Intellectual Property Rights and Access to Innovation

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Context: Multilateral and bilateral trade pressures on IPRs

Negotiations during the Uruguay round of the WTO on:

- Harmonization across countries and industries
- General increase in the duration, enforcement and scope of patents

Inconclusive theory or empirical findings: Optimal balance varies across industries and countries

(Scotchmer & Green 1990; Lerner and Jaffe 2004; Chin & Grossman 1990; Helpman 1993; Sakakibara & Branstetter 1999; Bessen & Maskin 2002; Scherer and Weisburst 1995; Kyle and McGahan 2012; Cohen et al 2000; Lanjouw and Cockburn 2001; Boldrin and Levine 2002; Qian 2007, 2009; Chatterjee et al 2014, Danzon and Epstein 2013)

Research Agenda: What are the impacts of TRIPS?

Impacts on Firms' Incentives and Access of Innovation

- The key question of IPR impacts on innovations is an extension of the debate on whether competition fosters innovation (Schumpeter vs. Arrow)

- My substantive research in this area:

1. How IP laws affect innovations
   - Patent laws stimulate domestic innovation only conditional on national innovative potential (Qian 2007)
   - Patent laws attract more FDI in countries with better educational attainment and economic infrastructure (Qian 2009)
2. What happens in the absence of IP enforcement
   - Impacts of competitive pressure from counterfeits (Qian 2008-2014)

Turning from studying incentives to the access of innovations

(Kyle and Qian 2015)

The TRIPS+ Agreement

- 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

Research Questions

How have IPR on pharmaceuticals changed access post-TRIPS? What are the pricing and sales impacts on these drugs?

TRIPS Compliances

Table 1: Distribution of country characteristics

Year of TRIPS compliance deadline	N
1995	25
1996	1
1999	1
2000	16
2001	2
2005	12
2012	1
Total	58
Income group (2000)	**N**
High OECD	20
High nonOECD	4
Upper middle	17
Lower middle	16
Low income	3
Total	60
WDI 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
Total	60

- More than 95% of all countries implemented pharmaceutical product patents by 2005.
- TRIPS is responsible for much of this shift.
- Our sample covers countries of various income levels and geographic regions

Empirical Design

- Approach: compare equilibrium outcomes for launch delay, price and quantity sold with and without IPRs. We can compare
  - Countries with IPRs to those without
  - The same country before and after national IPRs
  - Drugs with and without IPRs within the same country and across countries
- Challenges
  - Simultaneity of launch, price and quantity
  - Endogeneity of IPRs
    - IPRs are not randomly assigned across countries
  - Other (also endogenous) policies that undermine IPRs

The first two approaches can be problematic

IDENTIFICATION STRATEGY

IPRs are not retroactively granted following TRIPS compliance

- The initial application date of a drug's patent determines its "selection" into treatment (whether it is eligible for a patent)

- First application date is the "priority date": must apply in other countries within one year
  - A drug with a priority date in 1998 could not be patented in Thailand or India
  - A drug with a priority date in 2002 could be patented in Thailand but not India
  - A drug with a priority date in 2006 could be patented in both Thailand and India

Our claim is that this selection of a new drug into patent treatment internationally is exogenous in the short-run

MARKET OUTCOME DATA (launch, price, units sold)

- MIDAS database from IMS Health
  - Quarterly observations on price and sales at the package level, 2000-2013: use quantity-weighted average ex-mfr price per molecule or molecule combination (smallest-dose)
  - 59 countries
  - Also have the global and local launch dates for each drug

- Details (2 million molecule-country-quarter observations)
  - Includes only drugs first launched since 1990 and in at least 2 markets, and that we can match to patent data
  - Excludes diagnostics, hospital solutions and injectables
  - Excludes donations by drug firms and distribution outside of channels covered by IMS audits
  - Sales in local currency are adjusted for local inflation, then converted to 2013 US $

IPRs and Other Data

- Country-level Policies
  - Recommended national patent implementations – IV (WTO rules)
  - Actual TRIPS compliance years – treatment (WIPO)
  - National pharmaceutical price control, compulsory licensing, parallel imports, health care policies (various database and web searches)
- 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
- World Development Indicators (World Bank)
- Disease burden (market potential for drugs) – DALY (WHO)

Disease Coverage

Table 2: Distribution of molecules across diseases

Disease	N
Infectious and parasitic	102
Respiratory	49
Nutritional deficiencies	3
Neoplasms	116
Diabetes	36
Endocrine	11
Neuropsychotic	92
Sense organ	10
Cardiovascular	136
Digestive	44
Genitourinary	41
Skin	36
Musculoskeletal	39
Oral	1
Total	716

Patent Information

- Our definition of a patented drug is one for which a product patent is in force in a country (post-grant date, pre-expiration date)
- 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
  - However the patent system may not have provided TRIPS-required protections
  - We distinguish between patents granted before and after compliance

Summary Statistics

Variable	Mean	Std. Dev.	N
Ln(price per unit in US dollars)	1.718	2.508	337806
Ln(quantity)	3.513	2.913	337806
Active product patent	0.359	0.480	337806
Number of granted patents on drug in country	2.686	5.728	337806
Any active patent	0.616	0.486	337806
Active product patent granted post-TRIPS	0.009	0.094	337806
N granted patents on drug in country during post-TRIPS era	0.062	0.471	337806
Any active patent granted post-TRIPS	0.031	0.172	337806
Post TRIPS compliance deadline	0.950	0.218	337806
Country permits product patents	0.980	0.139	337806
TRIPS country	0.288	0.453	337806
Ln(DALY)	3.400	1.862	336459
Ln(GDP per capita)	2.369	1.116	337806
Life expectancy	76.364	5.390	337806
Ln(population)	3.245	1.533	337806
Number of local producers	1.629	2.387	337806
Number of local substitutes	8.887	7.162	337806
Number of global substitutes	49.100	62.308	337806
Price index of ATC class	1.508	4.265	337806

Regression Specification

- Estimate launch using discrete-time hazard with logit link
  - Heckman's selection model applied
  - IV: 1. Whether a drug was eligible for TRIPS-compliant patent protection in a particular country (within-window); 2. Whether current period falls within the standard patent term (within-term)
- Estimate price conditional on launch
- Estimate quantity conditional on launch
- Apply SUREG in combination with multiple imputation as robustness checks
  - Drugs not launched has missing price and quantity values
  - Bayesian imputations

Patented drugs are charged at higher prices. Quantities sold are higher for products with post-TRIPS patents

Table 7: Main Effect of Product Patent

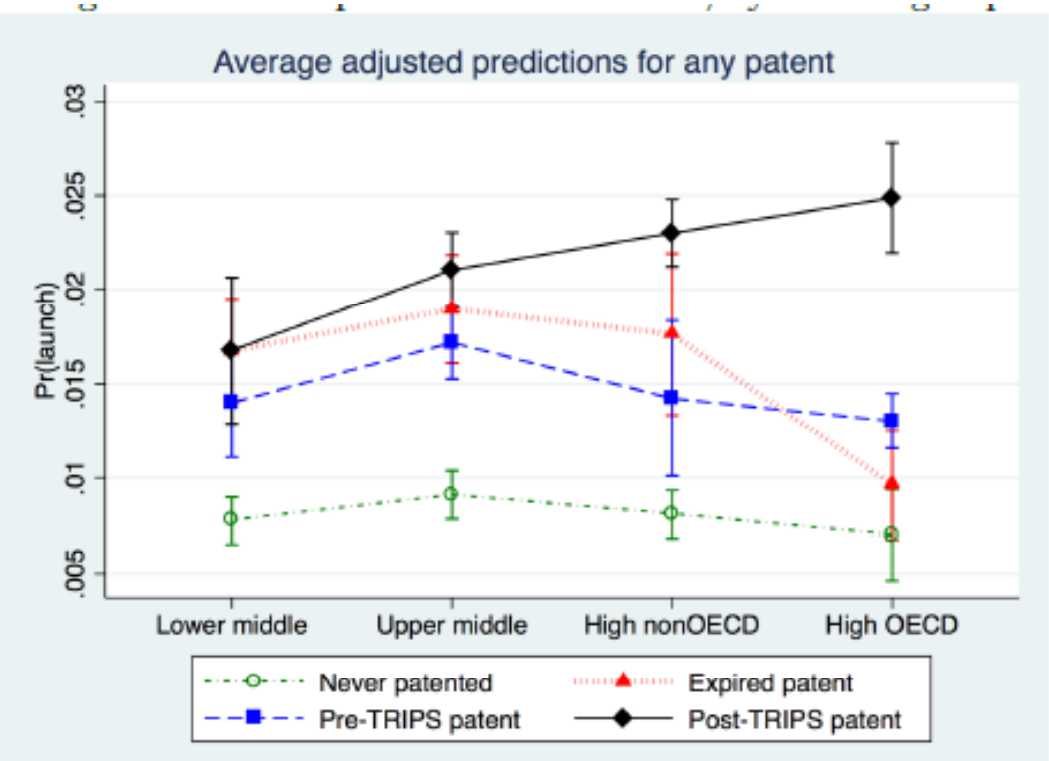
	Launch b/se	Price b/se	Quantity b/se
Expired patent	0.5969***	0.3005***	0.2820*
	(0.0512)	(0.1082)	(0.1482)
On patent	0.8808***	0.4774***	0.5324***
	(0.0538)	(0.1404)	(0.1893)
Log(DALY)	0.0098	−0.0611*	0.1856***
	(0.0173)	(0.0329)	(0.0571)
Ln(GDP per capita)	−0.0160	0.2842***	0.7687***
	(0.0501)	(0.0995)	(0.1334)
Life expectancy	0.0160	0.0255	0.0377
	(0.0111)	(0.0190)	(0.0226)
Ln(population)	0.0186	0.0274	0.7909***
	(0.0290)	(0.0436)	(0.0599)
Number of local substitutes	0.0076***	0.0033	0.0144***
	(0.0015)	(0.0068)	(0.0047)
Price index of ATC class	0.0040*	−0.0078	−0.0020
	(0.0022)	(0.0150)	(0.0051)
Log originator products in country, t-1	0.2102***	0.0521	0.1097***
	(0.0091)	(0.0374)	(0.0407)
Intercept	−6.3602***	−2.3302*	−4.0173**
	(0.8278)	(1.3860)	(1.5793)
N	1112013	620330	620330
Pseudo R^2	.0897		
Adj. R^2		.832	.765
Fixed effects	Year ATC	Year Drug	Year Drug

* p<0.10, ** p<0.05, *** p< .01. Standard errors are clustered by country.

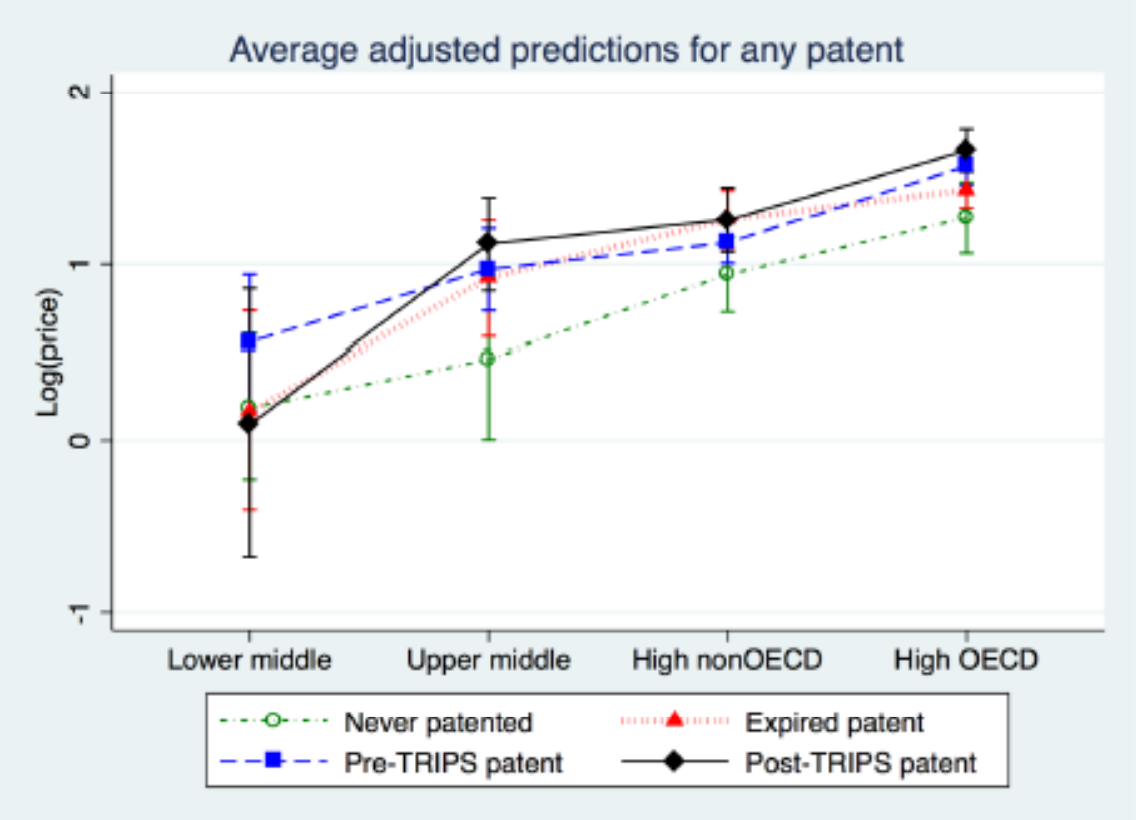
Disentangling Income Effects

	Launch b/se	Price b/se	Quantity b/se
Expired patent	0.6929***	0.2609***	0.3298**
	(0.1661)	(0.0819)	(0.1542)
On patent	1.1871***	0.4028***	0.6940***
	(0.1749)	(0.1132)	(0.1997)
High nonOECD × expired patent	0.0916	−0.0233	0.5445
	(0.1779)	(0.1528)	(0.3410)
Upper middle × expired patent	0.0184	0.2211	−0.1752
	(0.1740)	(0.1882)	(0.1910)
Lower middle × expired patent	0.0009	−0.2943	−0.1464
	(0.1863)	(0.1886)	(0.2016)
High nonOECD × on patent	−0.2495	−0.0674	0.2960
	(0.1932)	(0.1751)	(0.4699)
Upper middle × on patent	−0.4282**	0.2080	−0.6153**
	(0.1810)	(0.2100)	(0.2491)
Lower middle × on patent	−0.4806**	−0.0994	−0.5539*
	(0.2078)	(0.1936)	(0.2773)
Drug has data exclusivity in country-quarter		0.1090	−0.1145
		(0.0863)	(0.0860)
High nonOECD	0.3455	−0.1788	−0.8883*
	(0.2217)	(0.1788)	(0.4985)
Upper middle	0.3963*	−0.4005	−0.1766
	(0.2282)	(0.3831)	(0.3510)
Lower middle	0.2657	−0.4485	−0.4956
	(0.2647)	(0.7233)	(0.6062)
Log(DALY)	0.0141	−0.0728**	0.1574***
	(0.0154)	(0.0309)	(0.0523)
Ln(GDP per capita)	−0.0006	0.1338	0.6102***
	(0.0820)	(0.2599)	(0.2235)
Life expectancy	0.0186	0.0233	0.0196
	(0.0120)	(0.0167)	(0.0157)
Ln(population)	0.0336	0.0179	0.7585***
	(0.0296)	(0.0498)	(0.0640)
Number of local substitutes	0.0076***	0.0022	0.0122**
	(0.0015)	(0.0063)	(0.0047)
Price index of ATC class	0.0036	−0.0067	−0.0027
	(0.0024)	(0.0141)	(0.0051)
Log originator products in country, t-1	0.2082***	0.0458	0.0928**
	(0.0091)	(0.0373)	(0.0358)
Intercept	−6.9383***	−1.4191	−1.6939
	(1.0585)	(1.4676)	(1.1644)
N	1112013	620330	620330
Pseudo R^2	.091		

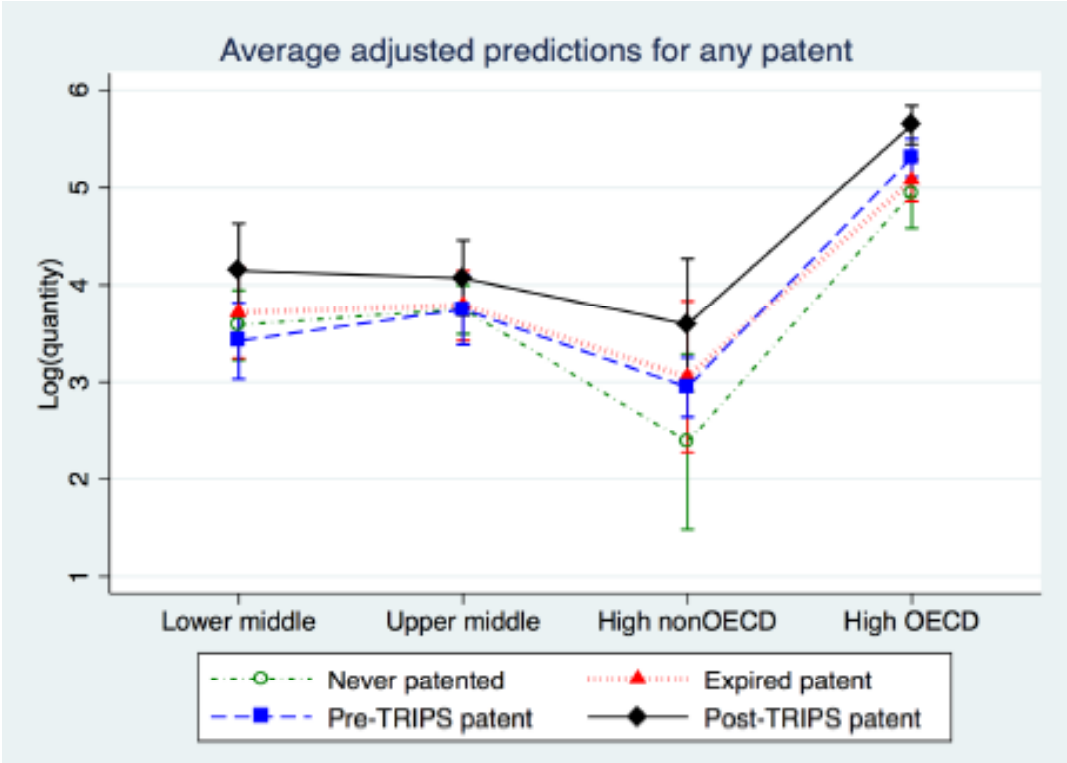
Post-TRIPS product patents witness the most statistically significant relationship between Patenting and the launch speed



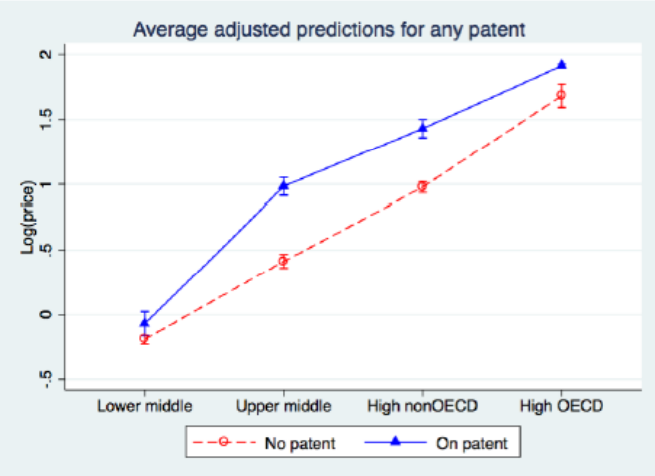
POST-TRIPS PRODUCT PATENTS ARE ASSOCIATED WITH A SMALLER PRICE PREMIUM IN RELATIVELY POOR COUNTRIES

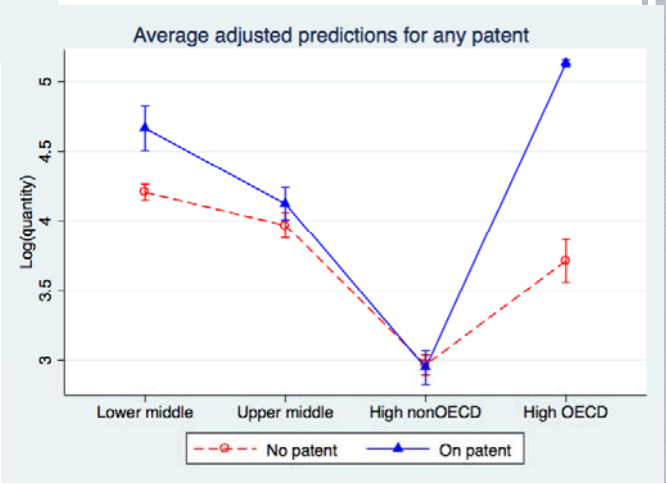


POST-TRIPS PRODUCT PATENTS DO NOT SIGNIFICANTLY DIFFER FROM PRE-TRIPS PATENTS IN SALES EXCEPT IN THE HIGH-INCOME COUNTRIES



IV Estimates Show Larger Magnitudes





Patent Protection and Launch by Disease Type

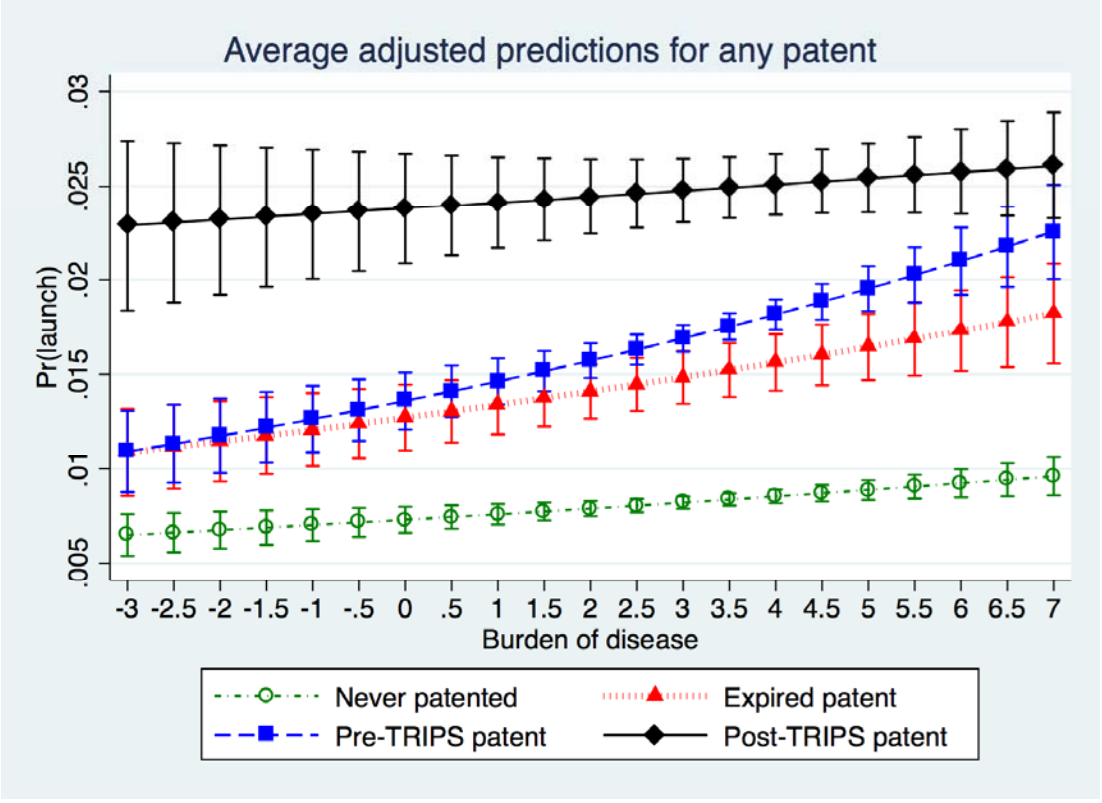
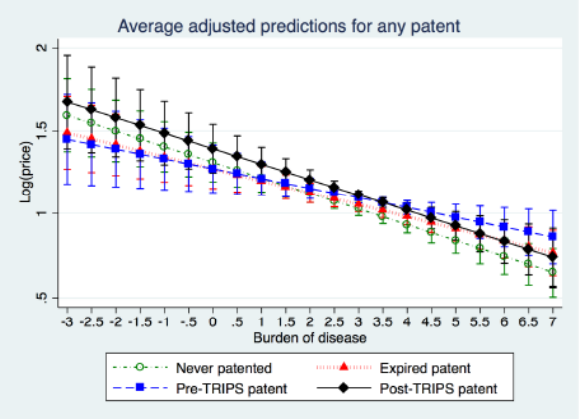
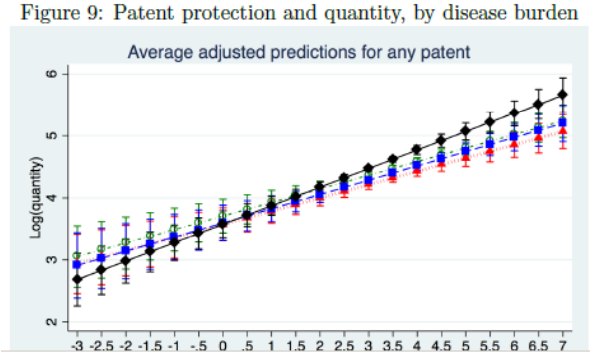


Figure 8: Patent protection and price, by disease burden



Price premium is lower for diseases that has a higher burden, and quantity sold are higher. The relationship is most pronounced for the post-TRIPs patented drugs.

Figure 9: Patent protection and quantity, by disease burden



SUMMARY OF RESULTS

- Patents are associated with faster launch
  - Launch incentives matter more for originators than for generics
- Patents are associated with higher prices
- Effect on quantity is imprecisely estimated, but products with post-TRIPS patents have higher sales
- We have also checked that prices of older substitute drugs are not rising in response to the presence of patented drugs

Caveats

- Any effect we find reflects the implementation of IPRs as practiced so far
- In particular, TRIPS-permitted flexibilities may weaken them
  - Patent office rules (India)
  - Compulsory licensing (India, Brazil, Thailand, South Africa)
  - Price controls (most countries, including developed)
- We have not included the potential interaction with NGO activities or political pressures on price
  - Primarily focused on HIV, Malaria and TB
  - Impetus behind the formation of "patent pools"

Conclusion

- Understanding the static effects of IPRs in emerging markets is critical
  - Affects everyday lives as well as marketing of new drugs
  - Important for various policy debates, including price controls, licensing, etc.
  - Relevant for "TRIPS-plus" bilateral trade agreements
- The results suggest that the effects are nuanced
  - IPRs are associated with higher prices, although cross-country price discrimination has increased post-TRIPS
  - IPRs are also associated with faster launch and higher quantities, although these estimates come with a wider confidence interval