

Exhaustion of Patent Rights and Parallel Trade

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Exhaustion of IP rights

- ▶ National exhaustion: rights are “exhausted” when the IP owner places a product on the market in that country
 - ▶ Cannot use IP to prevent resale within that country
- ▶ Other countries treat rights as “exhausted” when first sold elsewhere
- ▶ Different national policies for different forms of IP, different trading partners
- ▶ When rights are exhausted, price arbitrage is possible

Parallel trade

- ▶ (Or grey market trade, or product diversion, or reimportation)
Arbitrage of international price differences of products whose IP is exhausted
- ▶ Important in many sectors
 - ▶ Luxury goods
 - ▶ Textbooks
 - ▶ Software
- ▶ Especially important in pharmaceuticals
 - ▶ National-level price controls, differences in income levels -> wide variation in prices
 - ▶ -> Responses by originators that may limit access

Benefits of exhaustion

- ▶ Reduces enforcement costs for governments
- ▶ Removes a potential barrier to trade
- ▶ Enables competition in distribution channels
- ▶ Arbitrage -> more uniform pricing

Is uniform pricing desirable?

- ▶ Probably not, in a global sense.
 - ▶ Most standard economic models predict that total welfare is higher under differential pricing.
 - ▶ But the benefits and costs are not equally distributed.
- ▶ Definitely not, for poorer countries.
 - ▶ A uniform price chosen by a monopolist will be “too high” in poorer countries.
 - ▶ Risk of withdrawal from poorer countries, or rationing.

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- ▶ **National-level price controls for pharmaceuticals are explicitly permitted in the EU precisely because of access worries.**

Counterarguments

- ▶ Originators will find other ways to implement differential pricing.
 - ▶ Second-degree price discrimination rather than third degree
 - ▶ Use of licensing rather than sales, other changes to contracts
- ▶ Originators don't use differential pricing to promote access even with national exhaustion.
 - ▶ Only the richest consumers in poor countries are targeted, with high prices.
 - ▶ If true, exhaustion will have limited effects.

Empirical evidence

- ▶ Mostly concerns parallel trade of drugs within the EU.
 - ▶ Country-level studies: high-price countries (Germany, Sweden) generally benefit from lower prices.
 - ▶ Pan-EU studies: price differentials persist; extent of parallel trade varies considerably by country.
- ▶ Non-price responses are important:
 - ▶ Delayed launch, supply interruptions (rationing) in low-price countries.
 - ▶ Product differentiation to make parallel imports less substitutable.

Empirical evidence

- ▶ Out of 2342 EMA licenses for parallel distribution in 2013:
 - ▶ Germany designated as importer for 1065
 - ▶ Sources: CZ (1002), RO (965), PL (956), BG (855)
- ▶ Similar patterns for national-level licenses
 - ▶ Top 5 sources for Norway in 2013: PL, BG, CZ, RO, IT
 - ▶ Relative GDP per capita is 3-14X higher in Norway

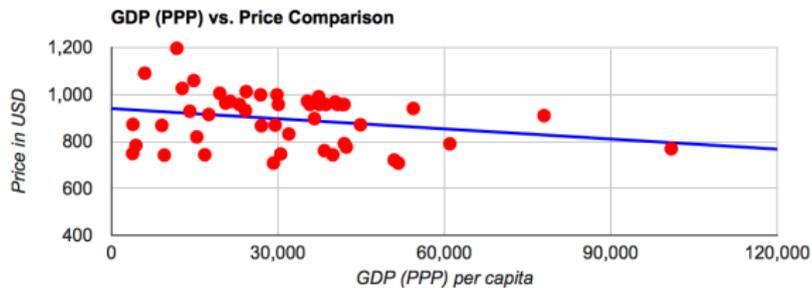
Survey evidence

- ▶ Survey of product diversion in middle and low income countries funded by DfID.
 - ▶ Target respondents: pharma managers, distributors, NGOs in developing countries
 - ▶ Questions on extent of product diversion, and pre-emptive steps to prevent it.
- ▶ Responses indicate concern over intra-country diversion as well as diversion between countries
- ▶ However, little data (even internally) on the magnitude
- ▶ Full results to be released in the coming weeks...

Anecdotal evidence

- ▶ Greece experienced drug shortages post-crisis.
 - ▶ Parallel trade cited as one cause.
- ▶ Canadian pharmacies experienced drug shortages in the early 2000s.
 - ▶ Internet pharmacies shipping to the US.
 - ▶ Cross-border purchases by individuals.

iPhone price as % of GDP per capita



Notes on Data:

GDP (PPP) per capita data from International Monetary Fund (2012).

Price data for the iPhone 5S 16GB taken from Apple Store website where available, otherwise from Apple authorised resellers. Hover over the country in the table on the right for the specific source. Prices in local currencies updated on 18th November 2013.

Other consequences of parallel trade

- ▶ Originators argue that parallel trade creates quality risks.
- ▶ Originators argue that parallel trade lowers profits, and therefore R&D.
 - ▶ Economic models without a strategic regulator (using price controls) generally agree.
 - ▶ However, optimal policy depends on consumer benefits as well.
 - ▶ Is the additional R&D welfare-enhancing?
- ▶ Parallel trade might reduce “free-riding.”
 - ▶ Setting a low price locally has a larger impact on global firm profits
 - ▶ In response, regulators in low-price countries should raise prices if they care about R&D incentives.
 - ▶ Benefits accrue mainly to rich countries and originators.

Differences across countries and settings

- ▶ Negative effects of exhaustion are greatest when:
 - ▶ A large, rich (high price) country allows parallel imports from small, poorer (low price) countries.
 - ▶ Safety or quality risks are significant.
 - ▶ Scope for second degree price discrimination (versioning) is limited.
- ▶ Positive effects of exhaustion are greatest when:
 - ▶ Price differences reflect market inefficiencies rather than differential pricing.
 - ▶ Parallel trade enables access that would not otherwise occur.
- ▶ Suggests appropriate policy differs by country and sector.
- ▶ Lack of alignment of national interests can be problematic.