

Intellectual Property and Access to Medicines

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The patent system and pharmaceuticals

- ▶ In general, the patent system works well as an incentive mechanism in pharmaceuticals
 - ▶ One of the most research-intensive sectors, responsible for significant health gains
 - ▶ Cost structure of drug development and imitation costs make patents more important than in other sectors
 - ▶ Issues in other sectors (e.g. telecom) less salient
- ▶ Empirical evidence:
 - ▶ Larger markets attract more investment
 - ▶ Richer markets attract more investment
 - ▶ Investment responds to the length of patent protection
 - ▶ Lack of patents \neq access
 - ▶ But important exceptions/gaps exist

Larger markets attract more investment

- ▶ In general, this is a good thing!
 - ▶ Cardiovascular disease kills many people, and now we have many treatments
- ▶ Downside: orphan diseases
 - ▶ Rare diseases are less likely to attract investment, absent other policies

Richer markets attract more investment

- ▶ Most studies focus on developed countries, esp. the US
 - ▶ Diseases with a large burden in rich countries attract more investment
 - ▶ Poorer countries can benefit from treatments if the disease burden is similar
- ▶ Downside: neglected diseases
 - ▶ Diseases that are primarily in poorer countries are less likely to attract investment
 - ▶ Patent protection does not appear to change this

Investment responds to the length of patent protection

- ▶ Long development times -> reduced patent life once a product reaches the market
 - ▶ Lower profits -> lower investment overall
 - ▶ Distortion of investment towards “quick” development
- ▶ In general, much weaker evidence on this point
 - ▶ We don't know how many new drugs would be developed if patents were 21 years rather than 20
 - ▶ Other policies (e.g. data exclusivity) often provide protection
- ▶ The effects of “secondary” patents are also less established
 - ▶ Criticized as evergreening, patent thickets
 - ▶ Raise expected litigation and development costs for generics

Lack of patents \neq access

- ▶ In general, access is not assured in the absence of patents
 - ▶ Originators only seek protection where it is valuable -> not in many poor countries
 - ▶ If a market isn't attractive for the originator, it probably isn't for generics either
 - ▶ Some protection is necessary to cover the fixed costs of regulatory approval, building a market
- ▶ Patents in a few key countries matter more
 - ▶ Where large domestic market and manufacturing capacity exist (India, e.g.)
 - ▶ Spillovers for the countries they supply

Limitations of patents

- ▶ Patent system fails when profits or prices do not reflect social value
 - ▶ Antibiotics
 - ▶ Missing markets for health insurance, inefficiencies in delivery, etc.
 - ▶ In some cases, price controls or information problems in price-setting and consumption
- ▶ Patents are blunt instruments
 - ▶ Same term of protection, regardless of value/sector/product lifecycle
- ▶ Monopoly power -> monopoly pricing, limiting access in the absence of price discrimination or insurance

Resolving the access problem

- ▶ Often, policies that address the well-known problem of access to patented treatments can undermine incentives
- ▶ Encourage differential pricing by patentholders
 - ▶ Primarily the responsibility of rich countries
- ▶ TRIPS flexibilities
 - ▶ Recognize different needs of developing countries
 - ▶ But responsible use of these flexibilities is also needed
- ▶ Bear in mind that monopoly pricing should be temporary: are other policies promoting generic approval and competition effective?

Alternatives to patents: public funding or innovation prizes

- ▶ Is R&D directed at the right targets?
 - ▶ High social value -> Large grant or prize
 - ▶ How is this determined?
- ▶ Is the policy easy to implement?
 - ▶ Public funding requires the government to pay for failure
 - ▶ Will funders choose the best recipients, or the best connected?
 - ▶ Is it practical to establish a prize fund for every needed treatment?
- ▶ Will governments free ride on each other?
 - ▶ Defense spending creates a deterrence effect that benefits allies...
 - ▶ Research spending creates spillover benefits to other countries...

When are these alternatives superior?

- ▶ Global consensus on need and financing
 - ▶ HIV, TB, malaria
 - ▶ Antibiotics
 - ▶ Ebola, Zika?
- ▶ Optimistic take:
 - ▶ Global Fund and others have contributed to substantial increases in access for HIV, TB, malaria
 - ▶ Some coordinated efforts on antibiotics
 - ▶ Ebola and Zika vaccine development is promising
- ▶ Pessimistic take:
 - ▶ Big pharma presence remains: why only one bidder for the Zika license?
 - ▶ Other bottlenecks to access may persist