



Differential Pricing: Reconciling R&D, IP and Access

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Reconciling the Objectives

Two Policy Objectives:

- Access to and affordability of existing drugs
- Incentives for R&D to develop new drugs
 - Requires intellectual property rights

The Key to Reconciling these Objectives

- International price differentials, which requires
- Separability of international markets

The Cost Structure of Research-Based Medicines

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



The Role of Patents in R&D

- Competition and free entry of copy products will force prices down to MC
- Marginal cost pricing ($P = MC$) will not pay for fixed costs of R&D
- Patents permit the innovator firm to bar copy products, in order to permit $P > MC$ for life of patent
- Patents are necessary, not sufficient, for innovator to break even, including the cost of R&D



R&D as a Global Joint Cost

- R&D is a “joint” fixed cost of serving all patients
 - Cannot be causally attributed to specific countries
- Necessary conditions for break even:
 - $P_j \geq Mc_j$: price in each country covers its MC
 - $\Sigma (P_j - Mc_j) \geq F$:
 - in aggregate, price-cost margins must be sufficient to cover the joint, fixed cost of R&D
- Uniform prices in all markets are not necessary or desirable to achieve global breakeven

Optimal Pricing to Cover Joint Costs: "Ramsey Pricing"

- "Optimal" = pricing to achieve highest social welfare
- Prices inversely related to price elasticity
 - price-insensitive consumers pay more than price-sensitive consumers
- Applies to R&D-based drugs while on patent
- Differential pricing is common for other industries with joint costs (utilities, airlines etc.)
- Pharmacoeconomics implies similar price differentials
- Differential pricing requires separable markets

Market Separability is Breaking Down

1. Regulation based on International Price Comparisons

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

2. Parallel trade

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

=> Low price in one country spreads regionally/ globally

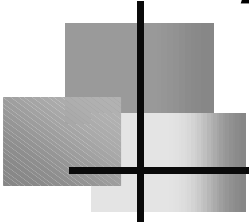
Manufacturer Response to Breakdown of Separate Markets

Economic Theory

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

Evidence

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



A Single Price is Inequitable and Inefficient

- A single, relatively high price is unaffordable for low income countries
 - => reduce utilization or lose access to new drugs, though they can pay $P_i \geq MC_i$
- Single price reduces manufacturer revenues
 - => fewer new drugs than with price differentials
 - => all patients will be worse off in long run

Price Differences Are Not Cost Shifting

- Two separate markets:
H = high income, L = low income
- Existing medicines:
 - the price in H is unaffected by the price in L, if markets are separate
- Prospective new medicines:
 - 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

- Trade benefits consumers, provided that
- Low cost suppliers have lower real costs
 - low input prices or more efficient production
- Low prices for pharmaceuticals reflect aggressive regulation + weak patents
 - not superior efficiency
- 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

- Patent rights based on national boundaries
 - traditional in EU, US
 - => Patent holder can bar parallel trade
 - 2. Discourage regulation based on foreign prices
 - 3. Permit manufacturers to give discounts/rebates through confidential contracts to specific payors/governments
 - => Prices can differ without encouraging parallel trade or cross-national comparisons
- => With separate markets, manufacturers have incentives to charge low prices in low income countries



The Free Rider Temptation for Regulation

- R&D joint cost is sunk when prices are negotiated
- Who should pay for the joint costs?
 - => temptation to free ride
- Large buyers can force price to marginal cost through regulation or threat of compulsory licensing
 - no effect on supply of existing drugs
- Low prices in one country spill over to other countries, through parallel trade and international price comparisons
- If everyone pays marginal cost, no one pays for R&D!



Conclusions

- Differential pricing provides a way to pay for R&D while assuring access for low income countries
- If market separation is assured, to prevent “spillover” of low prices, patents need not imply high prices in LDCs
- Additional funding may nevertheless be needed:
- If developing countries cannot pay their marginal cost;
- 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