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

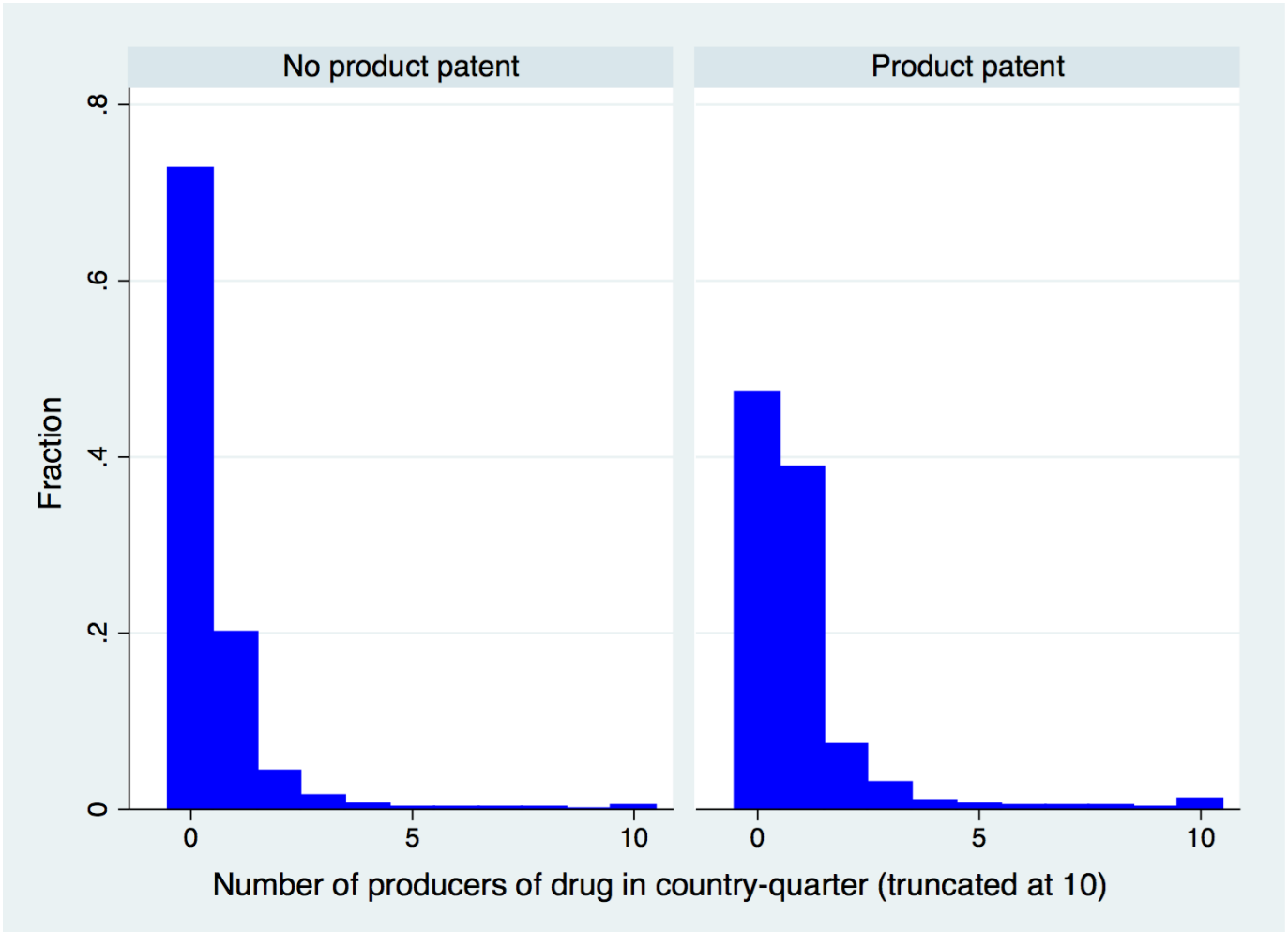
Empirical evidence

- 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 negligable

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



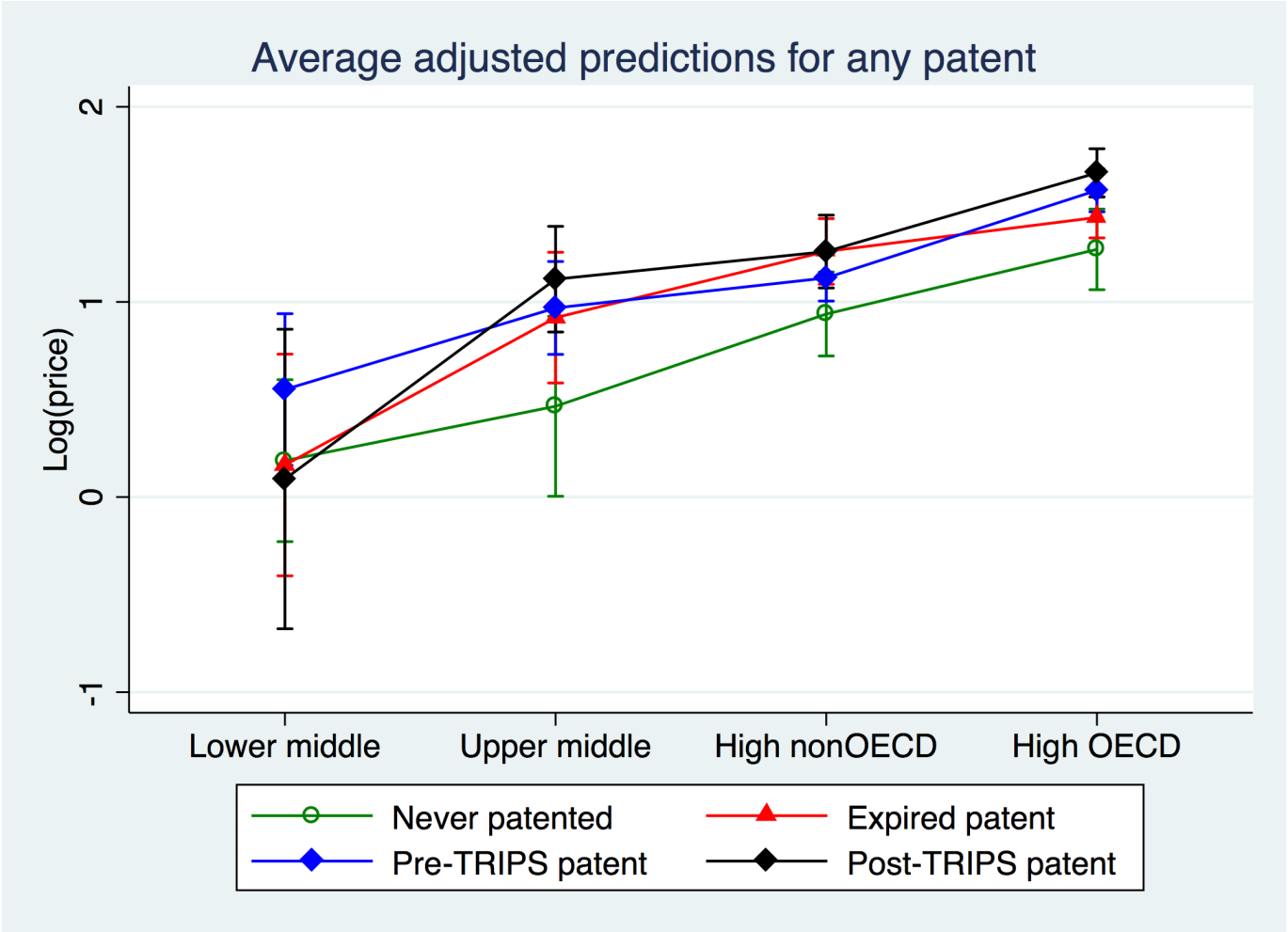
Simple statistics on access

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

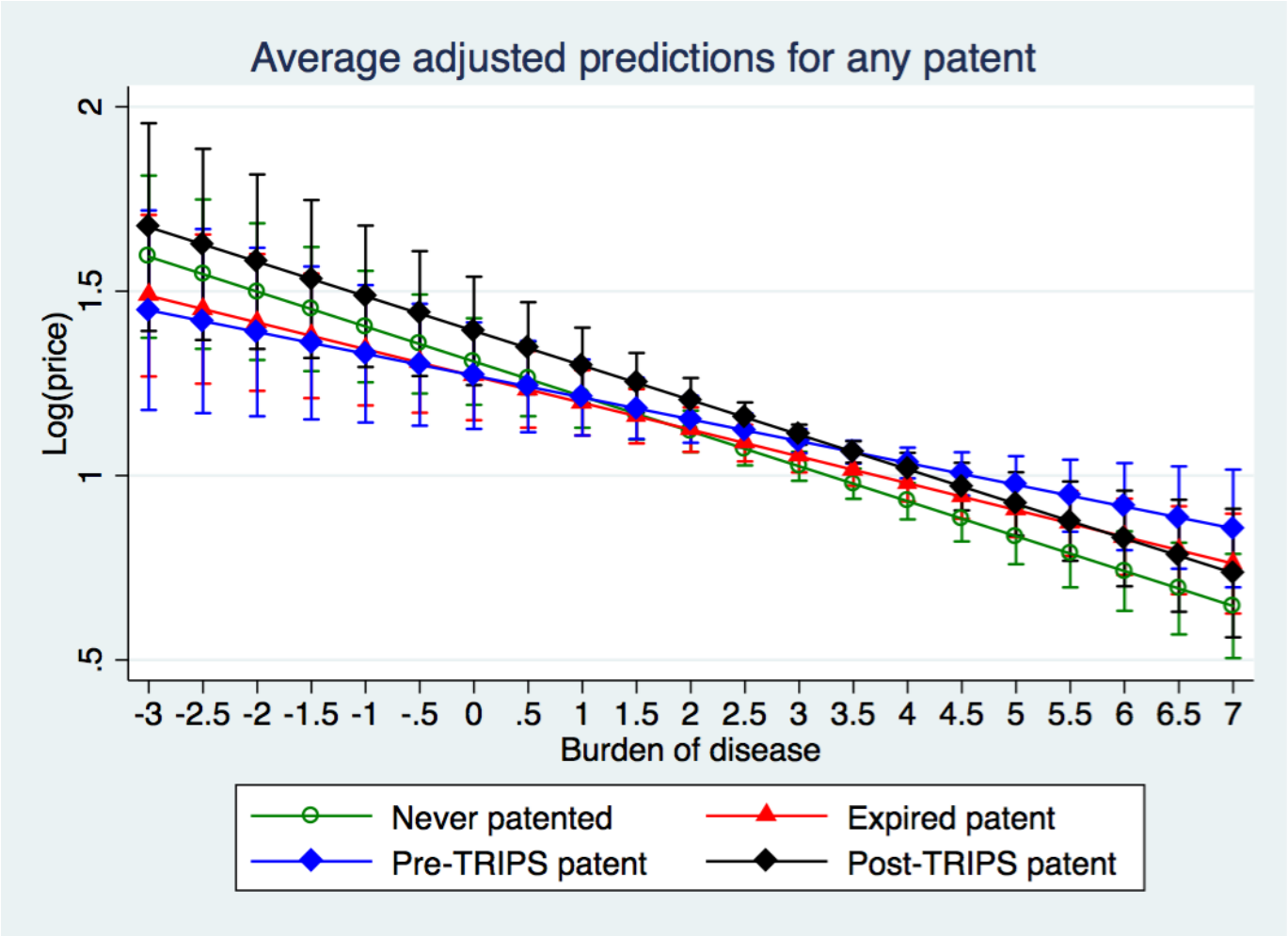
Key points

- 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
Log(price)
2
1
0
-1
Lower middle
Upper middle
High nonOECD
High OECD
Never patented
Expired patent
Pre-TRIPS patent
Post-TRIPS patent

Price: by burden of disease



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)