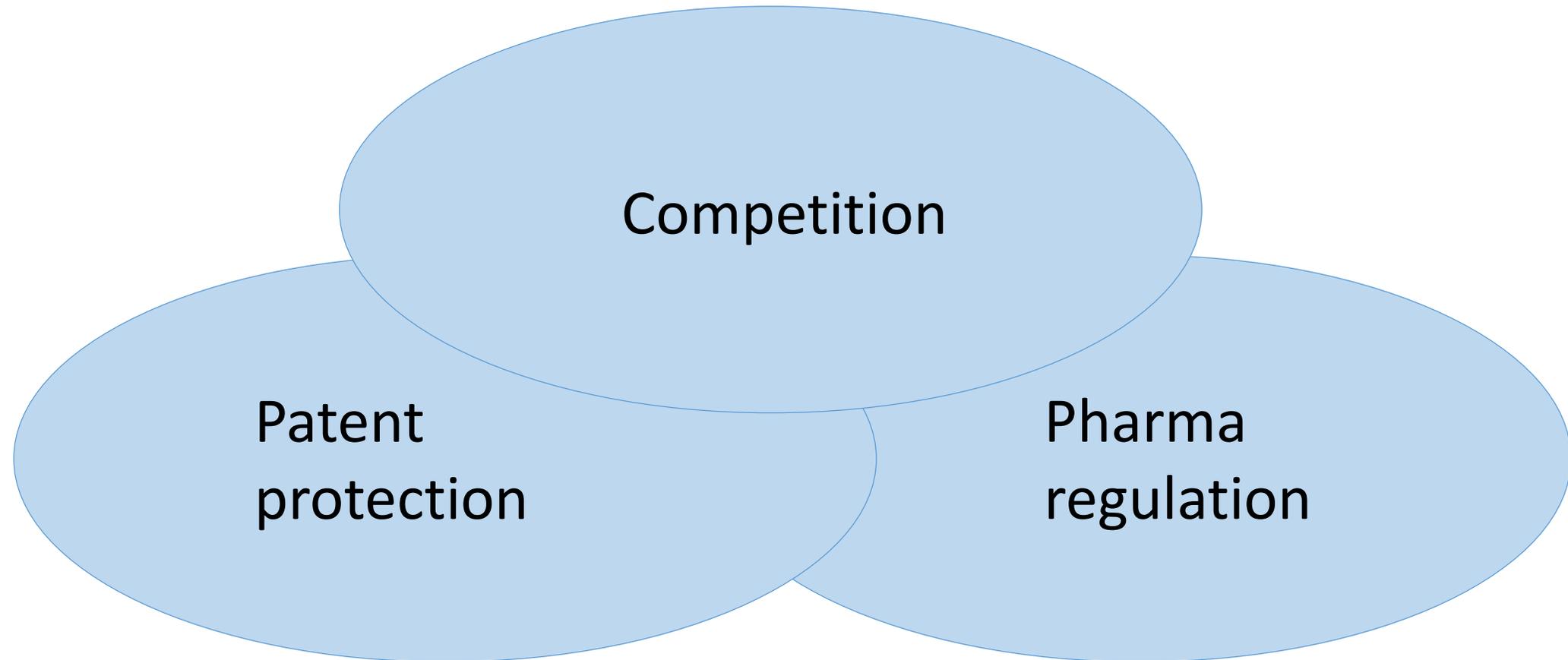


# The context-dependency of pharmaceutical antitrust

Dr Sven Gallasch  
UEA Law School  
Centre for Competition Policy,  
United Kingdom

This interplay is heavily context-dependent



# Examples of context-dependency

## Pay for delay settlements in the US

- Anticompetitive potential in the US
  - **Anticompetitive foreclosure** can be achieved by settlement with a *single* generic competitor
    - Hatch Waxman Act does not allow FDA approval of subsequent generic entrant until 180 day generic exclusivity for first-filing generic has expired (linkage between brand patents and drug approval)
    - Start of generic exclusivity is stipulated in pay for delay settlement

# Examples of context-dependency

## Pay for delay settlements in the EU

- Anticompetitive potential in the EU
  - Patent linkage is expressly prohibited
    - Drug approval only determined by safety and efficacy
    - Pay for delay settlement with single generic entrant cannot prevent subsequent generic entry (no US-style regulatory bottleneck)

Foreclosure only possible if all competitors are paid off

**HOWEVER, delay of a viable generic entrant possible that can facilitate unilateral anticompetitive conduct**

# Examples of context-dependency

## Product Hopping in the EU and UK

- Exclusionary strategy involving the brand company's reformulation of its brand drug
- Reformulation (product switching) itself not anticompetitive

*'as a strategy whose object it is to minimise the erosion of its sales and to enable it to deal with competition from generic products is legitimate and is part of the normal competitive process, provided that the conduct envisaged does not depart from practices coming within the scope of competition on the merits, which is such as to benefit consumers.'*

*C-457/10 P AstraZeneca v European Commission para. 130*

- Anticompetitive product hopping = Product switching PLUS
  - It is this PLUS factor that makes the conduct anticompetitive

# Examples of context-dependency

## The PLUS factor in AstraZeneca (2<sup>nd</sup> abuse)

- AstraZeneca's " *Losec-Post-Patent-Strategy*"
  - (1) the extension of the Losec product line by Losec MUPS, which is Losec in a tablet form instead of a capsule;
  - (2) the raising of technical and legal barriers to entry designed to delay generic entry
- Selective deregistration of marketing authorisations
  - Generic applicants could only apply for abbreviated drug approval process, if brand drug was marketed at the time of application



# Examples of context-dependency

## The PLUS factor in Reckitt Benckiser

- Reckitt Benckiser (RB) proprietor of Gaviscon Original
- RB also introduced Gaviscon Advance (patent protection until 2016)
- RB withdrew the original drug from the NHS prescription list
  - GP's no longer found Gaviscon Original when typing in "Gaviscon"
  - No generic substitutes for Gaviscon Advance available
- CMA's decision
  - Abuse of dominant position
  - Conduct outside the scope of competition on the merits (relying on AZ)
    - Incremental improvement of Gaviscon Advance questionable
    - Internal documents showing that withdrawal was intentional to prevent generic entry for Gaviscon Original (Operation White Tiger)



# Examples of context-dependency

Product hopping facilitated by EU pay for delay

## A potential unilateral theory of harm:

- Brand company can use settlement to pay off first viable generic entrant in order to prevent imminent generic entry
- Enables brand company to switch consumers to 2<sup>nd</sup> generation drug without the fear of generic competition
- Once switched consumers' prescriptions cannot be substituted with generic versions of original brand drug

# Examples of context-dependency

## Access to affordable drugs in Ghana

### Ghana affords patent protection for pharmaceuticals

- However only 3 pharma patents have been applied for between 2008 – 2015
- Patents do not play an important role for generic entry in Ghana

### Generic access seems to be a purely regulatory issue

- Procurement, distribution and pricing

### Impact on potential

### anticompetitive conduct

- Rather cartels and bid-rigging than pay for delay and product hopping

# Conclusion

Complex interplay of competition, intellectual property protection and regulation

HOWEVER, the level of complexity is highly dependent on individual cases



Significant impact on potential anticompetitive practices

# Future research – New UNCTAD Project

*“Increasing the access to affordable medicine in developing countries and LDCs: between regulation and competition”*

Dr Sven Gallasch  
Centre for Competition Policy,  
United Kingdom

Dr Mor Bakhom  
Max Planck Institute for Innovation  
and Competition, Germany

## Research objectives:

1. The status quo: identifying the relevant framework in participating countries
2. Identifying barrier for entry to the pharmaceutical market
3. Providing advice on the improvement of access to affordable medicine