

Strategic Patenting and Registration of Healthcare Products

Conference

EU Competition Law in Sales and Distribution of Healthcare Products

University of Basel, Faculty of Law, 19 May 2017

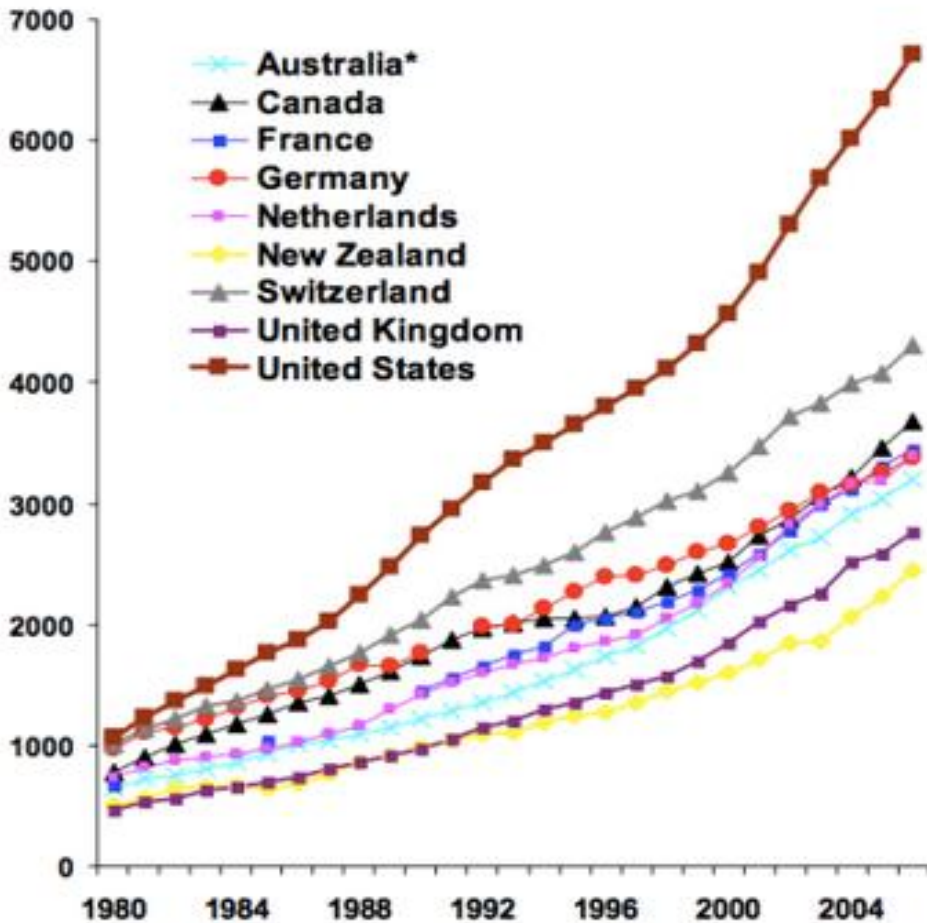
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Outline

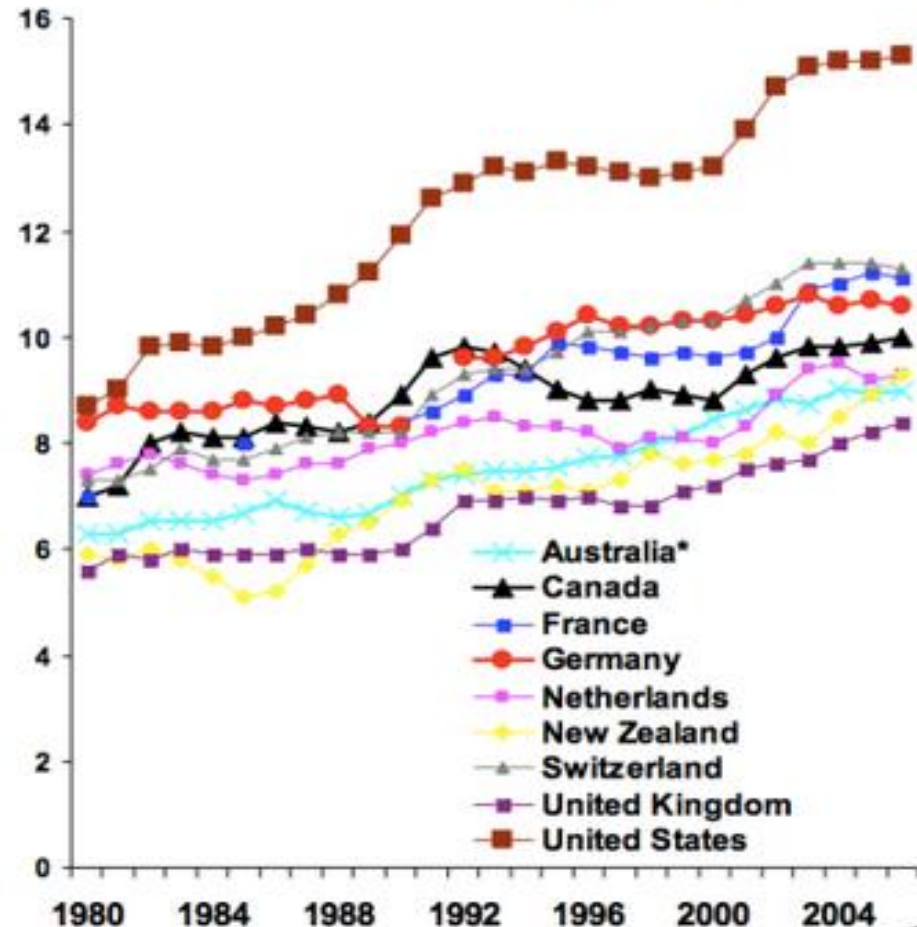
- I. Pharma Sector Inquiry
- II. Investigations and Cases
- III. Strateging Patenting and Registration?
- IV. Shortcoming in other Legal Frameworks?
- V. AstraZeneca (Losec)
- VI. Ratiopharm/Pfizer (Xalatan)
- VII. Conclusion

I. Pharma Sector Inquiry

Average spending on health per capita (\$US PPP)



Total expenditures on health as percent of GDP



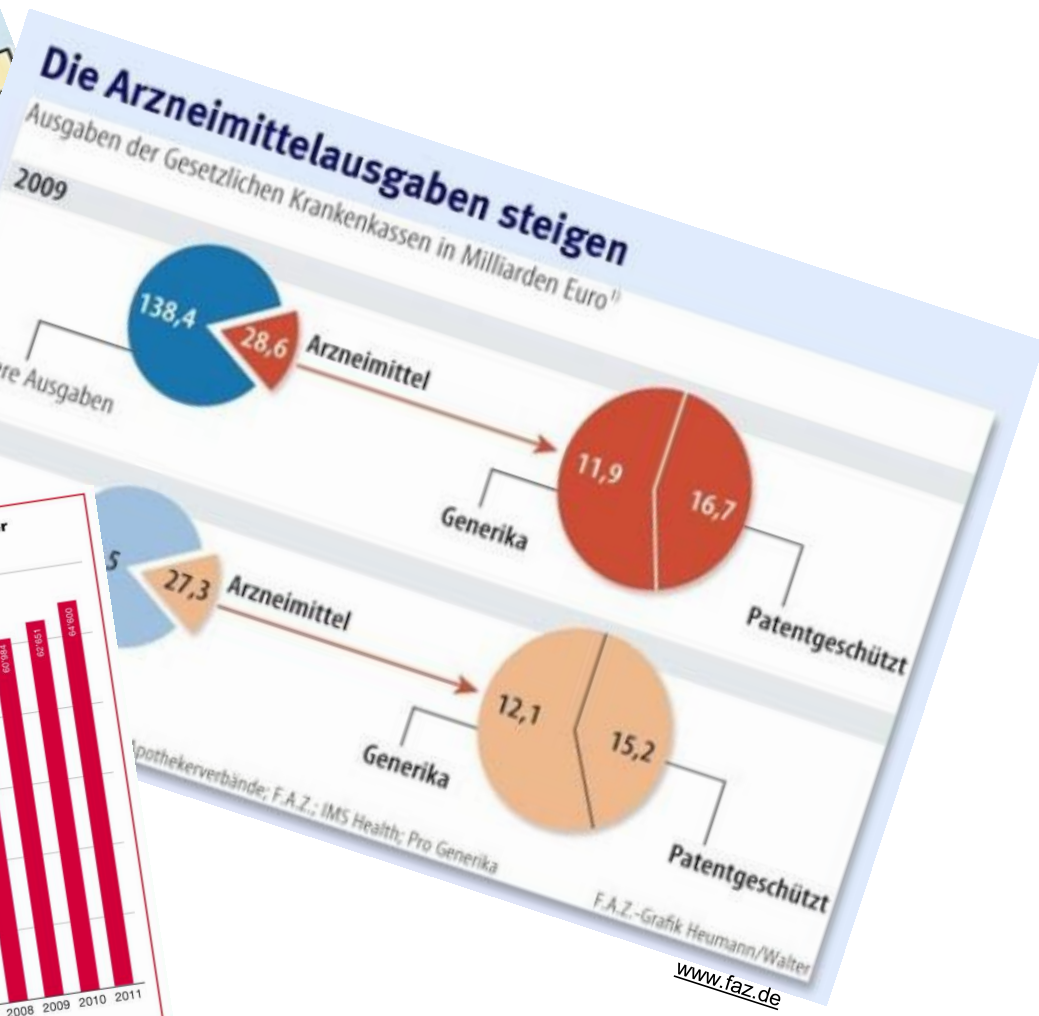
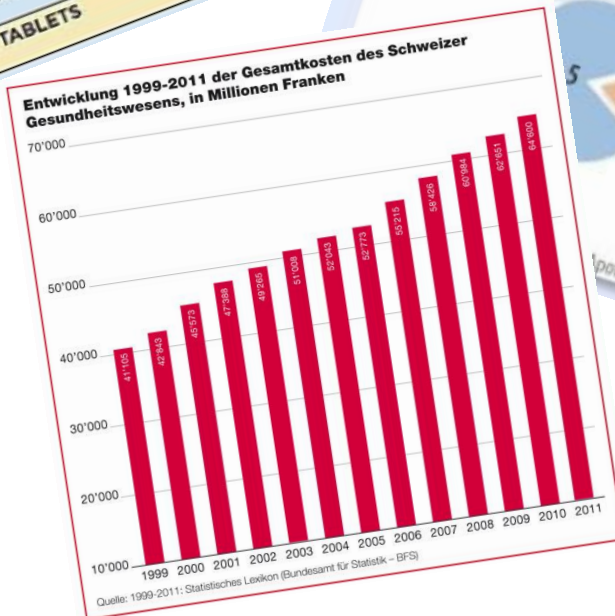
<https://epianalysis.wordpress.com/2012/07/18/usversuseurope/>

I. Pharma Sector Inquiry

How the drug prices have risen

PRODUCT	£ BEFORE	£ NOW
HYDROCORTISONE 10MG TABLETS	£5.00 2008	£44.40
FLUCLOXACILLIN 125MG/5ML IN 100ML ORAL SUSPENSION (SUGAR FREE)	£4.03 2009	£21.8
FLUCLOXACILLIN 250MG/5ML IN 100ML ORAL SUSP (SUGAR FREE)	£8.02 2009	
CIMETIDINE 800MG TABLETS	£16.01 2009	
FLUTAMIDE 250MG TABLETS	£7.00 2009	
ERYTHROMYCIN 250MG TABLETS	£6.6	200

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I. Pharma Sector Inquiry

EU Commission:

«EU's pharmaceutical are not working well: fewer new medicines are being brought to market, and the entry of generic medicines seems to be delayed»

Pharma Sector Inquiry (2008):

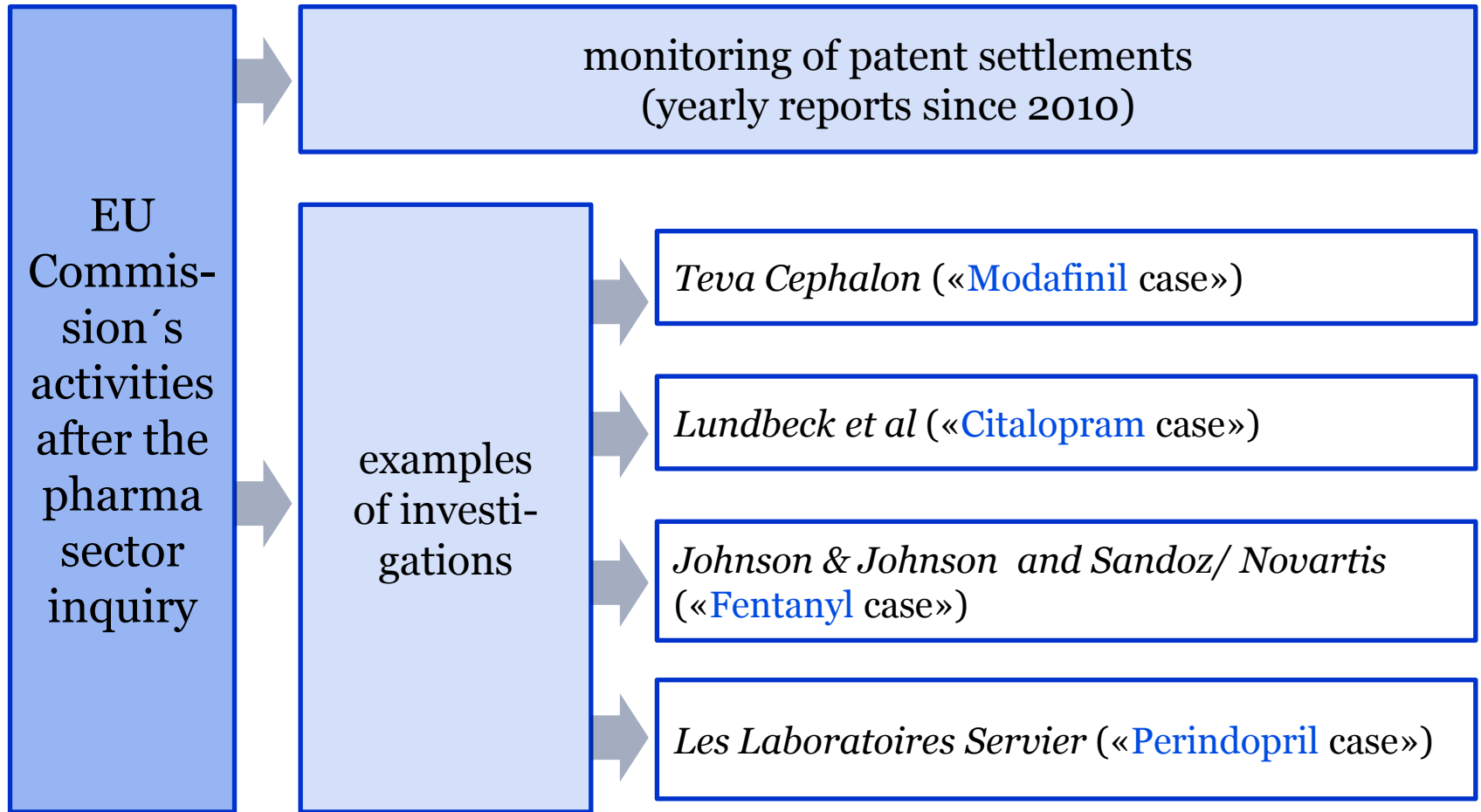
«examination whether agreements, such as settlements in patent disputes, have blocked or lead to delays in market entry and whether they have created artificial barriers to entry (through misuse of patent rights, vexatious litigation or other means)»

findings of the EU Commission's final sector inquiry report (2009)

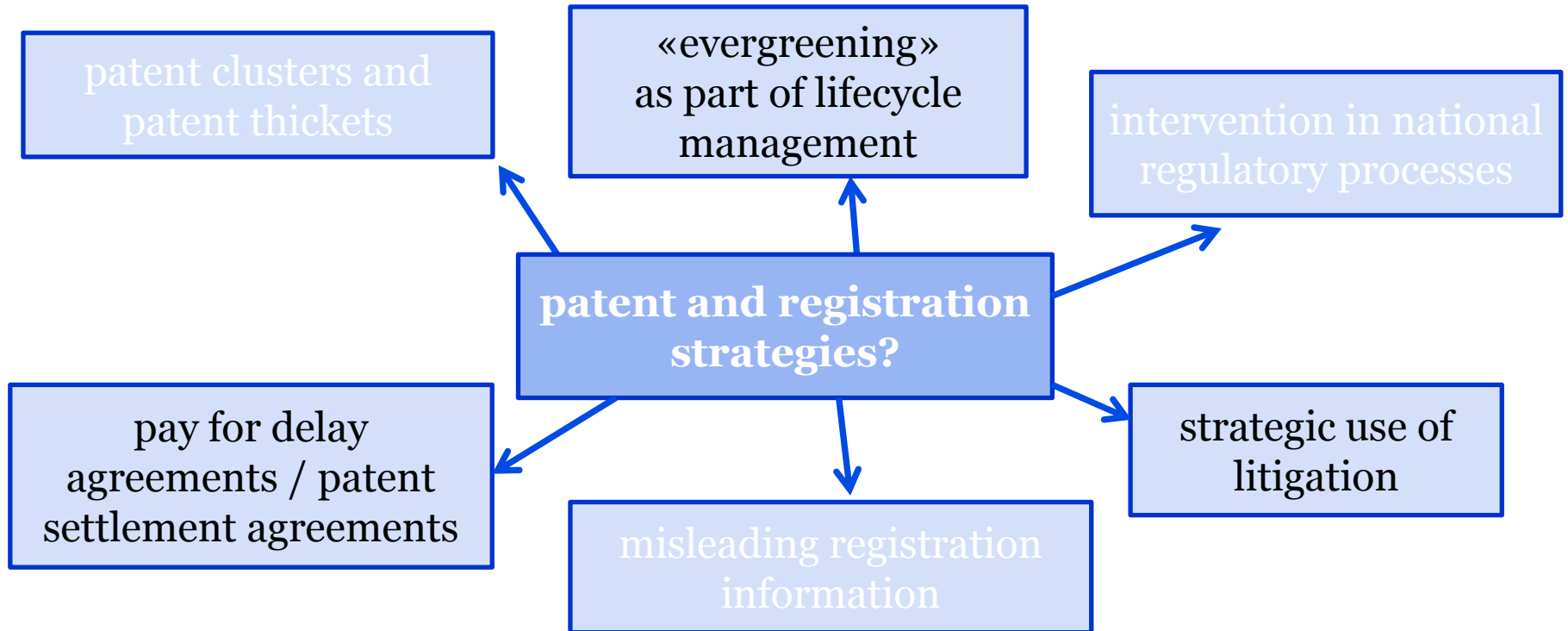
- market entry of generic drugs is delayed
- decline in the number of novel medicines reaching the market

«the sector inquiry suggests that company practices are among the causes, but **does not exclude other factors such as shortcomings in the regulatory framework**»

II. Investigations and Cases



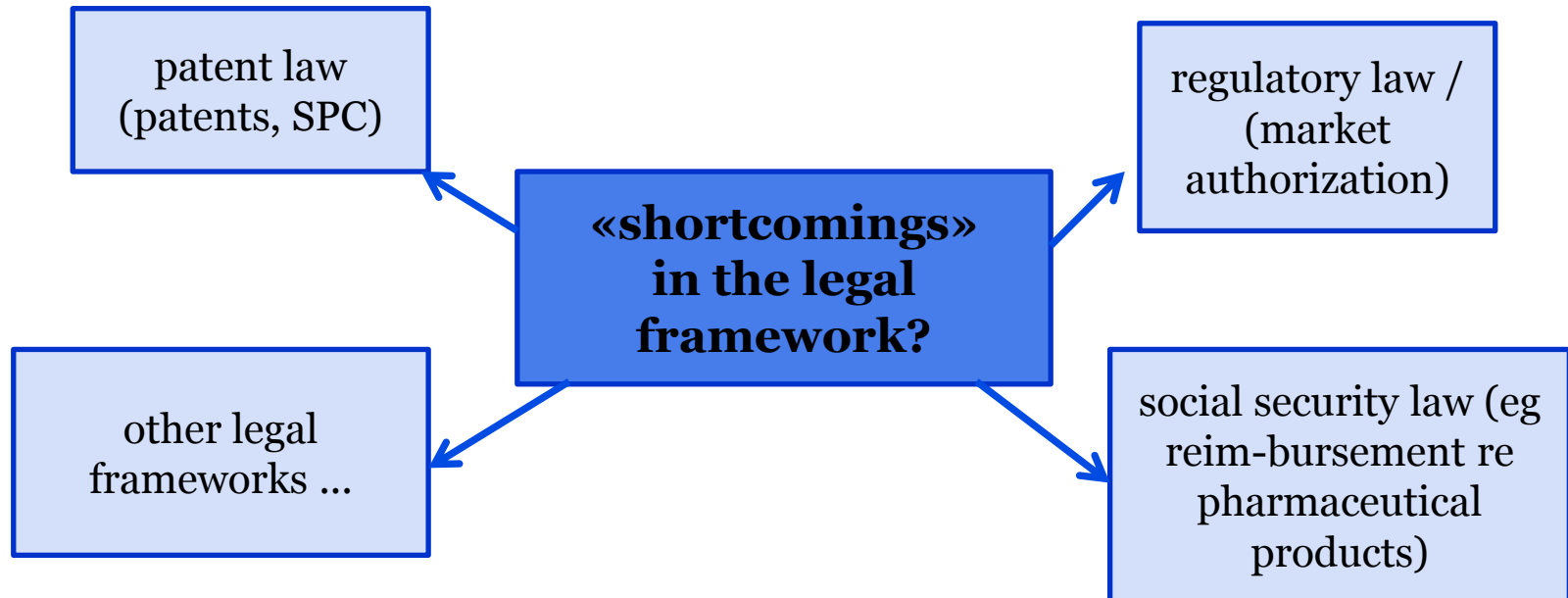
III. Strategic Patenting and Registration?



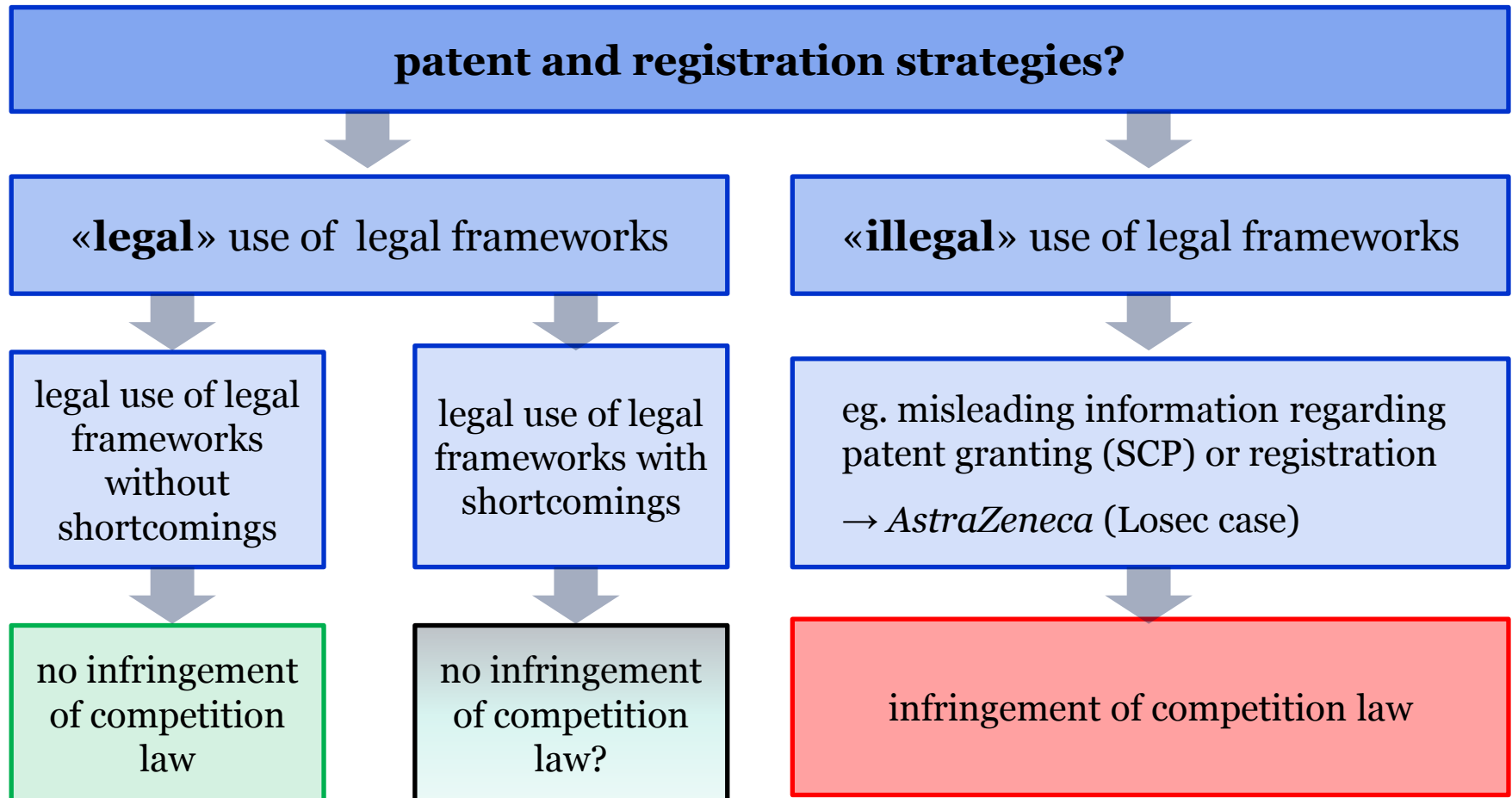
«tool box» (EU Commission):
overall strategy: block generic market entry
→ TFEU 101: restriction by object?
→ TFEU 102: misuse of dominant position?

IV. Shortcomings in other Legal Frameworks?

patent and registration strategies: competition law infringement or «shortcoming» in the legal framework?



IV. Shortcomings in other Legal Frameworks?



V. AstraZeneca (Losec)

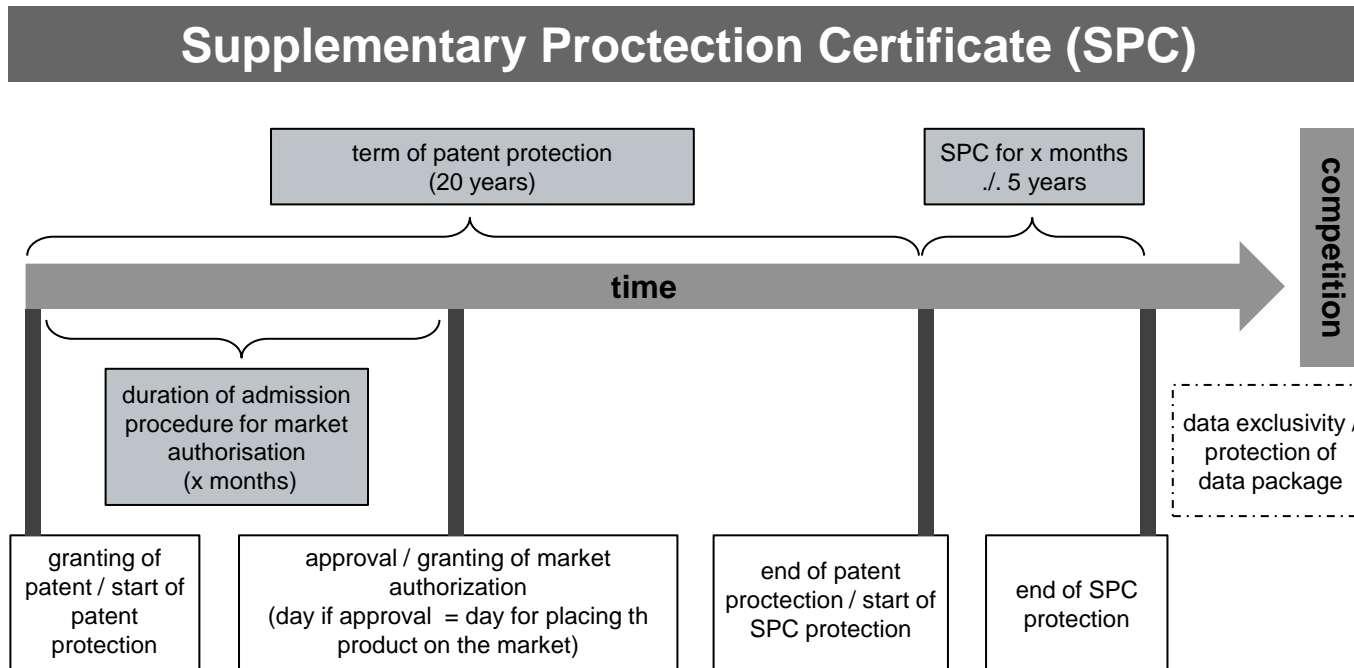
ECJ upheld Commission decision that AZ had abused its dominant position for Losec in two ways:

AZ made **misleading representations** to certain patent offices in Europe to obtain or maintain supplementary protection certificates (**SPCs**) that extended the exclusivity for Losec to which it was not entitled or only for a shorter duration

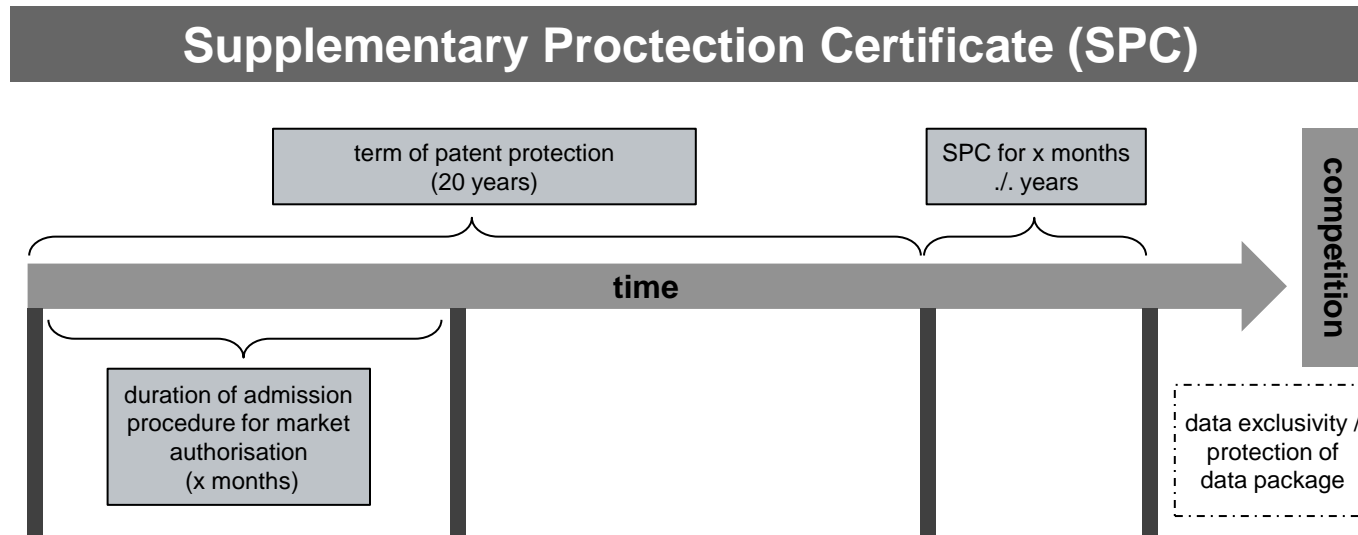
AZ **misused** the **regulatory system**, by submitting requests for **deregistration** of the marketing authorisation for Losec capsules in certain MS in order to block or delay the entry of generic products replicating AZ's Losec and to prevent parallel imports of Losec

first case in which two **novel abuses** were held to infringe TFEU 102 and the first time that the ECJ ruled on an abuse of a dominance case in the pharmaceutical sector

V. AstraZeneca (Losec)



V. AstraZeneca (Losec)



EU Commission:

AZ has indicated the «date of the first pricing decision» instead of «date of the first authorisation to place the product on the market» in order to obtain a longer period of protection

- misleading representations to the patent offices of certain MS in order to obtain or maintain SPCs for Losec
- purpose of extending patent protection to which is not entitled in order to block generic competition
- outside the scope of «competition on the merits»

V. AstraZeneca (Losec)

open questions:

misleading representations to obtain or maintain **SPCs**

- a simple mistake in communication with the patent office is unlikely to be enough to find an abuse
- highly misleading representations made with the aim of leading public authorities into error is abusive
- it remains unclear as to what behaviour will amount to abusive conduct between these two extremes

misuse of the regulatory system by **deregistration** of marketing authorisation for Losec capsules

- deregistration abuse is of limited relevance because of the change in the laws to avoid a repetition of the AZ case
- **BUT:** question remains whether and if yes, to what extent a dominant position leads to an obligation to maintain market authorisations for simplified authorisation procedures for competitors (generic companies)

V. AstraZeneca (Losec)

**«competition
on the merits»**

boundary

**misuse of dominant
position
(exploitative or
exclusionary abuse)**

V. AstraZeneca (Losec)

EJC:

- TFEU 102 prohibits a dominant undertaking from eliminating a competitor and strengthening its position by using methods other than those within the **scope of competition on the merits**
- no company is liable merely for ordinary fallibility in dealings with regulatory authorities or a patent application was found not to meet the patentability criteria

boundary

«mine field»

- scope of obligations resulting from a dominant position?

[TFEU does not constitute an exhaustive list of forms of abusive behaviour]

VI. Ratiopharm/Pfizer (Xalatan)

Pfizer hold a European patent for Xalatan. The Italian Competition Authority found that Pfizer was in breach of TFEU 102 because of unlawfully delaying the entry of competitors for the market of Xalatan.

BUT: Pfizer simply used legal instruments available to obtain divisional patents for Xalatan in order to be entitled to a SPC for Xalatan which otherwise would not have been possible since Pfizer missed the deadline for the extension of the basic patent protection.

→ Pfizer's way of conduct was legitimate under patent law, but according to the authority anticompetitive

The authority placed too much focus on the anti-competitive effects of the conduct and shifted the balance too far in favour of the generic companies

disregard of the principle of «competition on the merits»

VII. Conclusion

- TFEU 102 leaves some scope for new forms of abusive behaviour and may lead to the question to what extent unfair competition of a dominant undertaking does constitute an abusive behaviour.
- It is not yet clear to what extent a dominant position may lead to obligation to protect competition (and competitors).
- Competition law should not be used as a tool to cure mistakes for shortcomings in other legal frameworks.

Thank you!



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