



Science For A Better Life

EU Competition Law

Pay for Delay Agreements

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Agenda

- Introduction
- Anti-Competitive Agreements
- Conclusions and some Cases for Discussions



Introduction



Balancing Patents and Antitrust

“Intellectual property enables vibrant technology markets”

“Intellectual property rights reward creativity and human endeavour which fuel the progress of humankind.”



“... sometimes intellectual property rights can be used to restrict competition. And this is bad news for competitiveness, growth and jobs. It can also harm consumers, who should have access to a wide range of innovative and creative goods and services at reasonable prices.”



Antitrust Enforcement on Key IP Areas of Activity

Patent Settlements

especially agreements between originator and generic in pharma

Filing / Acquisition of IPR

focus on activities of dominant company seen as abusively excluding potential competitors

Licenses/Other Agreements

including cross-licenses between competitors, co-promotion etc.

Enforcement of IPR

e.g. vexatious litigation

Life Cycle Management

including “product hopping”, selective de-registration of products

Refusal of License / Access

including refusal of access to data seen as necessary for competitors





Anti-Competitive Agreements

- General
- Patent Settlements / Reverse Payment Agreements

Prohibition of Anti-Competitive Agreements: General

Art. 101(1) TFEU prohibits

- **agreements** or **understandings** between undertakings
- which have the **object** or **effect** of **preventing / restricting/ distorting competition**, and
- which may affect trade between member states.

except where the agreement satisfies **all** of the following criteria

- ✓ Improves production / distribution or promotes technical / economic progress,
- ✓ Allows consumers a fair share of the benefits,
- ✓ includes only restrictions indispensable to obtaining positive benefits, and
- ✓ does not eliminate competition for substantial part of products concerned.

Art. 101(1) and IPR

Exercise of IP rights is limited by Art. 101(1) TFEU in the same way as exercise of any other property right, i.e. if IPR are the subject of an agreement / understanding restrictive of competition, Art. 101(1) may apply.

In **practice**, main impact of Art. 101(1) on IPR exercise relates to:

- Licensing, purchase or sale of patents / other IPR;
 - R&D Collaborations and
 - **Patent settlements.**
- } *not covered in this presentation*



Not only formal written agreements but also **informal understandings** restrictive of competition are strictly prohibited under Art. 101(1), e.g.

- Collusion between competitors on patent filing, or
- Understandings between licensor and licensee on minimum price at which licensed products are to be sold.



Anti-Competitive Agreements

- **General**
 - Patent Settlements / Reverse Payment Agreements
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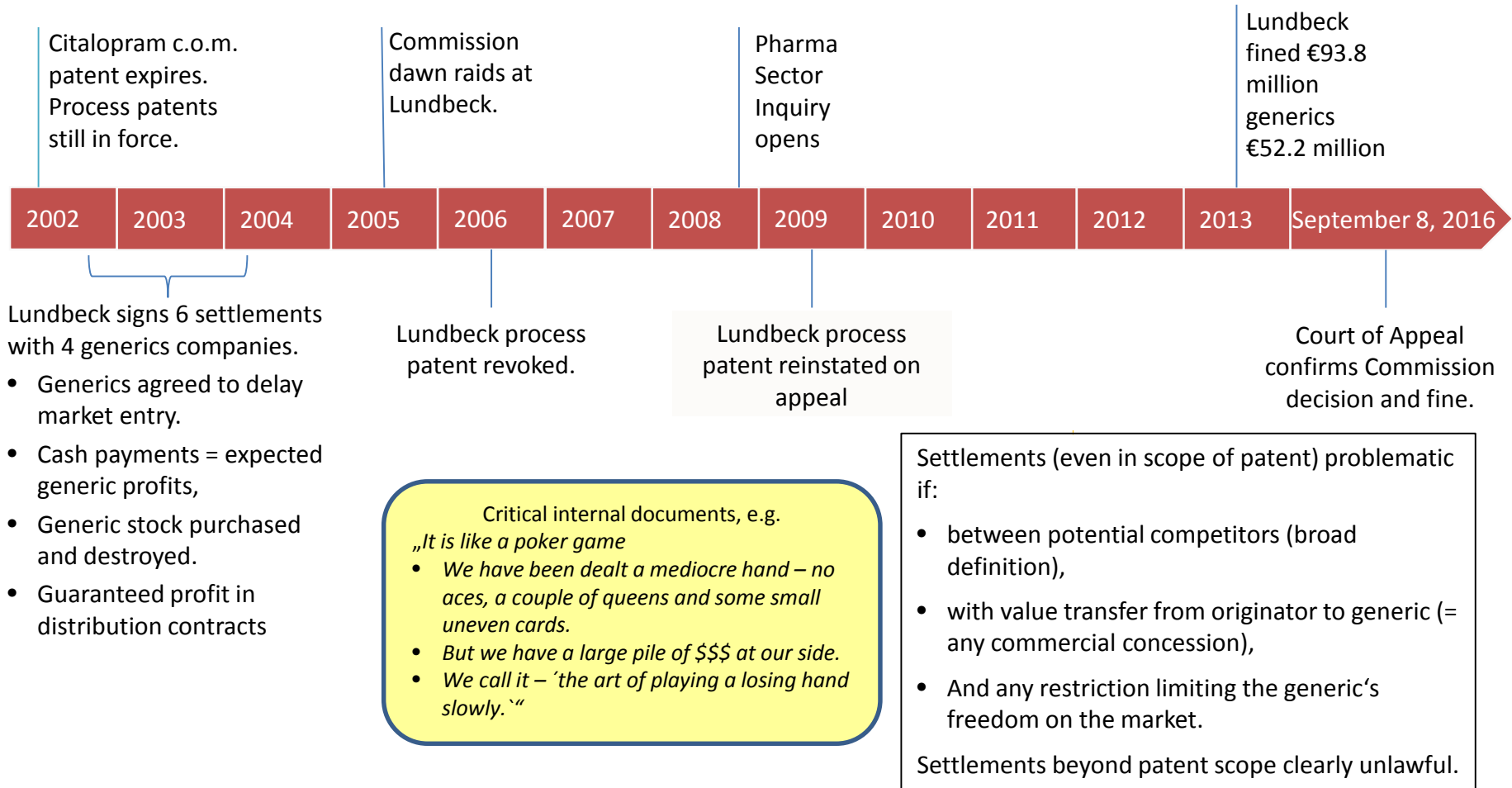
Patent Settlements: EU Focus



- „Patent settlement agreements ... are commercial agreements to settle patent-related disputes, e.g. questions of patent infringements or patent validity ... concluded in the context of patent disputes, opposition procedures or litigation where no final adjudication has been handed down
- European Commission: 3rd Report on the Monitoring of Patent Settlements



Lundbeck Patent Settlement



Servier Patent Settlements

20
03

Basic patent for perindopril expires. but process + formulation patents mean few non-infringing production technologies are available.

20
04

Servier acquires most advanced non-infringing process technology – several generics can no longer produce. Servier does not use technology.

20
05
-
20
07

Generics challenge Servier patents. Servier settles challenges when generics come close to entering the market.

- Generics agreed not to enter market until expiry of Servier patents.
- Servier made value transfer (cash, license + distribution agreement).
- Cash payments based on expected profit.

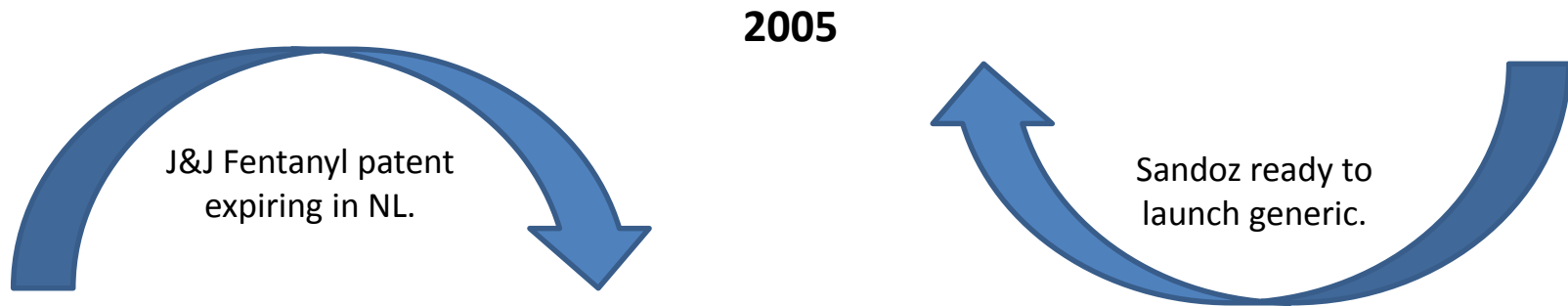
July 2014: Commission fined Servier €331 million, generics (Unichem, Matrix, Teva, Krka, Lupin) €96 million.

- Infringement by object of Art. 101(1)
- Infringement of Art. 102 (abuse of dominance)

Decision under appeal.



Co-Promotion Agreement: Janssen & Sandoz



Co-Promotion Agreement July 2005:

- Sandoz co-promotes new version of J&J's fentanyl patch in NL in return for monthly fee.
- Monthly fee exceeded likely profits from Sandoz's own patch.
- Agreement continued until end 2006 when 3rd party ready to launch generic Fentanyl.

Dec. 2013: Commission fined both parties for agreement to delay generics / market sharing.

- Clear documentary evidence that goal was to prevent Sandoz from entering market, including calculations of how high fee should be to compensate Sandoz.
- No appeal by Janssen / Sandoz.

Patent Settlements: EU Commission Guidance

- Agreements between competitors at Lol stage subject to intense scrutiny.
- Any agreement with object / effect of delaying / limiting generic entry is unlawful and subject to major fines.

Patent Settlements EU Approach		Limitation on Generic Entry	
		No	Yes
Value transfer from originator company to generic company	No	Category A	Category B.I.
	Yes		Category B.II.

- Category A settlements unproblematic
- Category B.I. unproblematic unless, e.g. outside exclusionary zone of patent or based on patent originator knows is invalid
- Category B.II. major focus of antitrust scrutiny



Some Cases for Discussions and Conclusions

Some cases for discussions:

Scenario 1: Early Entry, No Payment

- Compound patent has expired, 2 years left on process patent
- Originator and Generic commence litigation, then settle
- Parties agree that Generic may enter 12 months prior to patent expiry

Scenario 2: Early Entry, Payment of Royalty

- Same as Scenario 1 except that Generic pays a royalty
- Does it make a difference if email exchanges between the parties leading up to the settlement suggest that royalty payments being traded off against time?

Scenario 3: Pan-European Settlement

- Compound patent has expired; process patent expires in two years
- Parties are litigating at first instance in UK
- Generic has registered in Denmark and is about to enter
- Originator has won in Germany and was awarded damages; Generic has appealed
- Parties enter into a pan-European settlement whereby all litigation is dropped and Originator gives up claim to damages in Germany. Generic granted immediate entry in Denmark. Agrees not to enter in other European markets until expiry of patent

Conclusions

The effect of Lundbeck et al for the competition law practitioners

Regular interdisciplinary Information Sessions, including:

- Patent / IP counsel
- Business Development and Licensing Function
- Marketing /TA Leads / Market Access
- Legal
- Other ? , eg Finance / Controlling

Focus / Task:

- Exchange of Information
- Same level of understanding for market trends and strategy
- Not: one – sided front-end training session by legal

Information / Training on best practices for emails ...

Conclusions

Key Role of Documentation as Evidence of Intention

'We should remind ourselves what our objective is here ... **to delay for as long as possible, the introduction of a generic name** and subsequent black listing for Gaviscon while we cannibalise our NHS franchise with Gaviscon Advance.'
(Reckitt Benckiser)

'... there is abundant documentary evidence that the two key purposes underlying AZ's ... capsule deregistration and ... tablet/capsule switch ... were to prevent or ... delay generic ... market entry as well as to stop parallel trade ...'

'It is like a poker game. We have been dealt a mediocre hand – no aces, a couple of queens and some small uneven cards. But we have a large pile of \$\$\$ at our side. We call it –'the art of playing a losing hand slowly'
(Lundbeck)

'[a deal] just had to be done ... [Agreements were] mechanisms for paying a certain amount ... [Agreements related to a] weak patent [and] stopped [the generics] entering the market.'" (GSK)

One generic company acknowledged that it was being "bought out of perindopril". Another insisted that "any settlement will have to be for significant sums", to which it also referred as a "pile of cash". In internal documents, Servier commented on their "great success = 4 years won", referring to the expiry of the perindopril molecule patent back in 2003.



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Thank you!