
EU perspective



Source: Final Report concluding the Pharmaceutical Sector Inquiry of 8 July 2009

EU perspective

Figure 7: Number of B II patent settlements per type of value transfer (January 2011 - December 2011)

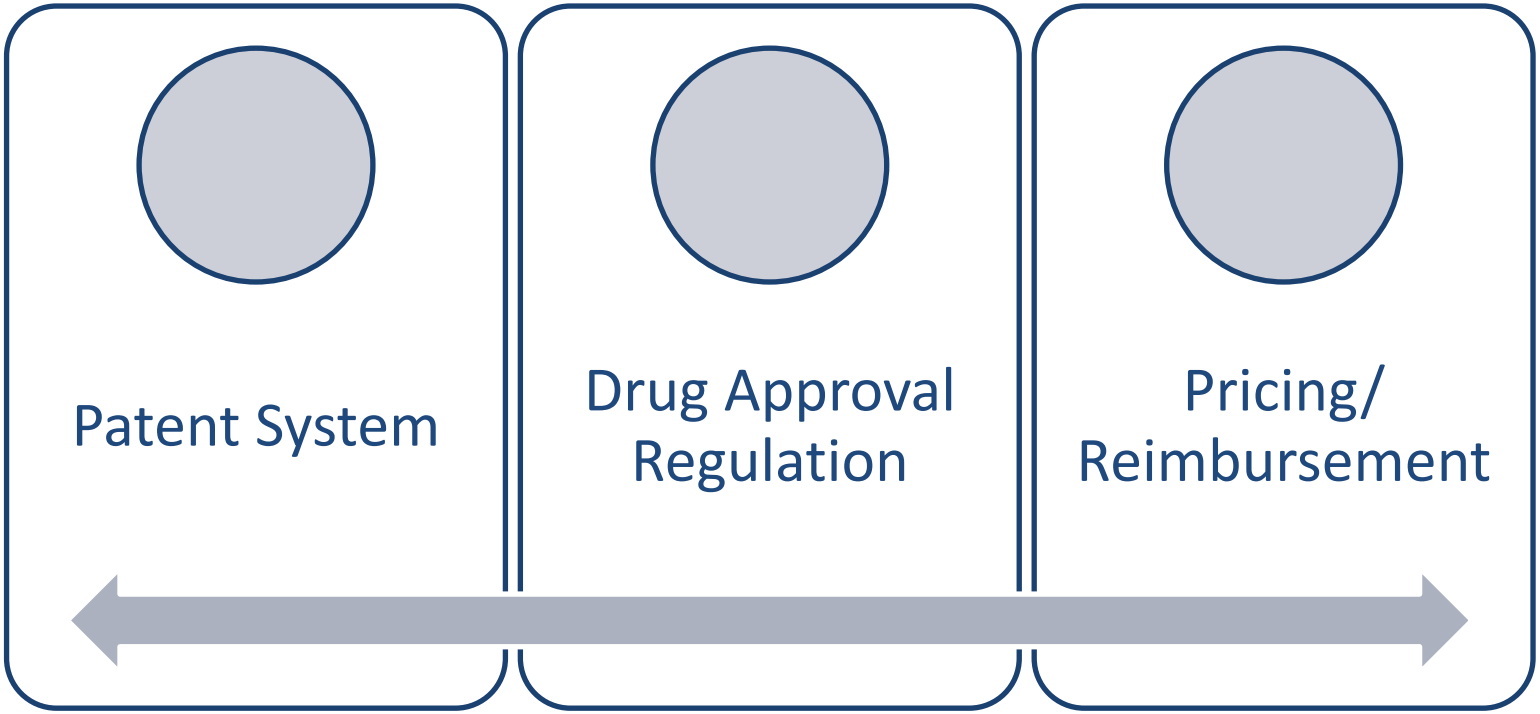


Source: European Commmission, 3rd Patent settlement Monitoring Exercise

EU perspective

The entire regulatory framework is relevant for assessing pay-for-delay agreements and in Europe it is clearly different compared to the U.S.

=> Less integrated System



The Interplay of EU Institutions affecting Originator-Generic competition

Overlapping Intellectual Property Rights

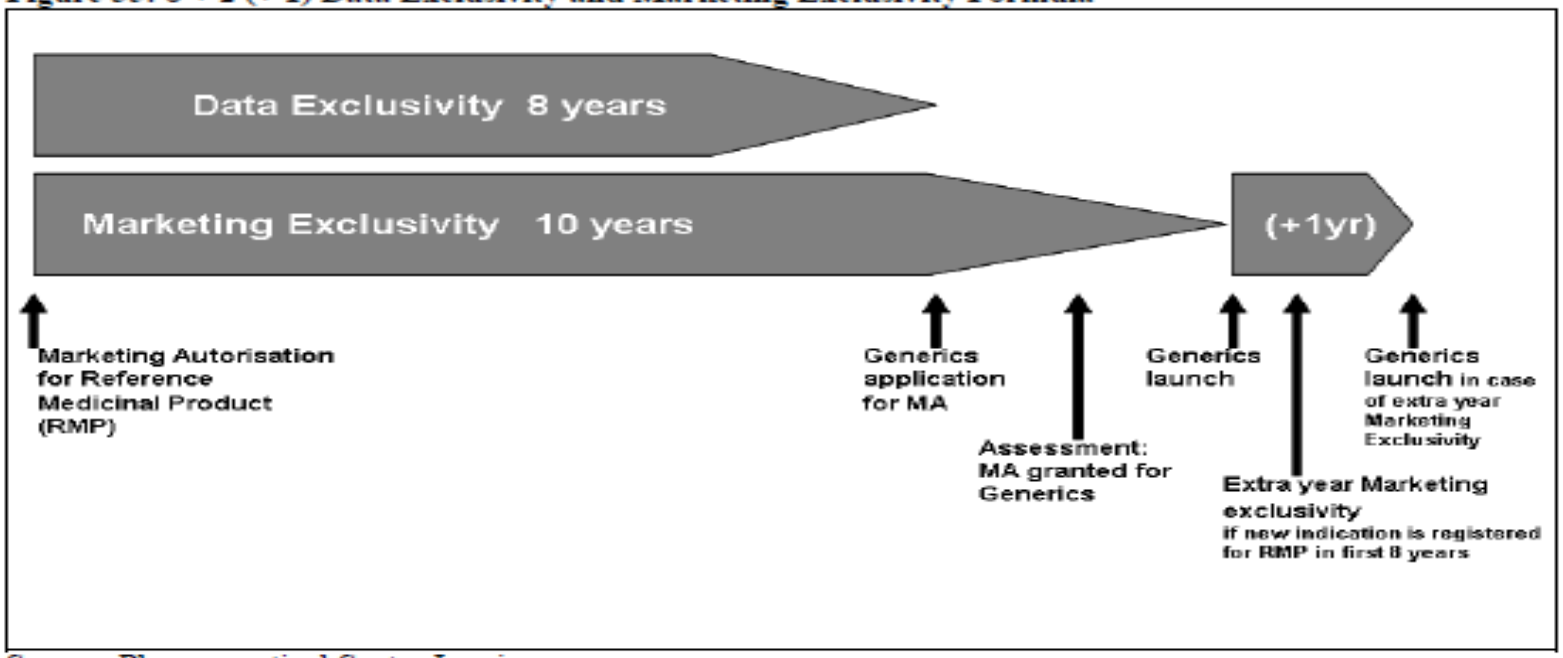
For the assessment of patent settlements the aspect of overlapping Intellectual Property is especially interesting consisting of

- patent protection
- Data protection for clinical trial data (however: generics have a access right)
- Marketing exclusivity granted by regulatory bodies

These mechanisms are available in the EU and the US and partly more important than patent protection.

The Interplay of EU Institutions affecting Originator-Generic competition

Figure 35: 8 + 2 (+ 1) Data Exclusivity and Marketing Exclusivity Formula



Source: Pharmaceutical Sector Inquiry

Source: EC Pharma Sector Inquiry – Final Report, p. 128.

The Interplay of EU Institutions affecting Originator-Generic competition

Case Groups: Lets assume in a settlement there is a value transfer from the originator to the generic. The parties agree that the generic can enter before patent expiry. Is there a problem?

- Scenario 1: Patent is close to expiry and there is no other form of marketing exclusivity
- Scenario 2: Patent still has significant lifetime but there exists some form of marketing exclusivity
- Scenario 3: Patent still has significant lifetime and there exists no form of marketing exclusivity

(Underlying Question: How important is the patent challenge for a potential invalidation)

The Interplay of EU Institutions affecting Originator-Generic competition

Assessment scheme?

$\Rightarrow$ One possibility would be an “effects-based” approach to ask if consumers are actually harmed by the settlement? (“what-if analysis”)

Europe:

-EC agrees to Weak Patent argument

-Newly adapted EC Guidelines consider Settlements with a significant value transfer from the originator to the generic or regarding patents granted on the basis of false information as problematic.

The Interplay of EU Institutions affecting Originator-Generic competition

Ongoing research:

-Empirical Work: Identification of Cases and Case Groups.

-From an economic perspective: Which settlements should be permitted and which not (what are the right models)?

-Way to a more sophisticated assessment scheme for patent settlements

=> what means “significant value transfer”

=> what is, if we have overlapping Ips

=> how can different forms of value transfers be analyzed

=> how can efficiency advantages be included in the analysis