

# TPP and Pharmaceutical Protections: Too Strong, Too Weak, or Just Right?

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# Pharmaceutical Industry and TPP

- Pharm and Bio-Pharm
  - High Cost of R&D and Marketing
  - Years of R&D, Clinical Trials
  - High failure rate, low drug approval rate
  - High consumer demand
    - Frequent target for imitation, counterfeiting; impatience for generic entry
- Trans-Pacific Partnership Agreement
  - Pre-existing regimes:
    - WTO TRIPS, WIPO, FTAs
  - What is the **value added** in terms of IPR?

# Critical Issues (provisions of TPP, Chapter 18)

1. Higher Prices
2. Delayed Entry by 'Generics'

Essentially how IP system *works*:  
Benefits (e.g., Innovation & Tech Transfer) vs. Costs

# 1. Price Effects

## Mitigating Factors

- Discipline on 'Monopoly Pricing'
- Competition with 'Old' Products
- Price Regulation
  - *Quinolones Study (Chaudhuri et al. AER 2006)*
    - *Importance of Distribution Networks*

# 1. Price Effects

- International Price Discrimination

- Recall:  $\text{Profits} = \text{Revenue} - \text{Costs}$
- Or  $\text{Profits} = P \times Q - \text{Costs}$

- Globally,

$$\text{Profits} = P_1Q_1 + P_2Q_2 + \dots + P_NQ_N - \text{Costs}$$

↑ ↑ ↑  
Different Markets

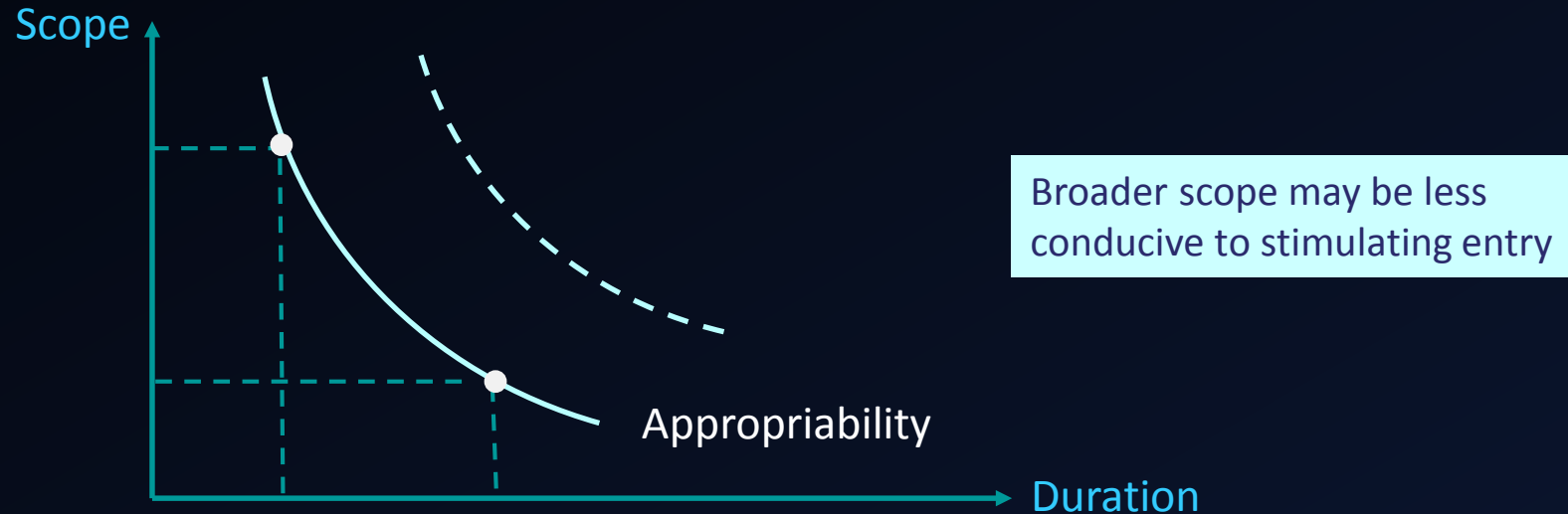
Limit Parallel Trade

# 1. Price Effects

- TRIPS Article 31, Doha Declaration
  - provisions for national emergencies
- Statistical Evidence of TRIPS-Plus FTA
  - Oxfam (2007) Report (Egypt vs. Jordan): huge percentage changes somewhat deceptive (*i.e., dealing with pennies*)
- WHO List of Essential Medicines
  - 90%+ are off-patent
- Cost of Biologic Medicines & Therapy
  - confirms need to strengthen innovation incentives, develop the *science*, improve R&D efficiencies

## 2. Delayed Entry by Generics

- Data Exclusivity/Data Protection
  - Testing is also Costly
- Market share of Generic Drug Producers is high
- In weak IP regions, generics may enter before brand names
- Alternative Means of Recouping Costs:



## 2. Delayed Entry by Generics

### Mitigating Factors

... of not getting 12 years Data Protection

- Profit from Brand Name Advantages, Brand Loyalty, Reputation
  - Hurwitz and Caves (1988)
- Other Options: Patent Term Extensions, Secondary Patents, Mergers and Acquisitions, Strategic Partnerships
- Complexity and Cost of Developing a 'Biosimilar'
  - Natural Barrier to Entry
- Test Data should add to society's stock of knowledge



# Potential Economic Impacts of TPP

- Ivus, Park, and Saggi (2016)
  - Enhance unaffiliated licensing (especially in pharmaceutical sector) in developing countries
  - Tech transfers contribute to local learning-by-doing
- Cockburn, Lanjouw, and Schankerman (2016)
  - Stimulate new drug launches – in more countries
  - Expanding marketing & distribution networks
- Koff, Baughman, Francois, and McDaniel (2011)
  - Positive association with goods trade and licensing
  - Complementary factors (governance, tax), Institutional capacity, Technical assistance
- Branstetter, Chatterjee, and Higgins (2015)
  - Negative association between generic market penetration and early stage pharm innovations
- U.S. International Trade Commission (2016), Publication # 4607
  - Impacts of TPP positive, but small (US real GDP to be 0.15 percent higher in 15 years)
  - IPR stimulates out licensing. MNC sales/revenues expected to be higher.
  - Impact on developing country partners not assessed.