Intellectual Property Rights, Price, and Access to Innovation: Evidence from TRIPS

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The TRIPS Agreement

- "Trade Related Aspects of Intellectual Property Rights" Agreement
- Negotiated during GATT and the establishment of the World Trade Organization
- Specified minimum levels of IPRs and enforcement as a condition of membership
  - 20 year patent terms, product patents, copyright, etc.
  - For many countries, this represented a substantial change in patent law, especially for pharmaceuticals
- Developing and least-developed countries were permitted a transition period, and argued for important exceptions

Static effects

- In theory, static welfare losses from IPRs can be solved by price discrimination
  - So long as a firm covers its marginal costs, it should be willing to sell in all markets
  - Barriers to international price discrimination: international reference pricing and the threat of parallel trade
- In practice, static welfare losses are also addressed by price controls
  - Almost all developed countries and many developing countries regulate drug prices
  - However, these policies also make launch less attractive and delay access
- IPRs may not be the only barrier to access
  - Some populations are too poor to pay even marginal cost
  - Access also requires infrastructure and distribution channels, complements like diagnostics, etc.

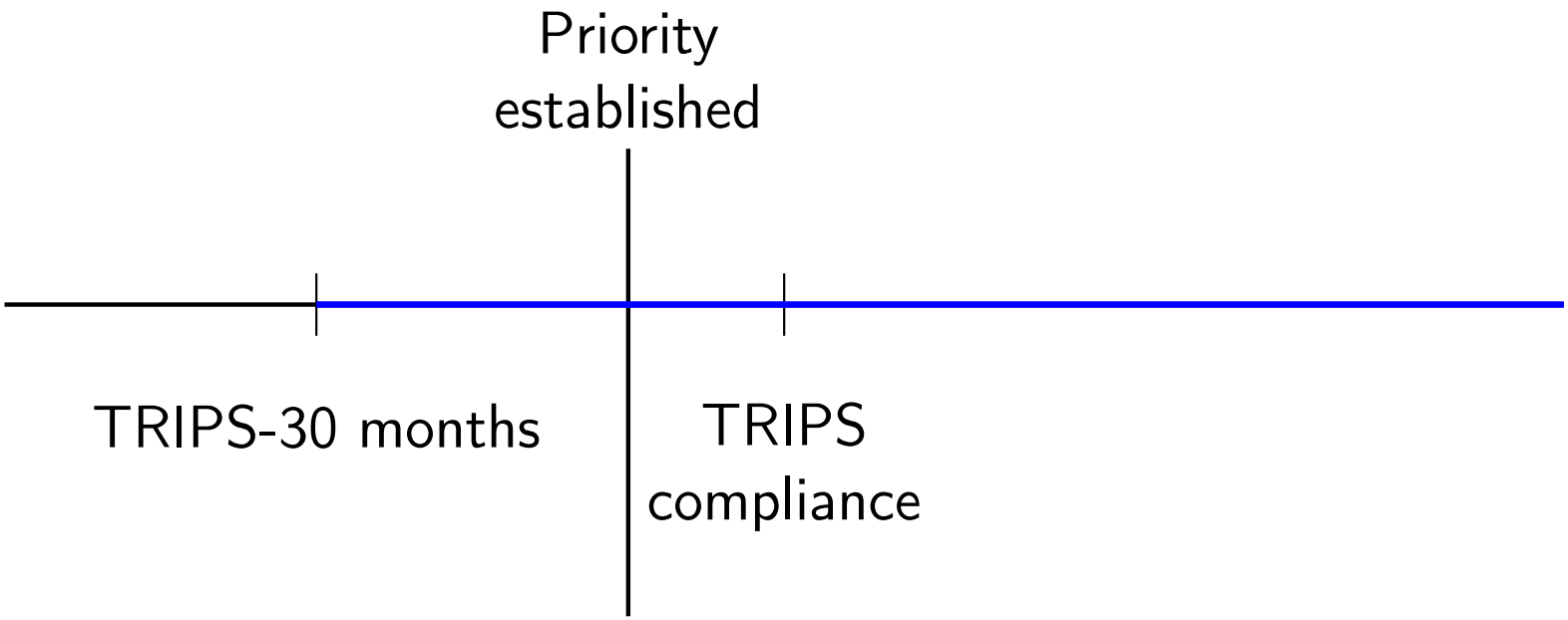
Empirical approach

- Goal: compare equilibrium outcomes for launch delay, price and quantity sold with and without IPRs
  - We can compare countries with IPRs to those without
  - We can compare the same country with and without IPRs
  - We can compare drugs with and without IPRs within the same country and across countries
- Challenges
  - Simultaneity of launch, price and quantity
  - Endogeneity of IPRs
  - Other (also endogenous) policies that undermine IPRs

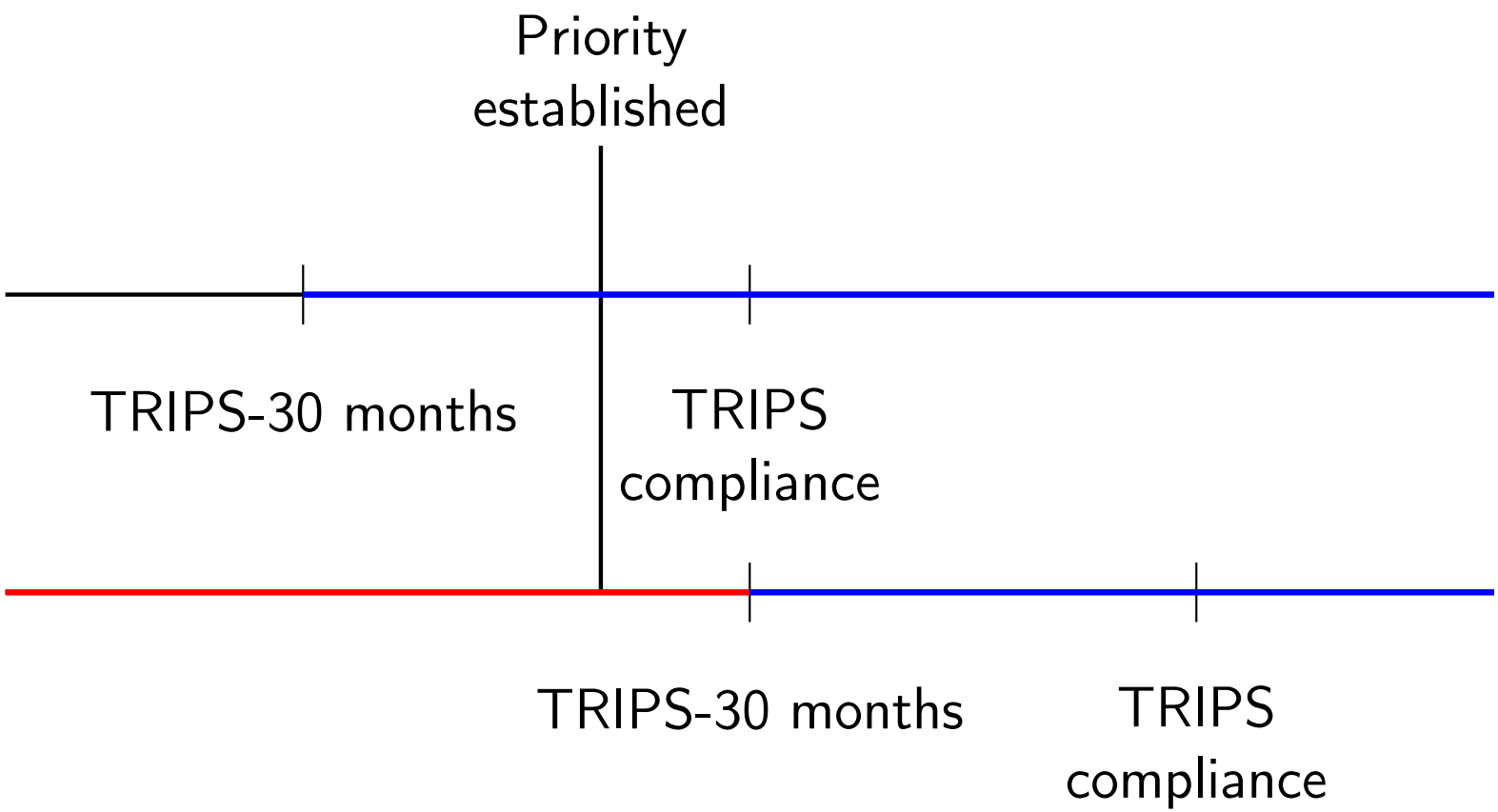
Endogeneity of IPRs

- Patent law changes do not apply retroactively: not all drugs can be patented in a country following its TRIPS compliance
  - "Prior art" disqualifies them from new patents
- First application date anywhere is the "priority date," which establishes date for evaluation of prior art
- Since inventor must apply in other countries within 30 months, the priority date determines its "selection" into treatment (whether it is eligible for a TRIPS-compliant patent in a particular country)

Timeline



Timeline


Priority
established
TRIPS-30 months
TRIPS
compliance
TRIPS-30 months
TRIPS
compliance

Regression specifications

$$\begin{aligned} Y_{ijt} &= \alpha_0 + \alpha_1 PatentedDrug_{ijt} \\ &+ X_{ijt}\mu + \phi_i + \tau_t + \epsilon_{ijt}, \end{aligned}$$

- Estimate launch using discrete-time hazard using logit link
- Estimate price conditional on launch using OLS
- Estimate quantity conditional on launch and price using OLS

Regression specifications

1. Distinguish between pre- and post-TRIPS patents
   - Claim: conditional on having a patent, selection into post-TRIPS status is exogenous
2. Instrument for patent status using indicator for priority date within TRIPS compliance period
   - Claim: TRIPS exogenously shifts the incentives to apply for a patent and the obligation of patent offices to grant it

Market outcome data

- MIDAS data from IMS Health
  - Quarterly observations on price and sales at the package level, 2000-2013; use quantity-weighted average price
  - 60 countries
  - Also have the global launch date and local launch dates for each drug
- Sales in local currency are adjusted for local inflation, then converted to 2013 US$
- We exclude certain classes of drugs (diagnostics, hospital solutions and injectables)
- We focus on drugs first launched since 1990 and in at least 2 markets, and that we can match to patent data (595)

IPRs and other data

- World Development Indicators (World Bank)
- IPR laws and enforcement
  - TRIPS required compliance (WTO rules)
  - Indexes from Ginarte-Park, Hamdan-Livramento -> actual TRIPS compliance
  - Year of legislation implementing product patents on pharmaceuticals (WIPO)
- Patent information for each drug (IMS Patent Focus)
  - Number and type of patent applications for each drug, by country
  - Includes the initial global patent application date, which determines eligibility for protection

Patent information

- Most drugs have multiple types of patents (product, process, etc.) with different application dates
  - Some drugs have patent extensions or supplementary protection certifications
  - Follow-on patents may be effective
  - Data exclusivity terms may also be in place
- There are many "pre-TRIPS" patents in developing countries
  - But the patent system may not have provided TRIPS-required protections
  - We distinguish between patents granted before and after compliance
- Our definition of a patented drug is one for which a patent is in force in a country (post-grant date, pre-expiration date)

Countries

Income group (2000)	**N**
High income: OECD	20
High income: nonOECD	4
Upper middle income	17
Low/Lower middle income	19
Geographic region	**N**
East Asia & Pacific	10
Europe & Central Asia	27
Latin America & Caribbean	9
Middle East & North Africa	9
North America	2
South Asia	2
Sub-Saharan Africa	1

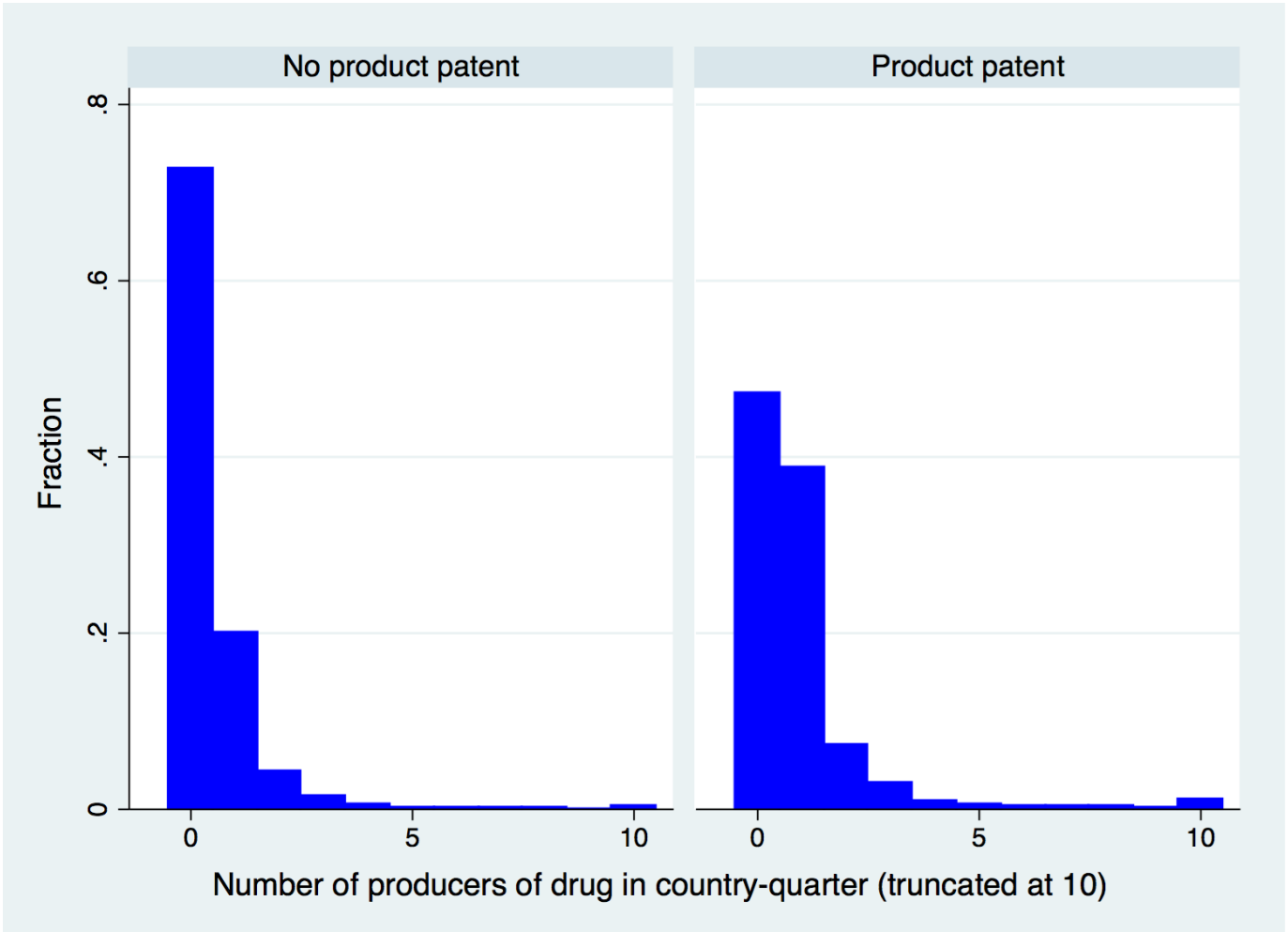
TRIPS compliance

Year of TRIPS compliance deadline	N
1995	25
1996	1
1999	1
2000	15
2001	2
2005	12
2012	1
n/a	2

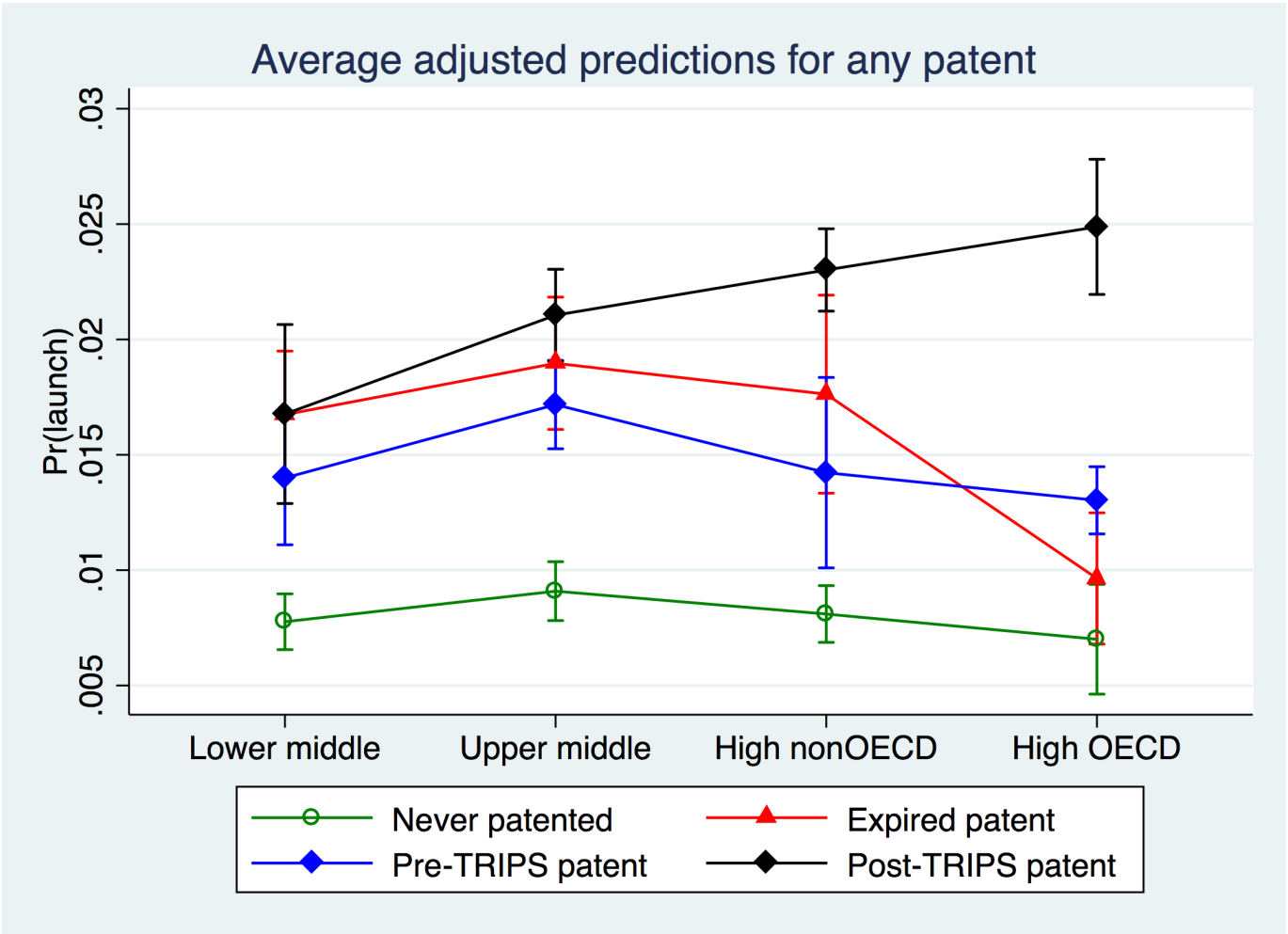
Simple statistics on access

	Launch	Orig 1st	Yrs to orig	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
No patent	0.31	0.73	3.51	0.43	7.50
Any patent	0.59	0.84	1.75	0.32	7.01
Product patent	0.60	0.84	1.50	0.31	7.01
Total	0.45	0.80	2.25	0.36	7.25

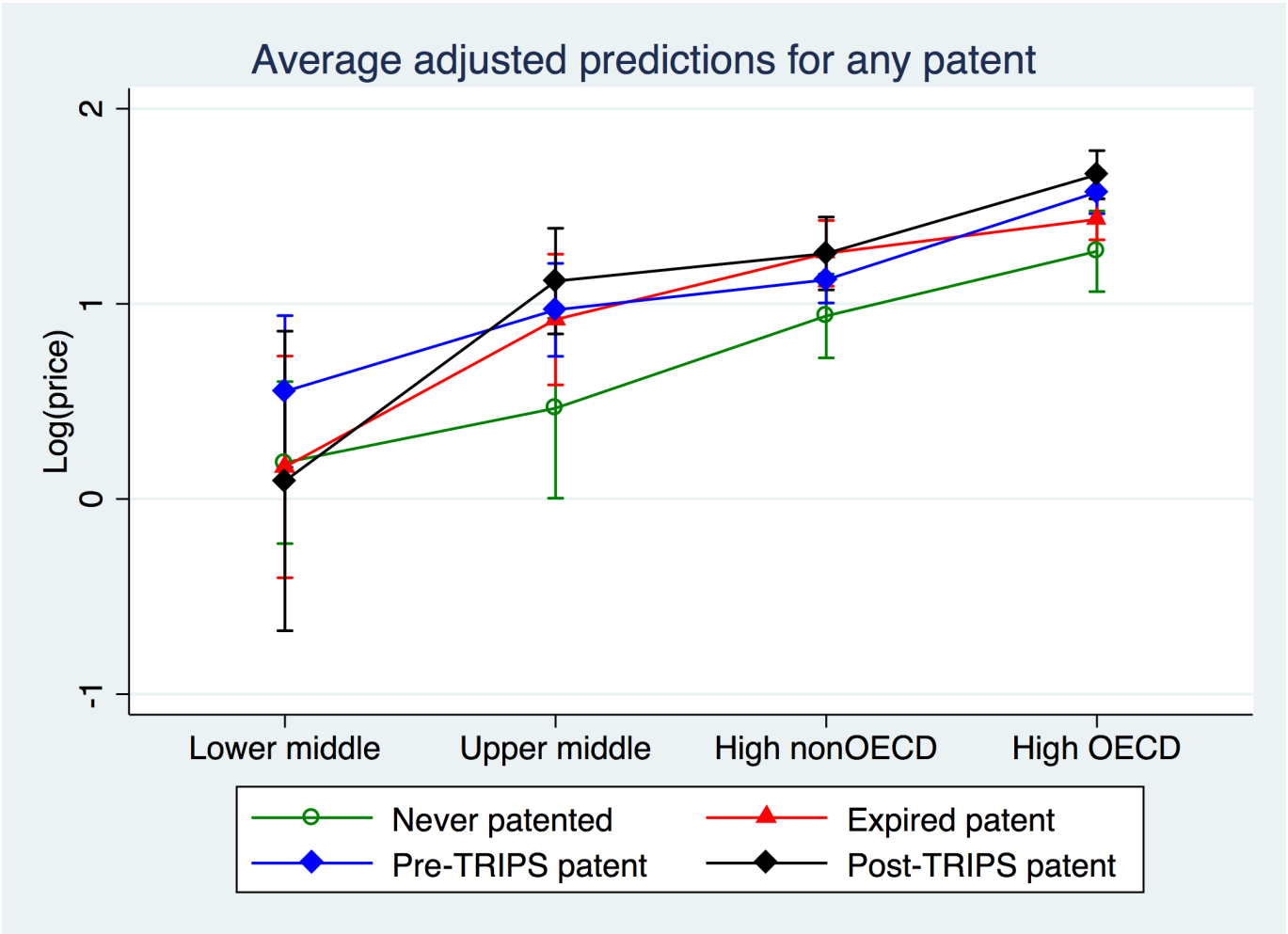
Patents and competition



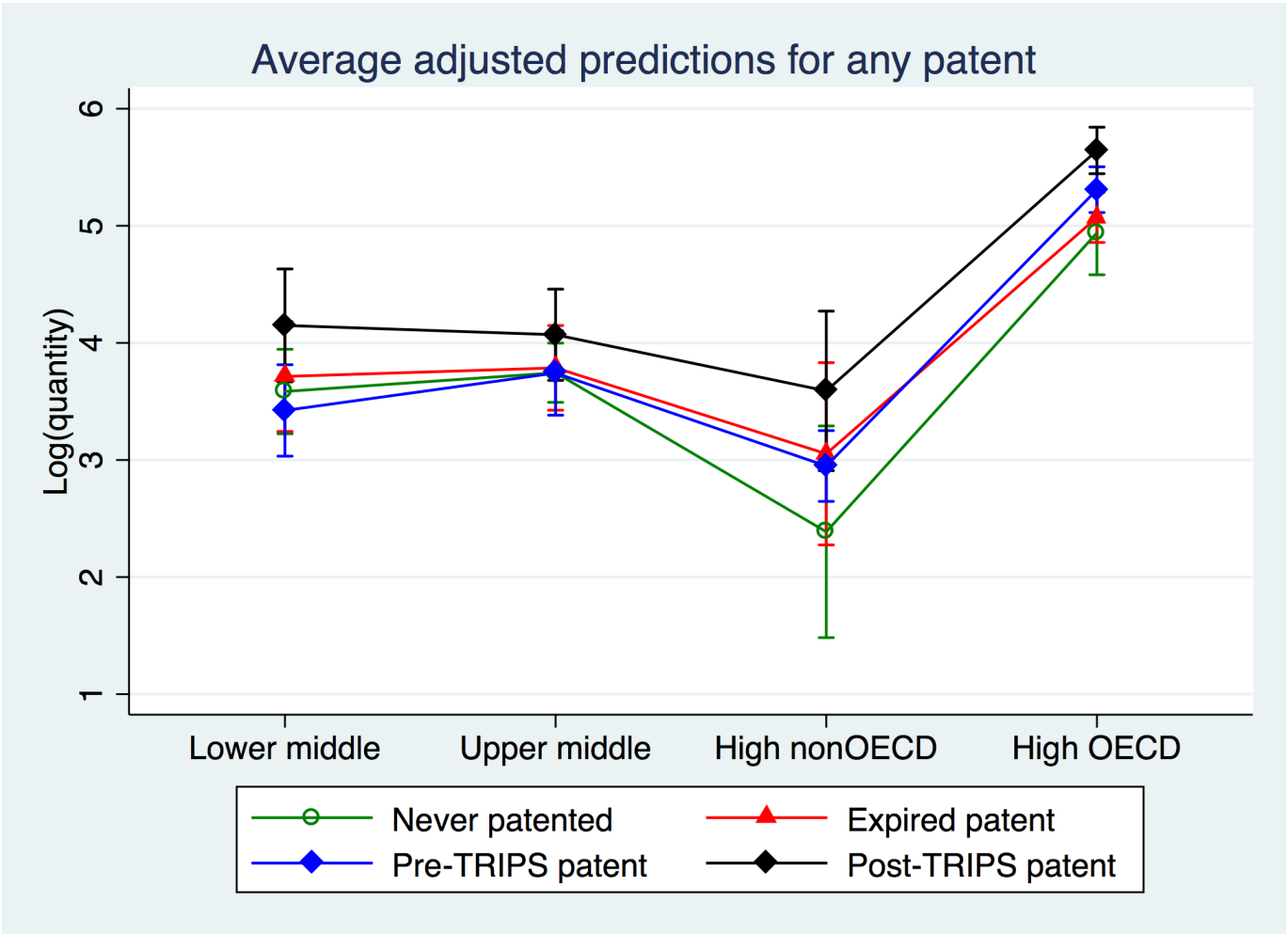
Launch


Average adjusted predictions for any patent
Pr(launch)
.005
.01
.015
.02
.025
.03
Lower middle
Upper middle
High nonOECD
High OECD
Never patented
Expired patent
Pre-TRIPS patent
Post-TRIPS patent

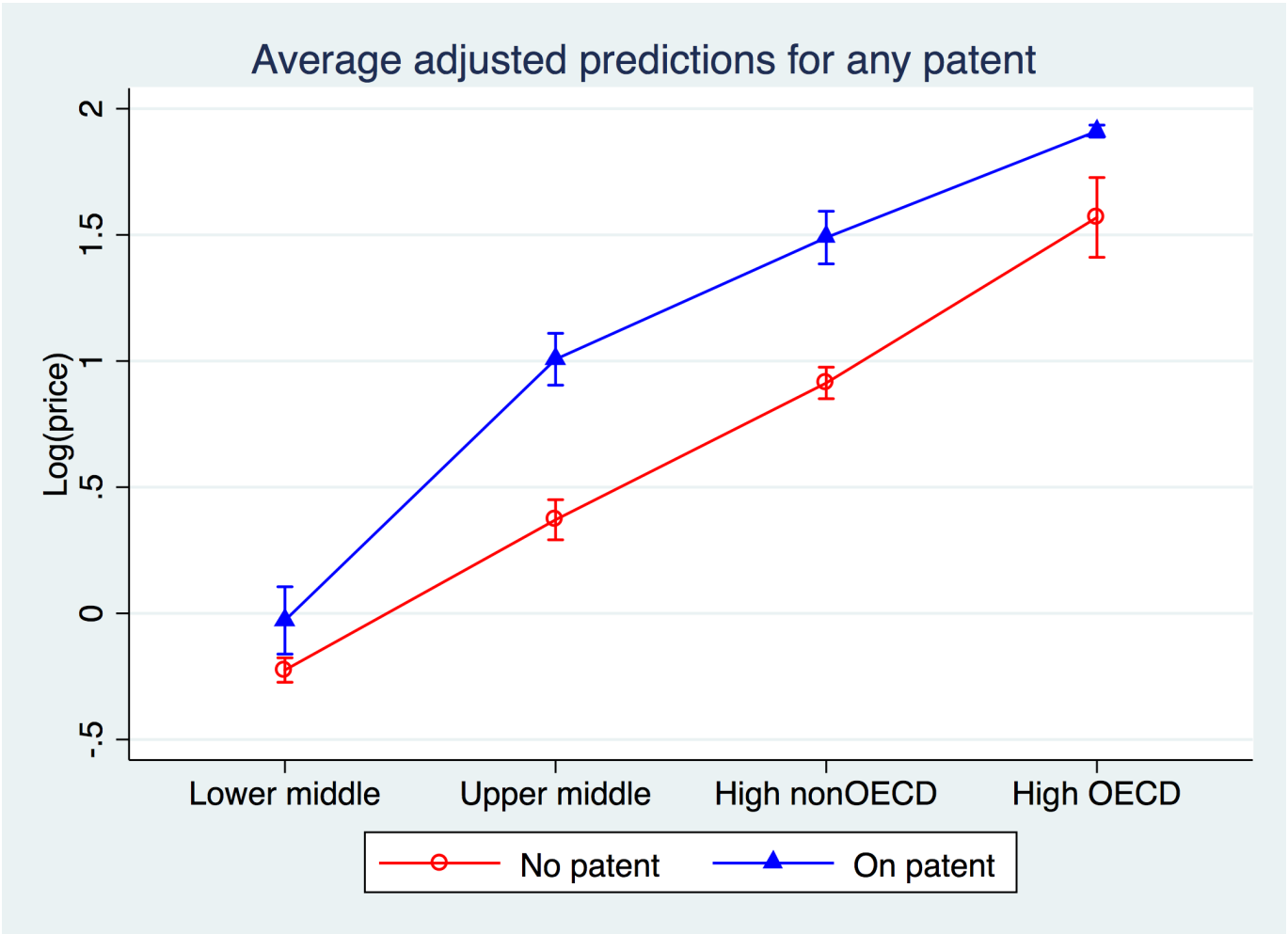
Price


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

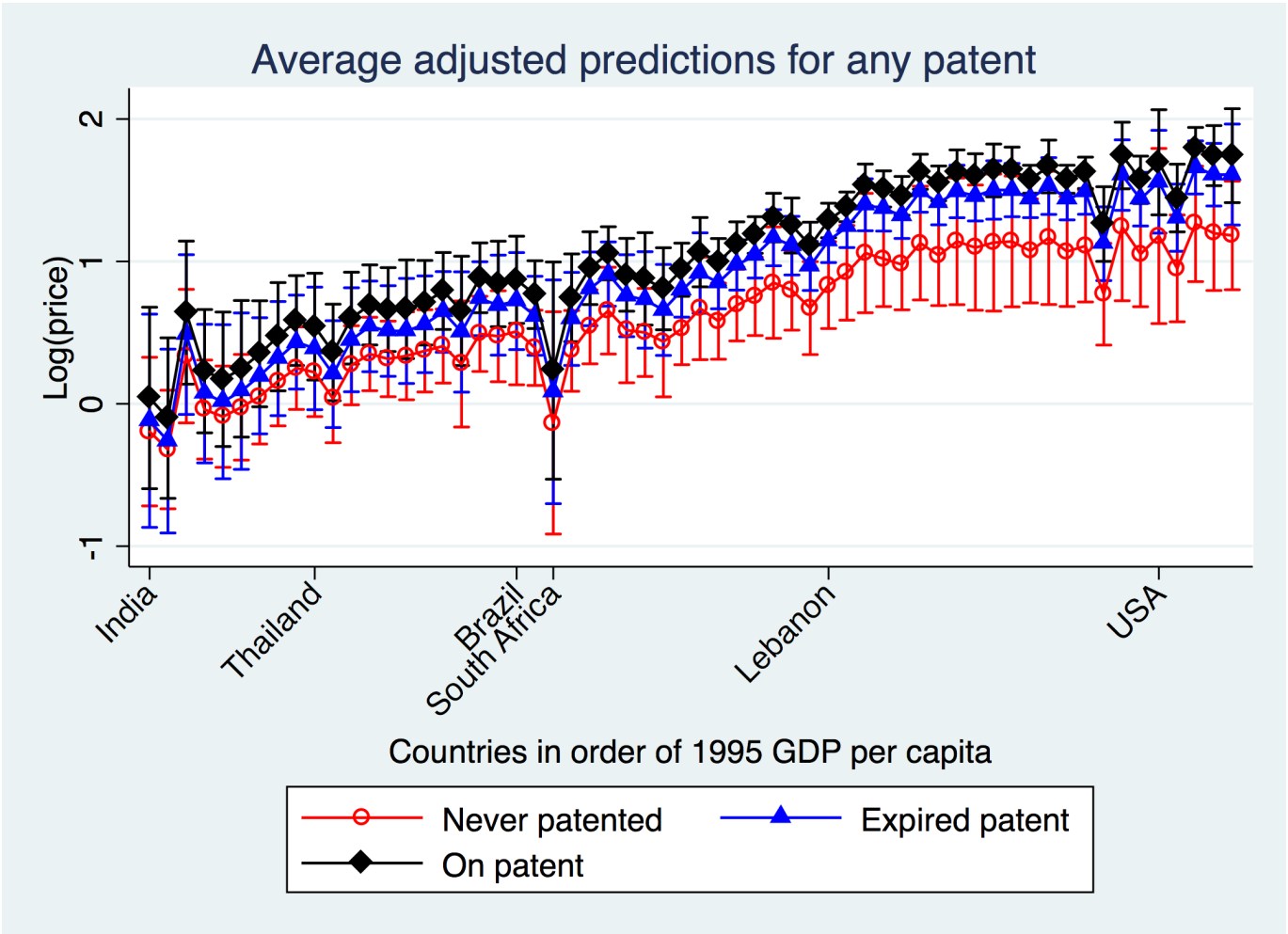
Quantity


Average adjusted predictions for any patent
Log(quantity)
1
2
3
4
5
6
Lower middle
Upper middle
High nonOECD
High OECD
Never patented
Expired patent
Pre-TRIPS patent
Post-TRIPS patent

Price: IV


Average adjusted predictions for any patent
Log(price)
-.5
0
.5
1
1.5
2
Lower middle
Upper middle
High nonOECD
High OECD
No patent
On patent

Price: by country



Summary of results

- Patents increase the speed of launch
  - Launch incentives matter more for originators than for generics
- Patents do have a sizeable impact on price
  - Substantial variation across countries
  - Post-TRIPS, the price premium has not increased in poor countries on average
- Patented products don't sell lower quantities
  - Patents provide originators an incentive to invest in developing the market

Caveats

- Any effect we find reflects the implementation of IPRs as practiced so far
- In particular, a number of policies or exceptions may weaken IPRs
  - Patent office rules (India)
  - Compulsory licensing (India, Brazil, Thailand, South Africa)
  - Price controls (most countries, included developed)
- We have not included the potential interaction with NGO activities or political pressures on price

Recent case

- Sovaldi, Gilead's new Hep C treatment, is $84,000 per course of treatment in the US (€54,000 in France)
- MSF's Access Campaign is opposing the patent application for Sovaldi in India
  - Claims that it could be produced for $250
- Gilead has announced plans to license Indian drug firms to sell a $2000 version

Conclusion

- Understanding the static effects of IPRs in developing countries is critical
  - Relevant for "TRIPS-plus" bilateral trade agreements
  - Important for the debates on the appropriate use of compulsory licensing and price controls
- Our results suggest that the effects are nuanced:
  - IPRs are associated with higher prices, although post-TRIPS patents do not seem to have increased prices further
  - But IPRs are also associated with faster launch and higher quantities