Patents, Innovation, and Development: Lecture 2

Bronwyn H. Hall

UC Berkeley, NBER, IFS London, and MPI Munich

Outline

- Lecture 1
  - Penrose and this topic
  - Some facts and a brief patent primer
  - Patents and innovation
    - What happens when countries join a regional system?
- Lecture 2
  - Patents and innovation in the development context
    - What happens when patent system is strengthened – Chilean experience?
  - Focus on pharmaceutical patents

Interim summary

- Some evidence that a patent system encourages R&D and growth in high income countries
  - Not necessarily conclusive
- Lots of reasons to think that having a patent system is not an important ingredient of policy for low or even middle income countries
  - Historical cross country evidence
  - Little impact on invention from regional system
  - Theoretical analysis supports the idea that more innovative and richer countries will favor stronger IP
  - More to come…..

Patents and development

- Historically patent systems develop in parallel with innovative economic growth (chicken-egg problem)
  - Venice glass industry and the first invention patents
  - UK had patent protection during industrial revolution, but…
    - innovation without patents in Europe – chemicals in 19C Germany (process but not product); Cornish pumping equipment (response to aggressive patent enforcement by Watt); Lyons silk weaving cooperative
  - 19C US – no national treatment until Paris convention
    - Encouraged local tech development and learning by imitation
    - Plant patent act in 1930, following demands from agric innovators
  - Taiwan – little use of IP until imitation strategy successful
    - Patenting in US starts in 1975 and jumps in 1985
  - Korea – use mainly utility (petty) patents in the early stages of development; little foreign patenting (Kim 2003; Lee & Kim 2010)
    - Korean patenting in US jumps in 1988

Patents and development

- Japan
  - Postwar system - one claim per patent, utility models, pre-grant opposition, early disclosure – designed for incremental/adaptive invention
  - MITI's role in negotiating tech transfer licensing agreements
  - Introduction of pharma product patents in 1970 did increase R&D in that sector (La Croix and Kawaura, IEJ 1996)
  - Strengthening of system in 1988-93 did *not* result in increased R&D (Branstetter and Sakikabara, RJE 2001)
  - Further reforms in the 1990s did *not* increase innovative performance (R&D productivity) either (Branstetter and Nakamura, 2003)
- China
  - Introduction of modern patent system in 1985 (Paris convention)
  - PCT in 1994, TRIPS in 2001, later amendments

TRIPS

- Mandates the same minimum standards for IPRs across the world
  - Coverage for copyright; geographical indications, including origin appellations; industrial designs; integrated circuit designs; patents; new plant varieties; trademarks; trade dress; trade secrets
  - 20 year patent term
  - Patents must be granted for "inventions" in all "fields of technology"
  - Enforcement, remedies, & dispute resolution procedures
- Some exceptions
  - exceptions for certain public interests are allowed (Art. 27.2 and 27.3)
  - Art. 10 – copyright appropriate for software
- Extensions for developing country implementation
  - The transition period expired in 2005; for least developed countries extended to 2013
  - 1 January 2016 for pharmaceutical patents, possibly extended

Art. 27.2 and 27.3 of TRIPS

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3. Members may also exclude from patentability:

   (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

   (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

How do patents help learning?

- Patent publication, patent licensing
  - Of limited value without accompanying tacit knowledge (e.g. Vaitsos 1972 finds all patent licenses in Andean countries accompanied by knowhow transfer)
  - Some evidence that reading pats useful for non-English speakers
- New capital goods, imitation, reverse engineering, tech transfer by MNCs to their subsidiaries in the country
  - All these affected by the development level in the destination country
  - Patent protection helpful if the country has absorptive capacity to imitate imported technology
- Tech spillovers from MNC subsidiaries to other firms in the country may be limited by patents

Two questions

- This leads to two separate questions whose answers may be somewhat at odds with each other:
  - Does stronger patent protection encourage technology transfer?
    - How does it affect behavior of foreign firms?
  - Does stronger patent protection encourage technology development?
    - How does it affect behavior of domestic firms?

Two questions (cont.)

The first question is easier to answer but the second is more important:

1. Foreign firms: stronger IP protection in the host country should encourage (or at least not discourage) transfer of technology.

   Note that this may or may not help local development.

2. Domestic firms: stronger IP could encourage their innovative activities, but can also discourage imitation and inhibit learning and catchup.

Some tech transfer evidence

- Early survey evidence that US multinationals evaluate IP enforcement before making investment abroad; empirical evidence on FDI in 16 developed countries supports this
  - Mansfield (1994), Lee and Mansfield (1996)
- Royalty payments, affiliate R&D spending, and foreign patent apps increase for US multinationals following IPR reforms in 16 foreign countries (mostly middle income).
  - Branstetter, Fishman, and Foley (QJE 2006)
- Country risk more important than IPRs in promoting tech transfer in chemical processing
  - Fosfuri (RP 2004)
- See Maskus (2004) survey for further evidence.

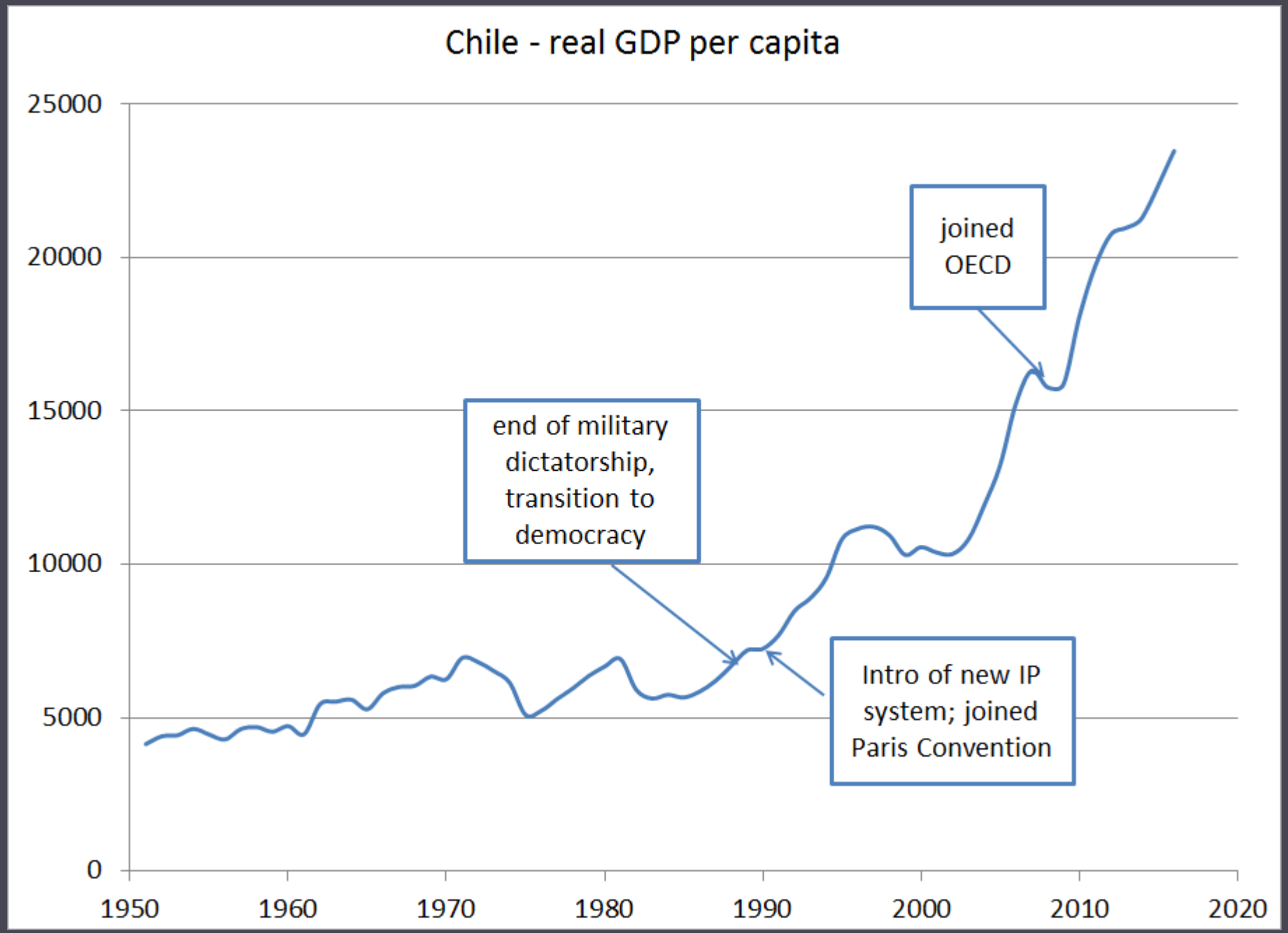
Tech transfer - summary

- For middle income countries that already have innovative capacity or capable of imitation
  - Both tech licensing and FDI respond to stronger IP regimes
  - Quality of technology transferred rises, and there is a shift toward licensing (markets for technology)
- Very low income countries see little response
- IPRs are not very highly ranked by MNEs as an influence on tech transfer/FDI, except for R&D facilities and very advanced technologies.

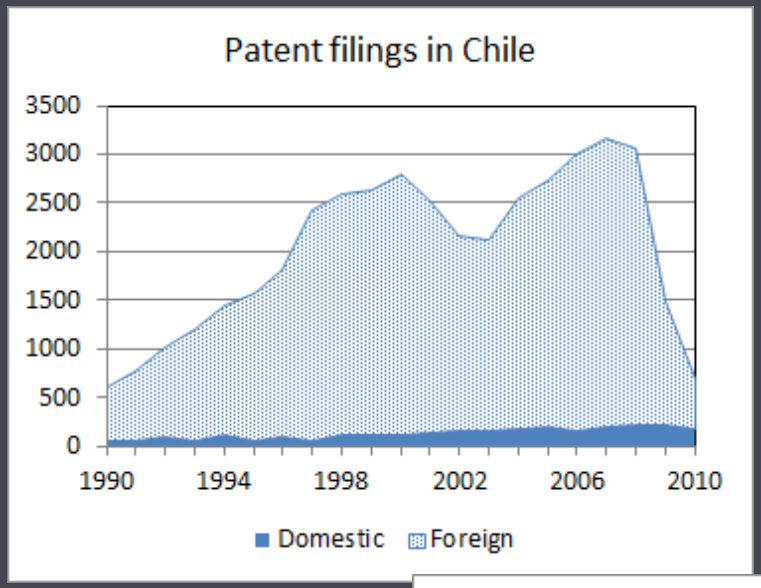
Study of Chilean IP use

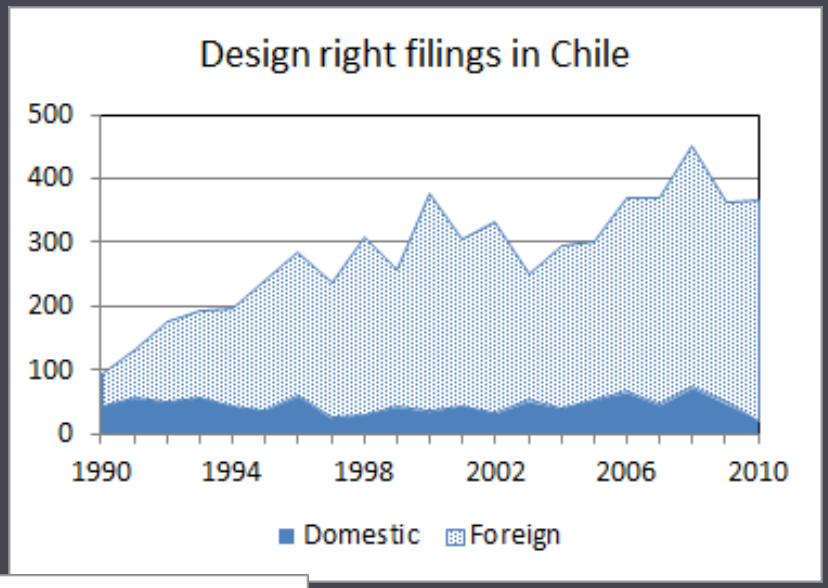
Based on joint work with Carsten Fink, Christian Helmers, and Maria Jose Abud Sittler

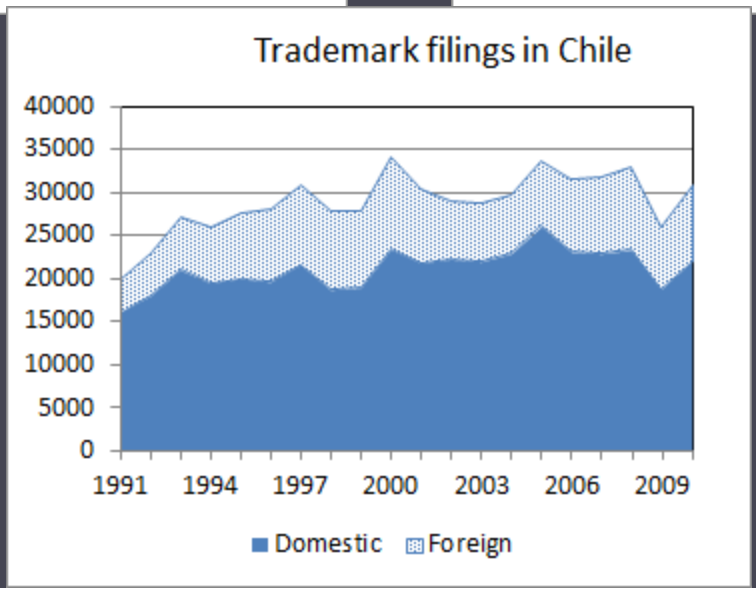
- Chile is now a middle income country, a member of the OECD
  - 1840 – first patent system
  - 1990/91 – new system, joined Paris convention
  - How did this affect Chilean firms?
  - Especially in pharmaceuticals
- Our WIPO study based on comprehensive data
  - All Chilean patents, trademarks, and design rights between 1991 and 2010
  - ENIA manufacturing census 1995-2005
  - Innovacion surveys 1997-1998, 2000-2001, 2003-2010
  - Complete list of drugs registered at the ISP (Institute of Public Health) 1934-2012, with owners and producers, active ingredients, etc.


Chile - real GDP per capita
25000
20000
15000
10000
5000
0
1950
1960
1970
1980
1990
2000
2010
2020
joined OECD
end of military dictatorship, transition to democracy
Intro of new IP system; joined Paris Convention

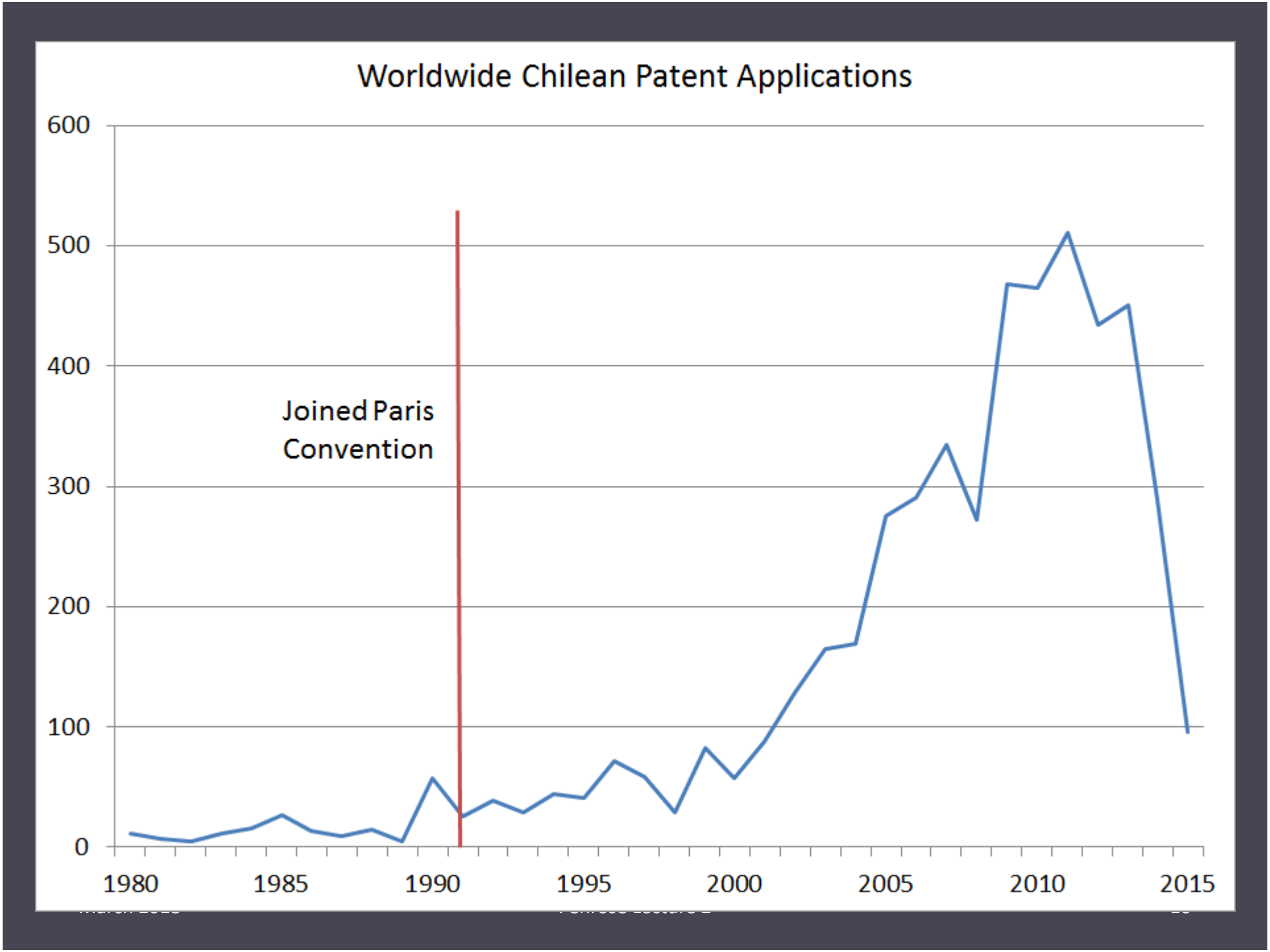
IP use overview – all filings

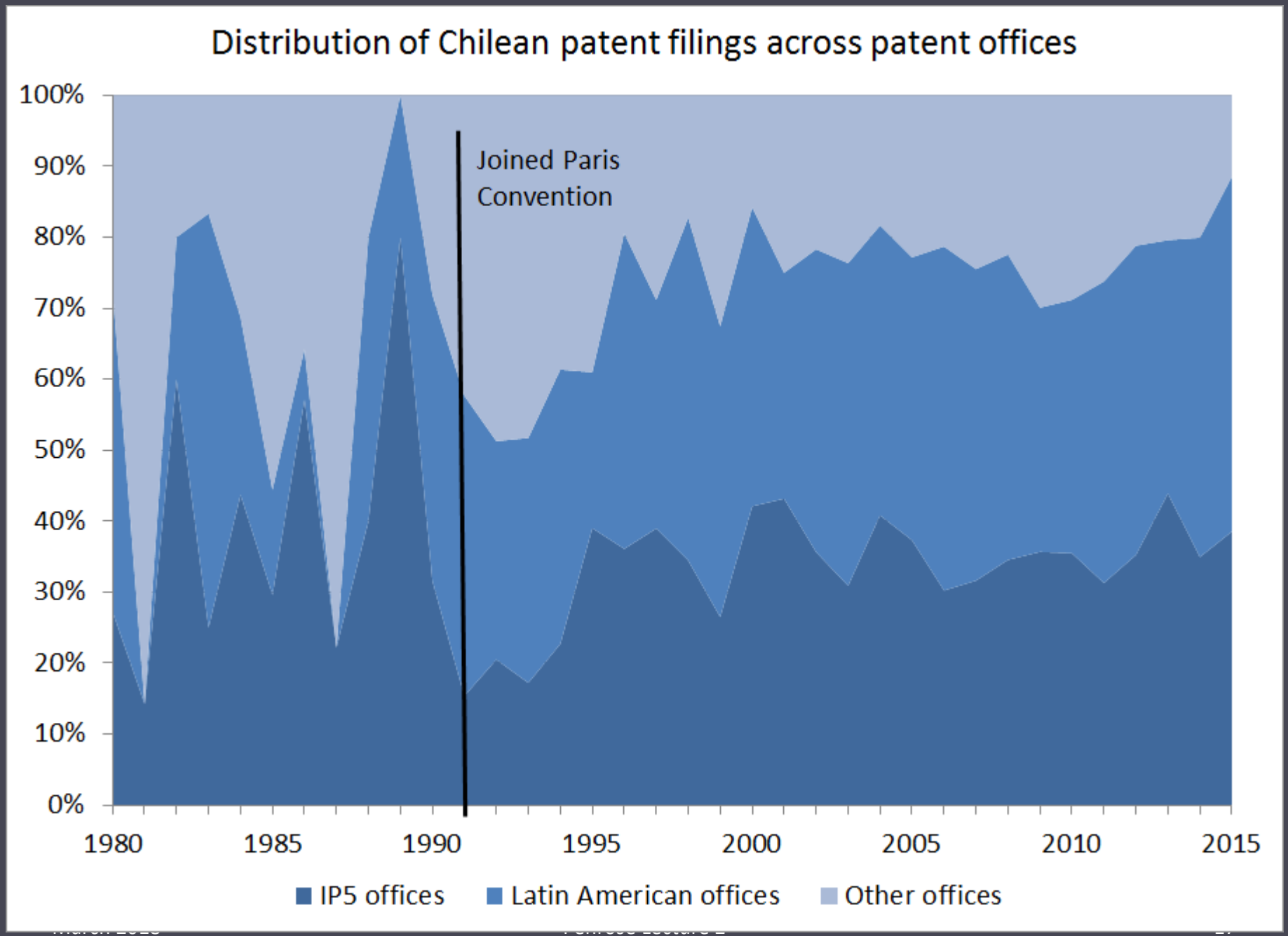






Note: scales differ by an order of magnitude

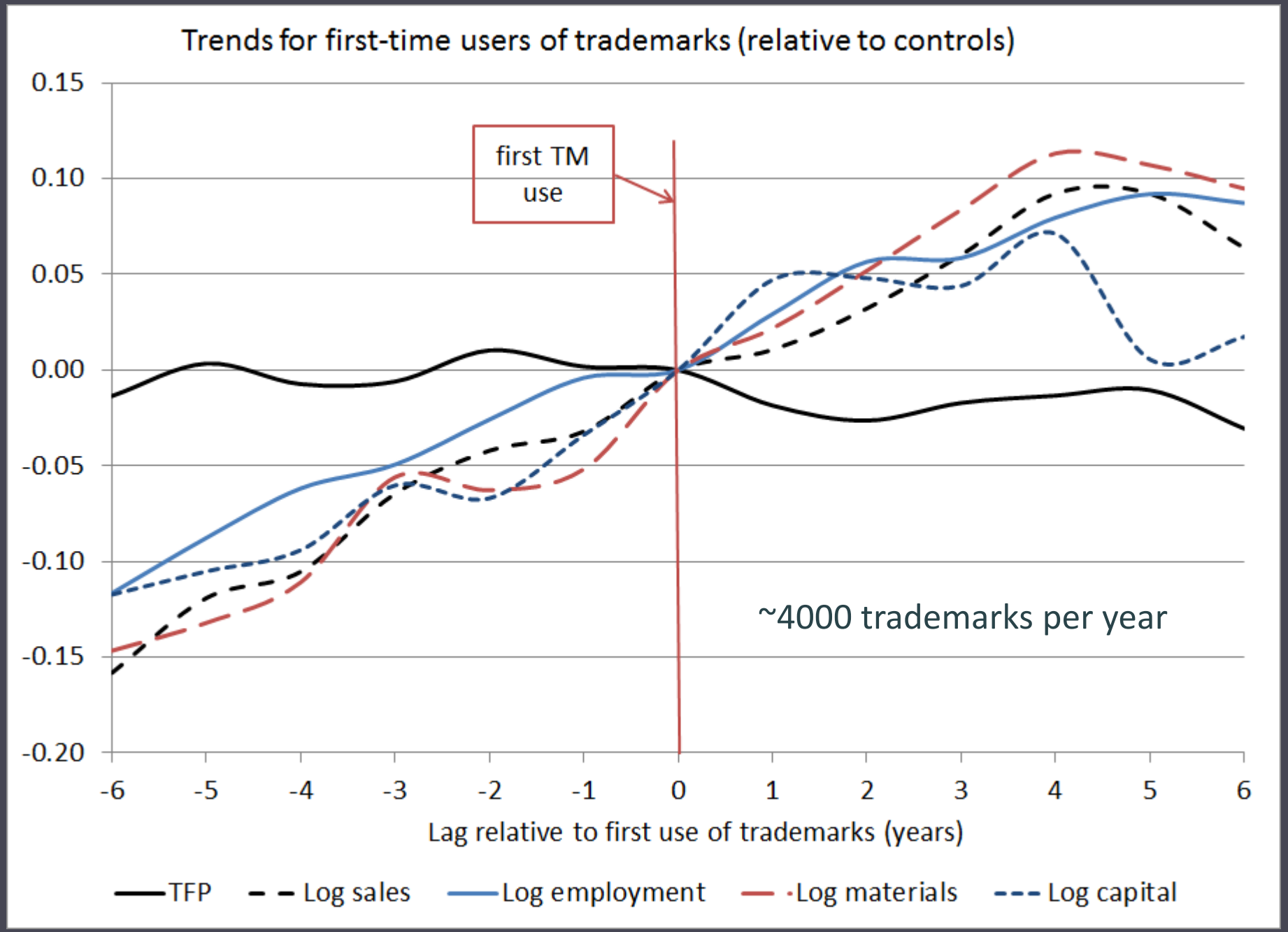

Worldwide Chilean Patent Applications
600
500
400
300
200
100
0
Joined Paris Convention
1980
1985
1990
1995
2000
2005
2010
2015

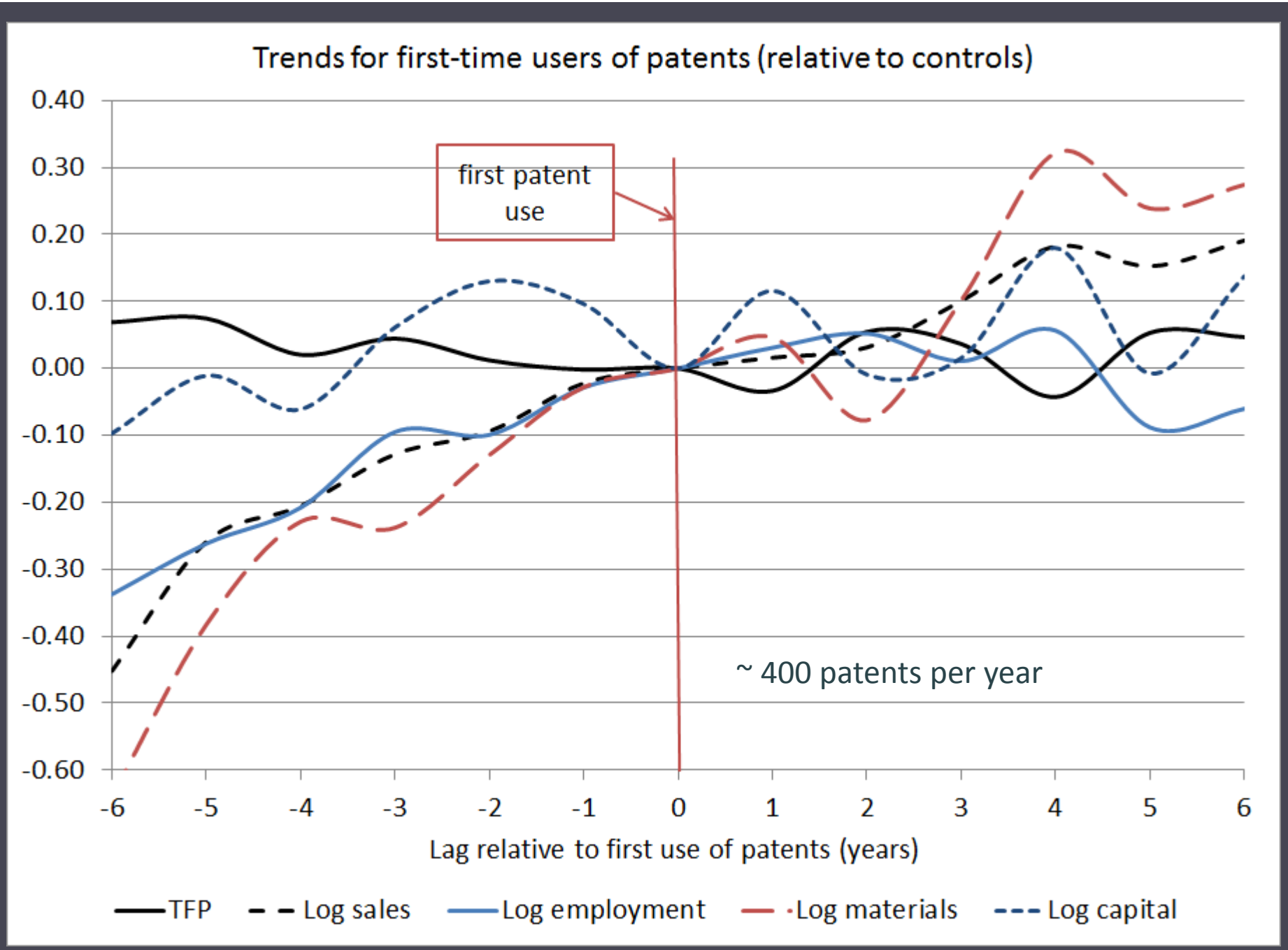

Distribution of Chilean patent filings across patent offices
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
Joined Paris Convention
1980
1985
1990
1995
2000
2005
2010
2015
IP5 offices
Latin American offices
Other offices

Results from our investigation

- Determinants of IP use: patents, trademarks and design rights as a function of firm size, capital intensity, ownership, exporting, location, market share, concentration
  - Size, exporting, market share, Santiago location generally positive
  - Foreign ownership positive for patents, negative for trademarks
  - Public firms do not trademark much.
- Performance impact: Diff-in-diff estimation for employment, sales, TFP after first time IP use.
  - Estimated with & without separate trends for treated and controls
  - "treated" firms grow faster before and after first time IP use, but TFP is unaffected. (see graph)

Using ENIA and IP data (50,000 obs on 7800 firms, 1995-2005)


Trends for first-time users of trademarks (relative to controls)
0.15
0.10
0.05
0.00
-0.05
-0.10
-0.15
-0.20
first TM use
~4000 trademarks per year
-6
-5
-4
-3
-2
-1
0
1
2
3
4
5
6
Lag relative to first use of trademarks (years)
TFP
Log sales
Log employment
Log materials
Log capital


Trends for first-time users of patents (relative to controls)
0.40
0.30
0.20
0.10
0.00
-0.10
-0.20
-0.30
-0.40
-0.50
-0.60
first patent use
~ 400 patents per year
-6
-5
-4
-3
-2
-1
0
1
2
3
4
5
6
Lag relative to first use of patents (years)
TFP
Log sales
Log employment
Log materials
Log capital

Conclusions

- Differences from developed countries
  - Most patents from outside the country
  - Foreign-owned firms less likely to do R&D
  - IP does not have any productivity impact (yet) – compare to Hall and Sena (2017) for the UK
- Similarities to developed countries
  - Heavy trademark use by domestic firms and individuals
  - Relationship of R&D to firm characteristics very similar
  - Relationship of innovation to firm characteristics also similar
- Next: What about pharmacuetical IP?

Patents and pharma innovation

- Do pharma product patents increase R&D spending?
  - Qian (2007) – 26 countries with pharma patents 1978-2002 + matched control countries
    - No increase in R&D or US patents from product pharma patent introduction
    - However, increases at higher levels of GDP per capita
    - IPR strength has inverted U impact conditional on other vars
  - Kyle & McGahan (2009) – variation in TRIPS intro of pharma patents, 1990-2006, at disease level
    - strong association between pharmaceutical patents and R&D effort for diseases that are prevalent in high income countries
    - no association for “neglected” diseases prevalent in low income countries

Patents and pharma diffusion

- Do pharma product patents affect diffusion?
  - Cockburn, Lanjouw, and Schankerman (2016) - 642 new drugs launched in 76 countries,1983–2002
    - Price regulation delays launch (introducing price controls increases lag by 25-80%)
    - Longer and stronger patents speed up launch (lag reduced 55% by long patent)
    - Similar results for countries at all income levels
  - Kyle and Qian (2014) – 716 drugs, 60 countries, 2000-2013
    - Compare drugs pre- and post-TRIPS compliance – patents speed launch, increase price and quantity
    - Price discrmination across countries does not depend on patent coverage of the drug
    - Price premium for patented drugs smaller post-TRIPS

Policy debate on pharma IP

- India's Glivec decision, 1 April 2013 – imatinib mesylate (anti-cancer drug) rejected by Supreme Court for obviousness
  - Crucial issue: are new forms (beta crystalline form) of known substances patentable?
  - Original discovery of imatinib goes back to 1993, before product patents were available in India
- Proposals to restrict secondary patents:
  - Brazil - Projeto de Lei n° 5.402/2013 (includes provision similar to paragraph 3(d) of India's Patent Act).
  - South Africa - proposed National Policy on IP: "[Legislation] should exclude diagnostic, therapeutic and surgical methods from patentability, including new uses of known products, as is the case under the TRIPS agreement."
  - TPP - draft Article QQ.E.1: critical issue - patentability of new uses or methods of using a known product and "enhanced efficacy of a known product" threshold.

Hall and Helmers (2015)

- Do foreign pharma firms use strategic patenting behavior to keep domestic generic producers off the market?
  - This measures impact on (broadly defined) “innovation”
  - More specifically:
    - How is entry into the manufacture of drugs for specific therapeutic categories affected by the presence of foreign pharma patents?
    - Do secondary patents delay entry by Chilean firms into drug production?
- What is the share of patents held by foreign pharma companies associated with drugs commercialized on the domestic market?
  - This measures the “working” of patents

Patenting strategies

"We were recently successful in asserting the crystalline form patent in [name of country], where we obtained an injunction against several generic companies based on these patents by 'trapping' the generics: they either infringe our crystalline form patent, or they infringe our amorphous form process patent when they convert the crystalline form to the amorphous form."

Anonymous pharmaceutical company quoted in EU Commission (2009)

"The entire point of the patenting strategy adopted by many originators is to remove legal certainty. The strategy is to file as many patents as possible on all areas of the drug and create a 'minefield' for the generic to navigate. All generics know that very few patents in that larger group will be valid and infringed by the product they propose to make, but it is impossible to be certain prior to launch that your product will not infringe and you will not be the subject of an interim injunction."

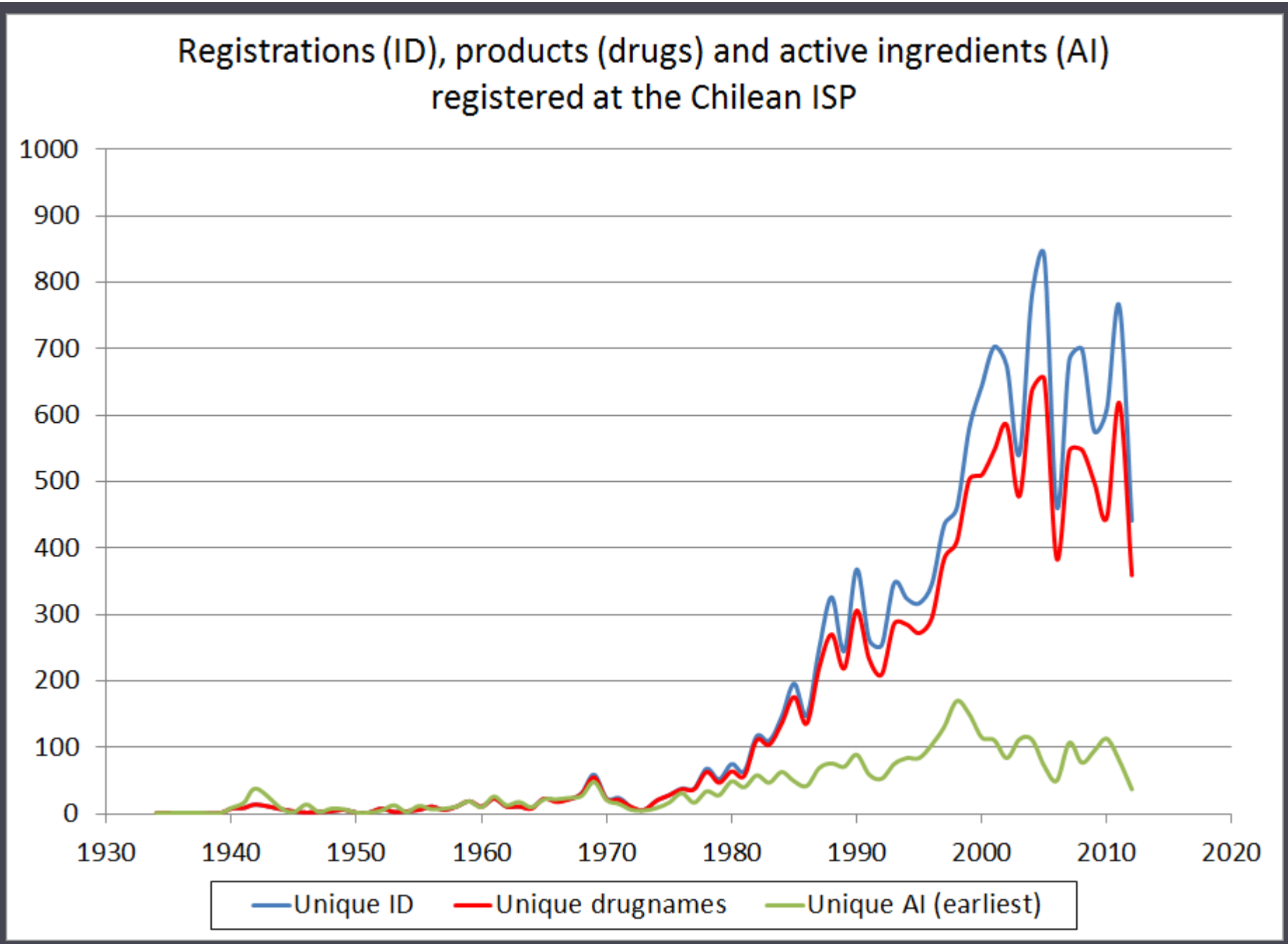
Anonymous generic producer quoted in EU Commission (2009)

Patenting strategies: empirical evidence

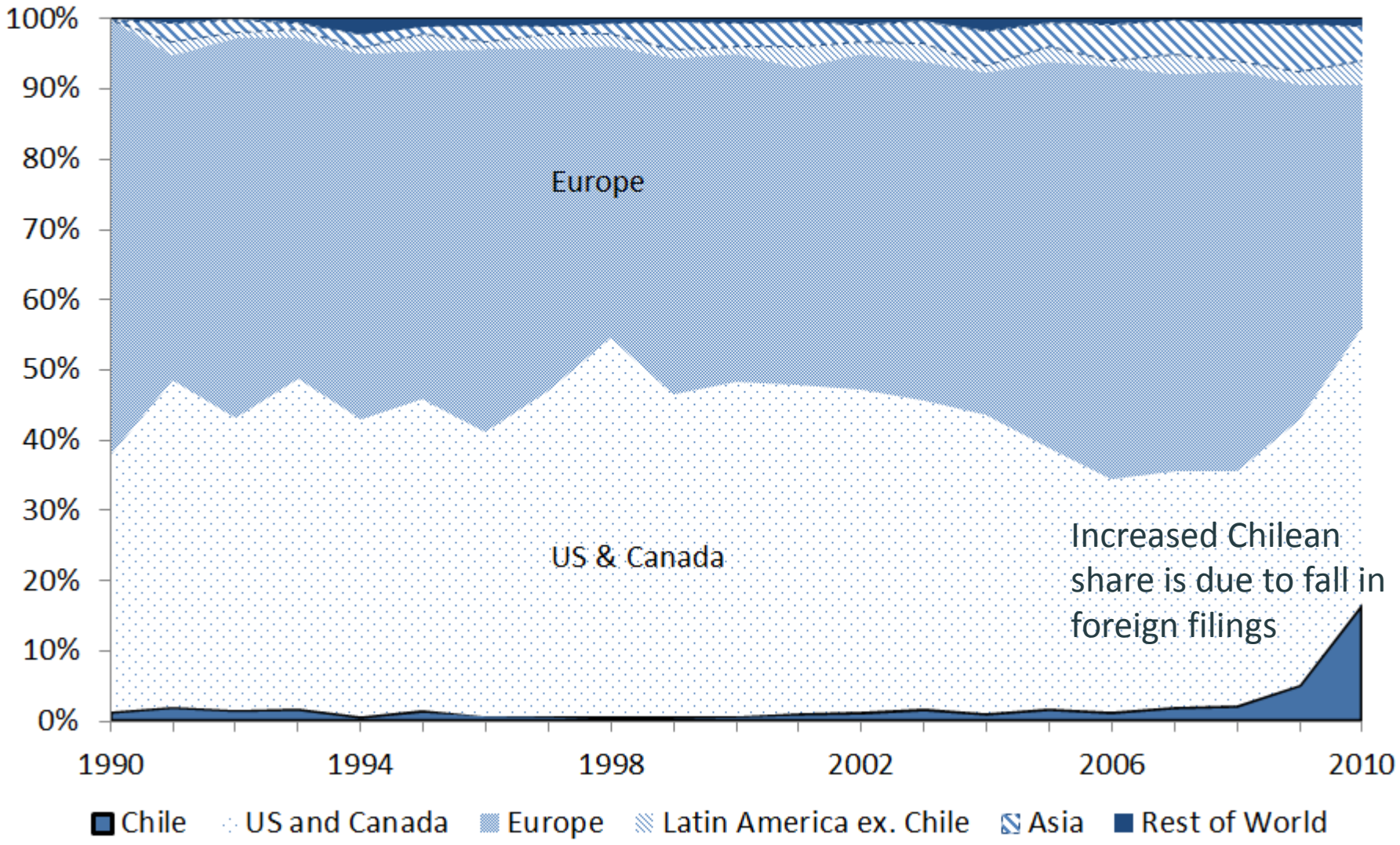
- EU Commission (2009)
  - primary to secondary patent ratio 1:7
    - pending patents 1:13; granted patents 1:5
  - Disproportionately more secondary patents after product launch
- Kapczynski et al. (2012)
  - Of new drugs with FDA in 1991-2005: 56% formulation, 24% salts, crystalline forms etc., 63% methods of use
  - Secondary patents filed after FDA approval and extend exclusivity lifetime by 4-5 years
  - More secondary patents the higher is the branded drug's sales
- Sampat and Shadlen (2016)
  - Compare Brazil, India and Argentina to US, EPO, and Japan
  - Little evidence that secondary patent provisions in the former have much effect

Pharma patents in Chile

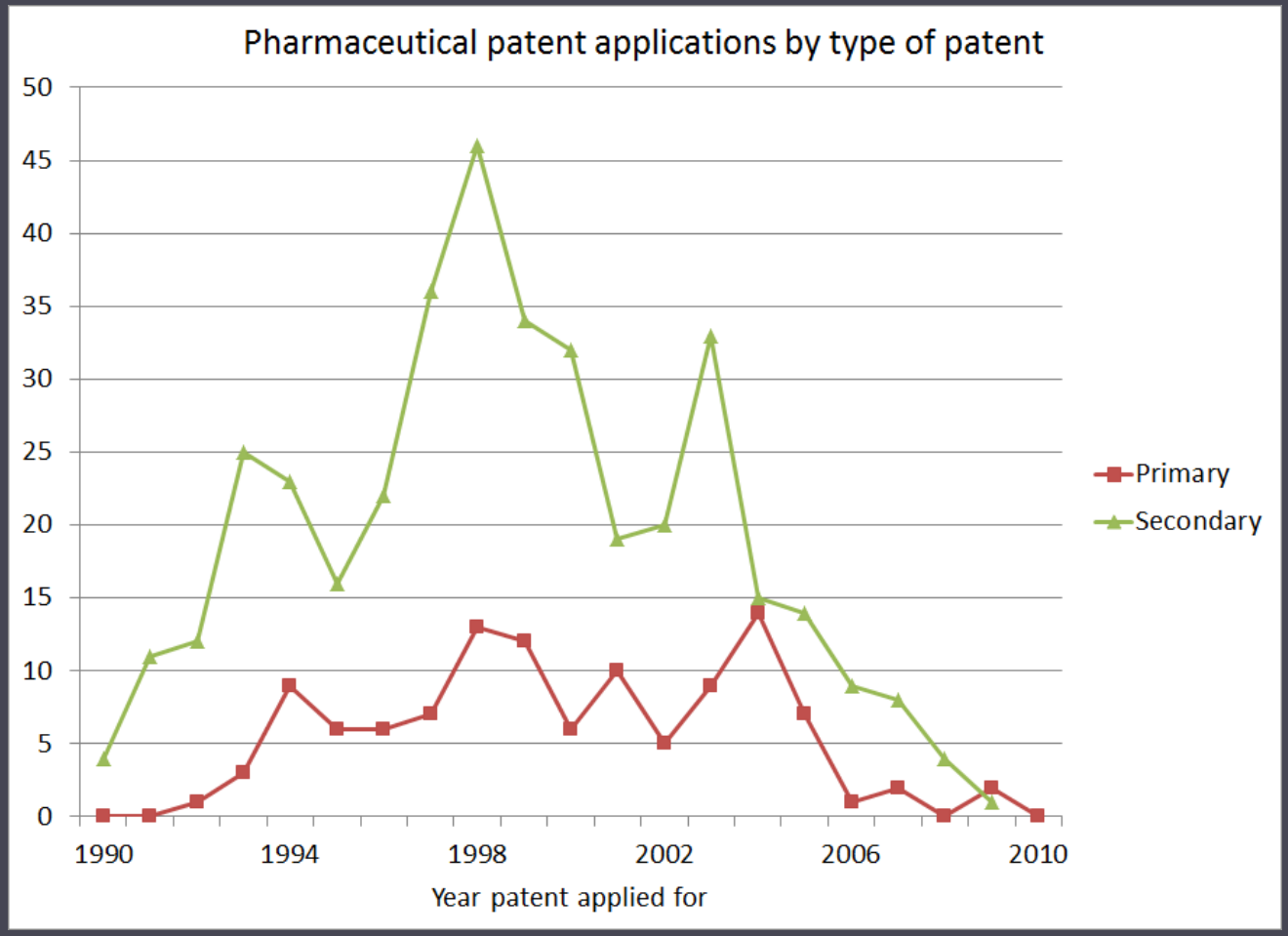
- Patents
  - Joined Paris convention in 1991
  - Joined PCT in June 2009 (very late in our data)
- Pharmaceutical patents
  - Not allowed until 1991; consistent growth since then
    - Excluded coverage for all pharma patents before 1991
  - Law amended several times for TRIPS and FTA/EFTA
    - Extend life from 15 to 20 years
    - Allow for extension due to delays in grant/registration
    - Softening of secondary use restriction
  - Only a small fraction (<2%) held by Chilean entities; largest source countries are US, Switzerland, Germany


Registrations (ID), products (drugs) and active ingredients (AI) registered at the Chilean ISP
1000
900
800
700
600
500
400
300
200
100
0
1930
1940
1950
1960
1970
1980
1990
2000
2010
2020
Unique ID
Unique drugnames
Unique AI (earliest)

Total pharmaceutical patent filings by domestic and foreign entities in Chile

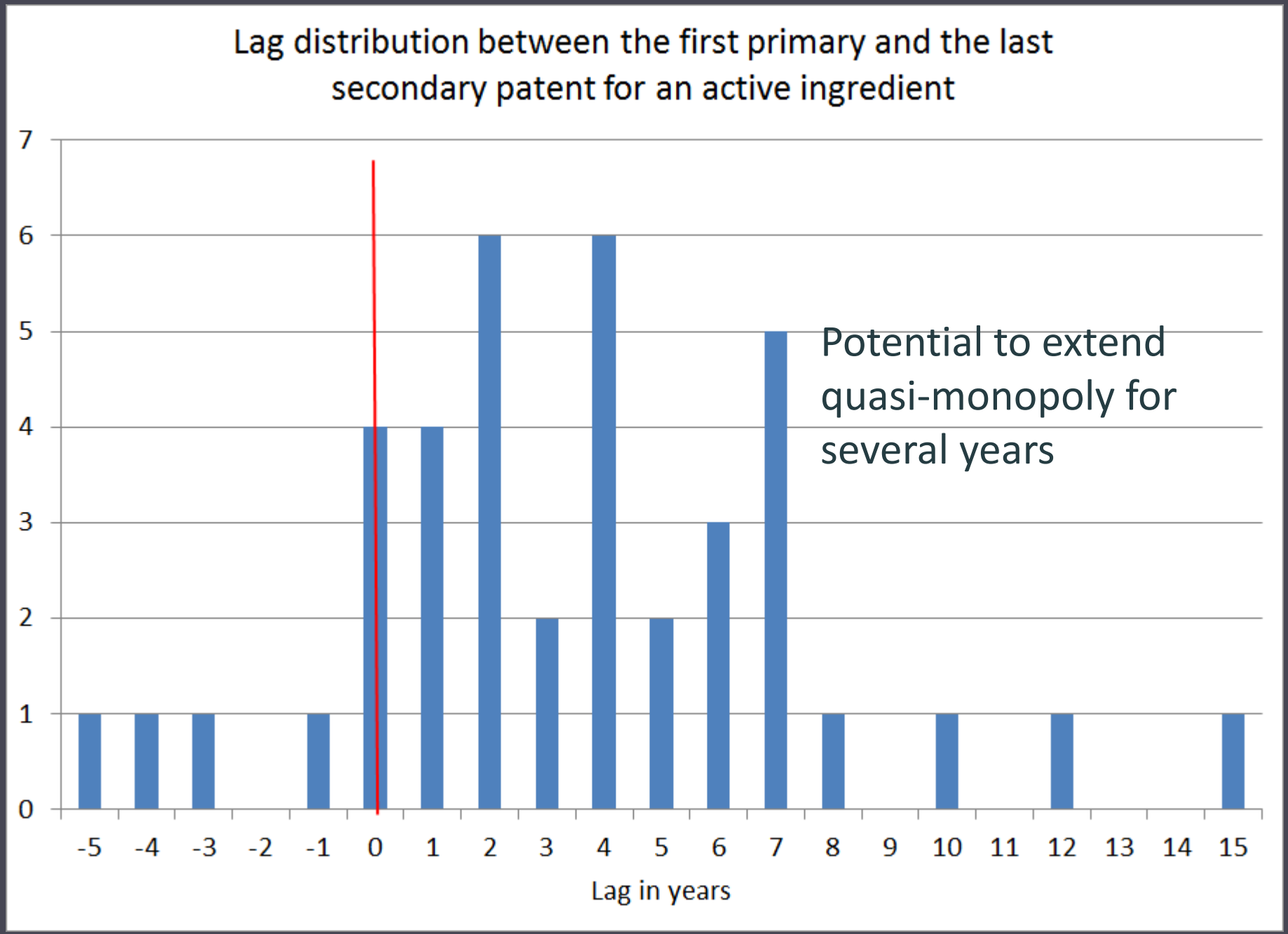


Primary vs secondary patents



113 (22%) of 504 matched patents are primary patents.

Primary patents more likely to have been granted.


Lag distribution between the first primary and the last secondary patent for an active ingredient
7
6
5
4
3
2
1
0
-5 -4 -3 -2 -1 0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
Lag in years
Potential to extend quasi-monopoly for several years

Top therapeutic classes protected by patents

- Anti-ulcer, anti-depressants, etc. are older drugs (pre-1991) and have few primary patents if any.
- Anti-virals (including HIV) and anti-neoplastics (anti-cancer) are newer.

Number of patents per therapeutic class

	Number		*Share*
Therapeutic group	*Primary patents*	*Secondary patents*	*Primary patents*
anti-viral agents	20	41	32.8%
anti-neoplastics	14	23	37.8%
anti-depressants	2	33	5.7%
anti-psychotics	1	31	3.1%
anti-diabetic agents	8	24	25.0%
analgesics	8	23	25.8%
nonsteroidal anti-inflammatory agents	7	20	25.9%
immunologic agents	9	13	40.9%
antibiotics/anti-neoplastics	5	17	22.7%
gastrointestinal agents (anti-ulcer)	2	19	9.5%
anti-fungals	3	16	15.8%
broncho-dilators	1	18	5.3%
anti-asthmatic combinations	3	15	16.7%
anti-histamines	2	15	11.8%
agents for pulmonary hypertension	1	15	6.3%
bone resorption inhibitors	0	16	0.0%
quinolones	3	12	20.0%
cholesterol absorption inhibitors	3	11	21.4%
hormones	1	11	8.3%
narcotic analgesics	2	10	16.7%
anti-infectives	2	10	16.7%
remaining classes	63	421	13.0%
Total	**160**	**814**	

Role of Chilean firms

- Mostly domestic manufacturing, quality control, importing, packaging, and distribution
- Two drugs have a Chilean firm as the source, but no patents:
  - meropenem trihydrate (generic antibiotic)
  - warfarin sodium (generic anti-coagulant)
- Two drugs have secondary patents owned by Chilean firms, no primary patents:
  - Larmax-D, an anti-histamine compound
  - Faronkal, a nasal decongestant compound used for sleep apnea
- Exploratory regressions:
  - Share of Chilean firms mfg each AI
  - Share of Chilean firms mfg in each therapeutic class

Conclusions

- Chilean companies manufacture common drugs with lots of different formulations
- They do not manufacture newer drugs that are patent protected.
- Almost all pharma patents in Chile held by foreign firms.
- Almost no products by domestic companies protected by patents.
- Across therapeutic classes
  - negative relationship between share of drugs patented by foreign companies and number of drugs manufactured by domestic companies.
- Weak evidence for strategic patenting behavior in pharmaceuticals in the form of extending patent life.

Last word

"If national patent laws did not exist, it would be difficult to make a conclusive case for introducing them; but the fact that they do exist shifts the burden of proof and it is equally difficult to make a really conclusive case for abolishing them."

(Penrose, 1951, p. 40)

Interpretation

- Firms adapt to the systems in which they find themselves and industrial structure evolves from that adaptation.
  - Example - the rise of firms specializing in knowledge creation following the strengthening of the U. S. patent system in the early 1980s (Hall and Ziedonis 2001; Arora et al. 2001).
  - Path dependence in industry structure, which makes it difficult to compare the performance of a system that is in place with one that may involve radical change in the way things are done.
  - Existing systems create rents for some firms and individuals, who then resist strongly any changes that might destroy these rents.

Some useful surveys

- Branstetter, Lee G. 2004. Do Stronger Patents Induce More Local Innovation? *Journal of International Economic Law 7*(2), pp. 359-70.
- Maskus, Keith E. 2004. Encouraging International Technology Transfer, Geneva, Switzerland: ICTSD and UNCTAD Issue Paper No. 7.
- ICTSD and UNCTAD. 2003. Intellectual Property Rights, Implications for Development Policy Discussion Paper, Geneva, Switzerland: ICTSD and UNCTAD.