CENTRE FOR COMPETITION POLICY

Pharmaceutical antitrust

Use but use with caution

Keynote Speech

Roundtable on:

Role of Competition in the Pharmaceutical Sector and its Benefits for Consumers

Seventh United Nations Conference to review the UN Set on Competition Policy
Wednesday 8th July 2015

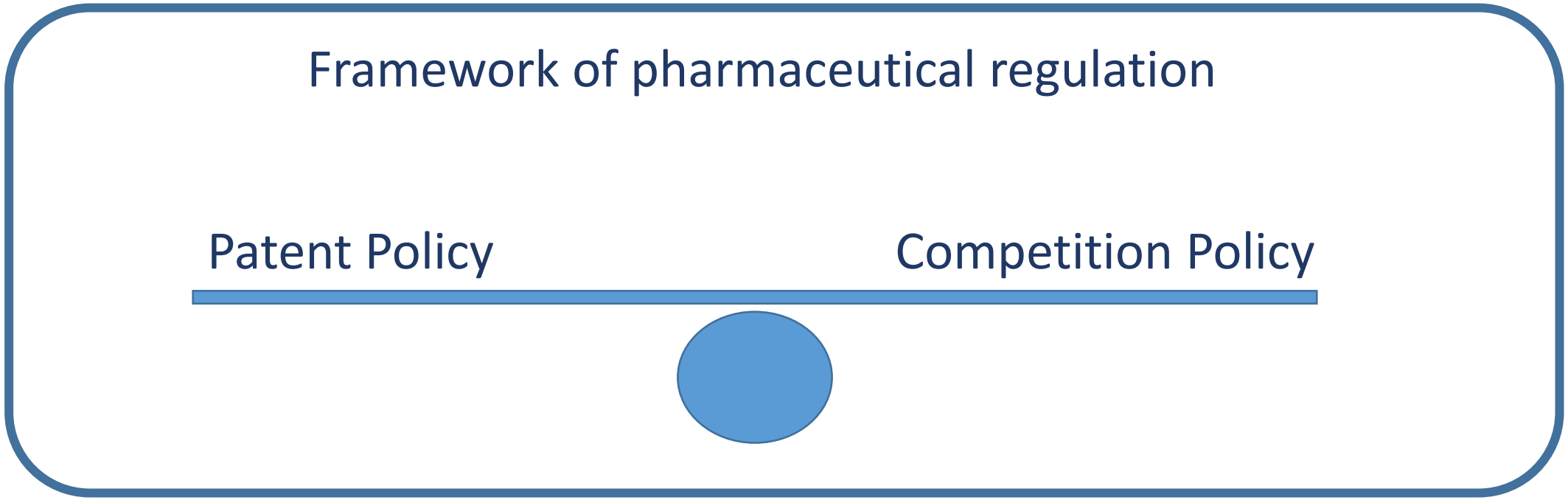
Dr Sven Gallasch
s.gallasch@uea.ac.uk

The views expressed are those of the author and do not necessarily reflect the views of UNCTAD

Should we use antitrust law to police shortcomings of patent policy or the regulatory regime in the pharmaceutical sector?

The clear answer is that is depends…

- It requires a major balancing task of policy considerations

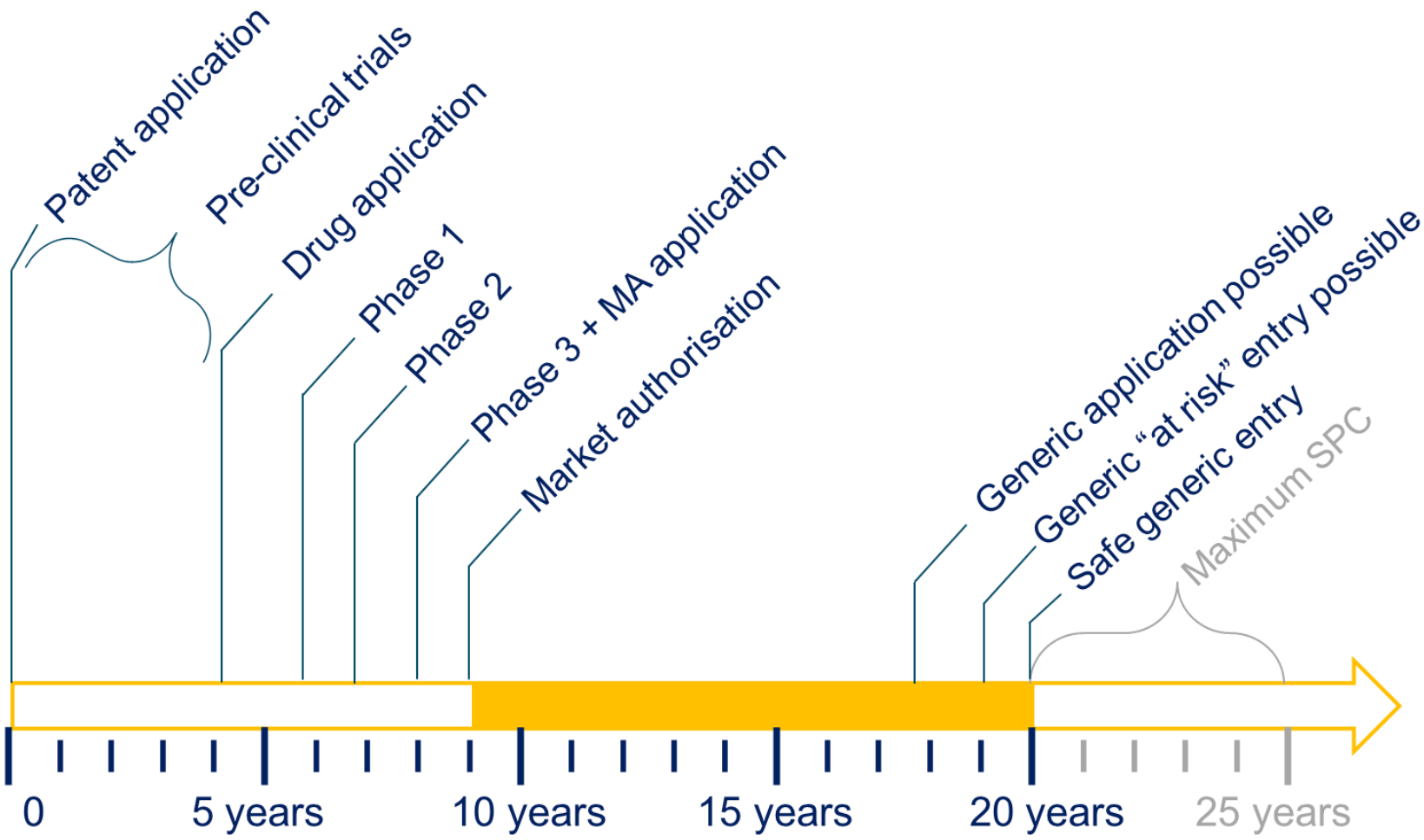


A reminder of some basic policy considerations

- Innovation is crucial - especially in the pharmaceutical sector
- Patent policy prioritises *dynamic* over *static* efficiencies

- Patents are granted to incentivise innovation
  - Patent rights are a “bargain with society”
  - Balance between innovation risk vs innovation reward

The skewed risk/reward balance in pharma



The impact on the skewed balance on the pharmaceutical sector

- Most costs for drug R&D are front-loaded
- All the reward/profit is generated towards the end of the patent life
- Profits have to be higher in order to be recouped in shorter period

- **BUT** leads also to the negative incentive to extend the profits beyond the patent life

Negative incentives call for antitrust scrutiny

'When it comes to generic entry, every week and month of delay costs money to patients and taxpayers. We will not hesitate to apply the antitrust rules where such delays result from anticompetitive practices.'

The difficult task of pharmaceutical antitrust

- Ensure/increase generic competition without stifling innovation
  - Trade-off again between static and dynamic efficiencies
  - Competition policy recognises both but is arguably prone to protect static efficiencies

- A good starting point is the following question:

  Is the conduct still part of the "bargain with society"?

  Or has the "bargain with society" already expired?

  Or is it in between?

Category 1: Conduct *within* the boundaries of the original patent right

- Italian Pfizer decision as a good example for such a situation
  - Supplementary protection certificates (SPC) are an essential tool to ensure adequate reward for pharmaceutical innovation
  - Concerns original brand drugs that require extensive testing and a lengthy approval procedure

- Implication for antitrust scrutiny
  - Antitrust intervention should be possible
  - But need for careful consideration of potential anticompetitive effects based on carefully developed viable theory of harm

Category 2: Conduct *outside* the boundaries of the original patent right

- UK Reckitt Benckiser decision as a good example for such a situation
  - Product hopping distorts the competitive process by deprived consumers of their choice of drug based on cost and therapeutic benefit
  - Extension of original brand drug innovation rewards by means of incremental innovation of questionable therapeutic benefit

- Implication for antitrust scrutiny
  - Antitrust intervention should not lead to a stifling of innovation
  - **Antitrust intervention in product hopping based on anticompetitive "facilitator"**
    - **Scrutiny of the degree of incremental innovation can be avoided**

Category 3: Conduct half-way between the other two categories

- Pay for delay settlements (the in-between case)
  - Significant enforcement in the US (*FTC v Actavis*)
  - First decision on EU level (Lundbeck)
- **Beware of the regulatory differences**
  - Hatch Waxman Act unique to the United States
  - Changes the anticompetitive potential

- Implication for antitrust scrutiny
  - Copy-paste of US approach likely to lead to unintended outcomes

Sven Gallasch, *Activating Actavis in Europe – the Proposal of a "structured effects-based" analysis for Pay for Delay Settlements* (CCP working paper)

Concluding remarks
A word of caution

- We should use the antitrust laws in the pharmaceutical sector
  - IP rights shape markets; therefore market rules should apply
  - Consumer welfare based on generic entry is crucial

- Antitrust intervention should be carefully measured
  - Over-enforcement should be avoided as false positives can be very costly

- Scrutiny of unilateral conduct should focus on 2nd category such as product hopping

Sven Gallasch, *Adding a New Dimension to EU Pharmaceutical Antitrust - Pay for Delay Settlements as Part of a Unilateral Strategy such as Product Hopping* (CCP working paper)

Thank you very much for your attention

Literature:

Sven Gallasch, *Activating Actavis in Europe – the Proposal of a "structured effects-based" analysis for Pay for Delay Settlements* (CCP working paper series)

http://competitionpolicy.ac.uk/documents/8158338/8368036/CCP+Policy+Brief+15-3.pdf/ (Policy Brief)
http://competitionpolicy.ac.uk/documents/8158338/8368036/CCP+Working+Paper+15-3.pdf/ (Working Paper)

Sven Gallasch, *Adding a New Dimension to EU Pharmaceutical Antitrust - Pay for Delay Settlements as Part of a Unilateral Strategy such as Product Hopping* (CCP working paper series)

http://competitionpolicy.ac.uk/documents/8158338/8368036/CCP+Policy+Briefing+15-2.pdf/ (Policy Brief)
http://competitionpolicy.ac.uk/documents/8158338/8368036/CCP+Working+Paper+15-2.pdf/ (Working Paper)