The effect of Intellectual Property Rights on innovation in the pharmaceutical sector

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Introduction

Over the last 30 years:

- introduction/extention national law protecting IPR in an increasing number of countries...
- 1995: TRIPS Agreement- minimum standards of IPR protection for all WTO members

Strong debate:
can IPR legislation stimulate enough innovation (dynamic gains) to justify the social welfare costs (static costs) associated with its implementation?

Literature review

Theoretical lit:

- independent vs. cumulative innovations: strenghening of patents encourages innovations

Empirical lit.:

- Whole economy:
  - Positive effect of IPR on domestic innovation and technology transfers...
  - ...but results may be difficulty translated into policy recommendations (Lo, 2011; Levin et al, 1987)

- Pharmaceutical sector:
  - just two cross country analysis (Qian, 2007; Liu and La Croix, 2011)
  - mixed-evidence

Pharmaceutical sector

Industry of the four "highs":

- high R&D costs (R&D/sales ratio $\approx$ seven times higher than the one characterizing all other manufacturing firms)
- high uncertainty (only 1 or 2 out of 10,000 new molecules identified during the lead identification phase survive all along the R&D process and end up as a marketable drug)
- high profitability
- high marketing costs (R&D/sales=17%; marketing/sales>17%. Marketing=1/3 of total costs.)

Novelties

- cross country analysis for the pharmaceutical sector (79 countries; 25 years)
- focus on poor countries (53 out of 79)

- homogeneous set of pharmaceutical IPR reforms (TRIPS compliant)
- treat separately "other" pharma IPR reforms

- more accurate measure of innovation (European vs. US patent data)

- use of count data models

- evidence in favor of patent reforms exogeneity

Definitions and measurement: innovation change

- pharmaceutical **patent** applications (IPC codes. No fractional count)
  - info available for many countries (vs R&D)
  - high propensity to patent
- counted by priority date (no lag other than: beginning of R&D/pat. $\approx$3 years)
- weighted for citations received in the 6 years from the priority date ($weightedpatent_i = (1 + C_i)^{0,6}$, Qian, 2007)
  - patents filed at the early stage of the development process
- fractional counted by inventor's country of residence (OECD)
- filed to the EPO
  - process and standards constant
  - patents filed in well-developed and profitable market (independently from inventor's domestic patent legislation conditions, Qian, 2007)
  - EPO: more non-OECD applications that USPTO
  - EPO: 95% of citations added by the examiner

Definitions and measurement: national patent law

Before TRIPS (1995): only 20 countries without pharma patents protection. All other countries with different levels of protection.

For sake of homogeneity:

- "national law"- laws respecting at least TRIPS requirement in terms of subject-matter to be protected, rights conferred and permissible exceptions, minimum duration
- "partial protection"- laws offering product +process protection but not fully TRIPS compliant
- "process protection"- laws protectiong only process

Data and descriptive statistics

- patent data: KITES database (79 countries, 1977-2001)
- law data: previous literature + IP laws (WIPOLEX database)
- controls: WB indicators, Fraisier Institute, UNCTADSTAT

Variable	Mean	Std. Dev.	Min.	Max.	N
weightedp	143.054	753.743	0	11218.523	1975
national_law	0.28	0.449	0	1	1975
schoolenr	20.984	17.916	0.077	97.142	1492
Pop	65610076.975	198653004.959	571891	1271850000	1975
GDPpc	6372.027	8630.337	54.505	38025.5	1853
econ_freedom	6.096	1.299	2	8.9	403
pharma_export	665649.815	1624595.226	0.873	8834430	451

- 11 countries (developing) with 0 patents all along the period (even without these: 48% of obs. have 0 patents)
- 7 countries already with national law in 1977; 51 introduced it.

Estimation techniques

Difference in Differences model:

$$weightedp_{c;t+3} = \beta_0 + \beta_1 national\_law_{c;t} + \beta_2 GDPpclog_{c;t} + \beta_3 ecofrelog_{c;} + \beta_4 Schoolenr_{c;t} + \beta_5 poplog_{c;t} + \beta_6 nepolaws + \beta_7 epo_{c;t} + \epsilon_{c;} \quad (1)$$

with **country and time FE**.

Dep. Var: weightep (at time $t+3$)$\Rightarrow$ only NON-NEGATIVE values.

$\Downarrow$

NB with unconditional FE and cluster SE

- able to deal with non-negative highly skewed dep.var. (var>mean)
- authomatically drops countries with all zero (biased results when zero not randomly distributed)
- $E(y|x) = exp(\beta_0 + \beta_1 x_1 + ...\beta_k x_k)$

Estimation techniques

NB assume that all important innovation are patented in EU (Qian, 2007). What if this is not true?

- ZINB with unconditional FE and cluster SE
  - zeros due to two different processes: decision not to patent (c=0); willing to patent but no innovation capabilities

$$f(y) = \begin{cases} f_1(c=0) + [1 - f_1(c=0)]f_2(y) & \text{if } y\text{=0} \\ [1 - f_1(c=0)]f_2(y) & \text{if } y \geq 1 \end{cases}$$

  - two part model
    logit model to explain the probability to be in "certain zero" case + count NB for the non "certain zero"
  - both process may depend on same variables, or variables may differ (no instruments: $\neq$ Heckman selection model)
  - includes also countries with all zeros

Exogeneity on national law

- National laws introduced as a consequence of US pressures (301 Special List) or of international agreements requirements.
- Wide divergence in per-capita income and in development of pharma sector among countries at the time of the reform (Branstetter et al, 2006).

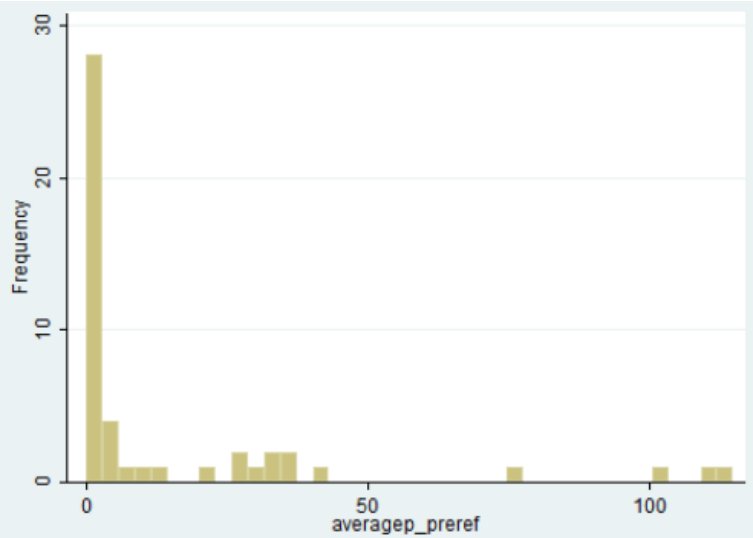

Figure: Propensity to innovate at the time of the reform.

Results

	(1) weightedp	(2) weightedp	(3) weightedp
national_law	0.0773	0.100	0.495***
	(0.0859)	(0.102)	(0.158)
GDPpclog	1.494***	1.446***	1.468***
	(0.476)	(0.494)	(0.417)
ecofrelog	0.936	1.016*	0.929*
	(0.622)	(0.565)	(0.557)
Schoolenrollmenttertiaryg	0.00329	0.00278	0.00443
	(0.00604)	(0.00627)	(0.00523)
poplog	3.518***	3.559***	4.066***
	(1.246)	(1.231)	(1.173)
nepolaws	0.0775**	0.0786**	0.0701**
	(0.0337)	(0.0340)	(0.0275)
epo	0.403**	0.389**	0.382***
	(0.160)	(0.156)	(0.145)
national_law_ing		-0.157	-0.641**
		(0.269)	(0.304)
partial_process			0.568***
			(0.178)
par_pro_ing			-0.788**
			(0.315)
_cons	-74.51***	-74.84***	-83.23***
	(21.21)	(20.87)	(19.46)

- effect of the national law:
  - developed countries: +64%
  - developing countries: +17%
- effect of partial or process protection:
  - developed countries: +76%
  - developing countries: +22%

Results: ZINB

	weightedp
legge_naz	0.441***
	(0.0739)
partial_process	0.510***
	(0.0751)
legge_l_ing	-0.681***
	(0.135)
par_pro_l_ing	-0.888***
	(0.156)
_cons	-85.70
	(431.1)
TIME DUMMIES	yes
OTHER CONTROLS	yes
logit	
lphex_54_95	-1.358***
	(0.283)
nepoleggi	-0.124
	(0.127)
legge_naz	-1.976**
	(0.970)
partial_process	-24.02
	(1331.9)
ldist_o	-2.680***
	(0.806)
_cons	32.64***
	(8.569)
lnalpha	

- effect of the national law:
  - developed countries: +55%
  - developing countries: +6%
- effect of partial or process protection:
  - developed countries: +66%
  - developing countries: +8%

Results: is the effect long-lasting?

	weightedp
legge_1_2	-0.0715
	(0.0566)
legge_naz	0.506***
	(0.173)
legge_4_5	-0.0326
	(0.0635)
legge_poi	-0.170
	(0.124)
legge_1_2_ing	-0.171
	(0.242)
legge_l_ing	-0.703***
	(0.271)
legge_4_5_ing	0.394
	(0.375)
partial_process	0.562***
	(0.183)
par_pro_l_ing	-0.854***
	(0.301)
GDPpclog	1.454***
	(0.413)
ecofrelog	1.002*
	(0.587)
Schoolenrollmenttertiaryg	0.00392
	(0.00553)
poplog	3.821***
	(1.245)
nepoleggi	0.0823**
	(0.0326)
epo	0.404***

Evidence in favor of exogeneity assumption

National law is explained by being subject to TRIPS requirement (for developed countries) and US pressures (for developing countries).

	First stage national_law	First stage law_developing	Second stage weightedp
USpressure	-0.0274	0.0396**	
	(0.0199)	(0.0178)	
trip	0.115***	-0.0588***	
	(0.0213)	(0.0193)	
legge_l_ing	0.916***		-0.719
	(0.0240)		(0.461)
legge_naz		0.733***	0.955*
		(0.0192)	(0.496)
legge_res			-0.832
			(1.327)
legge_ing_res			0.0664
			(1.410)
COUNTRIES AND YEARS FIXED EFFECTS	YES	YES	YES
_cons	3.114	0.809	-18.13***
	(3.282)	(2.938)	(2.653)
N	803	803	472
Test $legge\_res\&legge\_ing\_res = 0 : Prob > chi2 = 0.14$			

Durbin-Wu-Hausman test (adapted for count model with FE): no evidence of endogeneity (residuals not significant).

Conclusions

- The presence of national laws and mainly of other forms of protection (and not only their introduction) stimulates pharmaceutical domestic innovation (measured by EU patent application)...
- ... but the effect for developing countries is definitely smaller than for developed ones (imitation phase?)!
- There is no evidence of national law endogeneity.

THANK YOU FOR YOUR ATTENTION!