Patents and the Availability of Medicines in Developing Countries

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Overview

- Patents are barriers to entry, by definition
  - Except, of course, for the inventor (or originator, licensee...)
- Lack of generic competition can result in high prices
  - Major concern for policymakers and NGOs
- However, other factors may constrain prices
  - Competition from similar (not identical) drugs
  - Price controls or threats of compulsory licensing
  - Population’s inability to pay
Overview

- Patents may facilitate access under some conditions
- Regulatory approval is a fixed cost for any applicant, originator or generic
  - Generally, the first applicant bears the highest costs
    - Clinical data proving safety and efficacy
  - Subsequent entrants often rely on data provided by first
- First entrant may require protection from competition in order to recoup these costs
  - Data exclusivity or patents
- Without this protection, it is possible that no firm will enter
  - Originator probably has lower costs of providing clinical data than generic firms
  - If originator cannot cover those costs, it is unlikely that generics can
Empirical evidence

- Most studies of generic competition focus on developed markets
- These generally find that generic entry is more likely when:
  - The market is large
  - Originator prices are high
  - The formulation is relatively simple (oral solid, few ingredients)
- Some important differences from developing markets:
  - Stronger patent protection (historically) or data exclusivity
  - Insurance coverage for most of the population
  - Policies that require or encourage generic substitution
  - Significant advertising efforts by originators to build the market
Empirical evidence

- Studies of developing markets are more limited
- Most influential study by Chaudhuri et al. examines one drug class in India
  - Using data prior to the introduction of patents in India - prospective
  - Simulation indicates very negative effects on access due to patents
  - In part, this result is due to better distribution by local generic firms
- Recent study by Duggan et al. using data from India does not find a significant reduction in access
  - Examines drugs that have received patents post-TRIPS compared to those without
  - Price effects are negligible
Empirical evidence

Kyle-Qian (2015) examines a large set of developed and developing markets.

We examine the probability of launch, prices, and quantities sold.

Main findings:

- Patents are strongly associated with faster access to new drugs.
- Patents are associated with significant price premia in rich countries, but not in poorer markets.
- Patents are not associated with a reduction in quantities sold in developing markets.
Patents and competition

No product patent

Product patent

Number of producers of drug in country-quarter (truncated at 10)

Fraction

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## Simple statistics on access

<table>
<thead>
<tr>
<th></th>
<th>Launch</th>
<th>Originator 1st</th>
<th>Yrs to originator</th>
<th>Any generic</th>
<th>Yrs to generic</th>
</tr>
</thead>
<tbody>
<tr>
<td>High OECD</td>
<td>0.55</td>
<td>0.86</td>
<td>1.50</td>
<td>0.28</td>
<td>7.76</td>
</tr>
<tr>
<td>High nonOECD</td>
<td>0.40</td>
<td>0.82</td>
<td>2.75</td>
<td>0.25</td>
<td>4.76</td>
</tr>
<tr>
<td>Upper middle</td>
<td>0.44</td>
<td>0.79</td>
<td>2.76</td>
<td>0.39</td>
<td>7.01</td>
</tr>
<tr>
<td>Lower middle</td>
<td>0.35</td>
<td>0.69</td>
<td>3.75</td>
<td>0.49</td>
<td>7.26</td>
</tr>
<tr>
<td>Never patented</td>
<td>0.31</td>
<td>0.73</td>
<td>3.51</td>
<td>0.43</td>
<td>7.50</td>
</tr>
<tr>
<td>Ever any patent</td>
<td>0.59</td>
<td>0.84</td>
<td>1.75</td>
<td>0.32</td>
<td>7.01</td>
</tr>
<tr>
<td>Ever product patent</td>
<td>0.60</td>
<td>0.84</td>
<td>1.50</td>
<td>0.31</td>
<td>7.01</td>
</tr>
<tr>
<td>Total</td>
<td>0.45</td>
<td>0.80</td>
<td>2.25</td>
<td>0.36</td>
<td>7.25</td>
</tr>
</tbody>
</table>
Key points

- Originators are usually first to market everywhere
  - This makes sense: they have the clinical data to obtain regulatory approval
- Patents induce originators to enter
  - This usually outweighs the deterrence effect on generics
- Patents are not the only barrier to entry
  - Generics do not always enter, even when no patent exists
Price

Average adjusted predictions for any patent

Patents and the Availability of Medicines in Developing Countries
Price: by burden of disease

Average adjusted predictions for any patent

- Log(price)
- Burden of disease

- Never patented
- Expired patent
- Pre-TRIPS patent
- Post-TRIPS patent

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Key points

- Estimates are not precise
  - Few products have post-TRIPS patents in low income countries
  - Lots of heterogeneity
- Most evidence points to improvements post-TRIPS
  - Note: I am not claiming that all drugs are affordable!
  - But prices in low income countries are relatively lower for patented drugs post-TRIPS than pre-TRIPS
  - Patent premium is larger for low burden diseases than for high burden, which is encouraging
- Why?
  - Countervailing policies: price controls, compulsory licensing
  - Change in originator strategies: greater use of voluntary licensing, efforts to sell to growing middle classes rather than the richest 1%
Other remarks

- Some of the most expensive drugs today are large molecule biotech products
  - Much more challenging to manufacture -> should not expect as much generic/biosimilar entry as in the past, whether patented or not
- Other recent studies have highlighted potential quality issues for generic drugs in India and Africa
  - Not necessarily linked to patents
  - But economic theory generally predicts that brands have reputational concerns -> will invest more in quality
  - Highlights to need to focus on regulatory systems, distribution in addition to patents
Conclusion

- Access to treatments depends on many policies and market factors
  - Patents receive considerable attention, particularly for certain diseases (HIV, Hepatitis C)
  - But in many other cases, patents are not blocking generic firms
- TRIPS allows many policies to counteract some of the potential negative consequences
  - Price controls are used in almost every developed country (with mixed effects)
  - Option of compulsory licensing has likely increased voluntary licensing
- Experience post-TRIPS has not been particularly negative for access (nor particularly positive for R&D incentives)