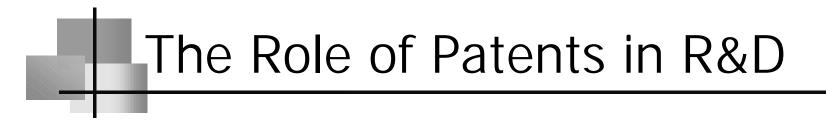


T.

### 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
  - $_{n} \geq 30$  % 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



n



n



## Market Separability is Breaking Down

- 1. <u>Regulation based on International Price Comparisons</u>
  - 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
  - <sup>n</sup> Permitted within EU, not yet from non-EU countries
  - IN 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

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

<u>Evidence</u>

- n Launch prices are uniform or in narrow band, BUT
- 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:
  - h 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
  - = > <u>lower</u> 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
- Low prices for pharmaceuticals reflect aggressive regulation + weak patents

n not superior efficiency

- n Parallel trade may actually increase costs: relabeling, quality concern
- <u>Conclusion</u>: 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
  - In this case, prices in high income countries cannot be counted on to pay for the common costs of R&D