





The Cost Structure of Research-Based Medicines

- n R&D expense is much higher for pharmaceuticals than for other industries
 - n 13-20% of sales for US companies
 - n ≥ 30 % percent of total cost of developing, producing and marketing a drug (including forgone interest)
- n R&D is a fixed cost, invariant to volume, sunk at launch
- n Marginal cost (MC) is relatively low:
 - n $\leq 25 - 50$ % of total cost (production, distribution)
- n Marginal cost pricing ($P = MC$) will not pay for fixed costs of R&D



The Role of Patents in R&D

n



R&D as a Global Joint Cost

n



Optimizing

Market Separability is Breaking Down

1. Regulation based on International Price Comparisons

- n Canada, Netherlands, Italy, etc.
- n Informal comparisons in many countries: UK, US
- n Minimum price => maximum price in all connected/referenced markets
 - n Toughest regulator sets the global price

2. Parallel trade

- n Permitted within EU, not yet from non-EU countries
- n US recently enacted reimportation provisions; not implemented but under debate

=> Low price in one country spreads regionally/ globally

Manufacturer Response to Breakdown of Separate Markets

Economic Theory

- n Manufacturers minimize losses by setting a single launch price
 - n near high end of the prior price range
 - n delay launch rather than accept a much lower price

Evidence

- n Launch prices are uniform or in narrow band, BUT
- n A uniform price for pharmaceuticals is not good public policy
 - n contrary to standard trade theory



Price Differences Are Not Cost Shifting

- n Two separate markets:
 - H = high income, L = low income
- n Existing medicines:
 - n the price in H is unaffected by the price in L, if markets are separate
- n Prospective new medicines:
 - n Sales in L with $P > MC$ contribute to joint costs
=> lower price in H needed to recoup R&D costs



No Efficiency Gains from Parallel Trade

- n Trade benefits consumers, provided that
- n Low cost suppliers have lower real costs
 - n low input prices or more efficient production
- n Low prices for pharmaceuticals reflect aggressive regulation + weak patents
 - n not superior efficiency
- n Parallel trade may actually increase costs: relabeling, quality concern

Conclusion: Parallel trade in on-patent, R&D-intensive products is not good policy



Policies to Maintain Separate Markets and Price Differentials

- n Patent rights based on national boundaries
 - n traditional in EU, US
 - n => Patent holder can bar parallel trade
- 2. Discourage regulation based on foreign prices
- 3. Permit manufacturers to give discounts/rebates through





Conclusions

- n Differential pricing provides a way to pay for R&D while assuring access for low income countries
- n If market separation is assured, to prevent “spillover” of low prices, patents need not imply high prices in LDCs
- n Additional funding may nevertheless be needed:
- n If developing countries cannot pay their marginal cost;
- n To develop drugs not used in high income countries
- n In this case, prices in high income countries cannot be counted on to pay for the common costs of R&D