The Political Economy of Pharmaceutical Patent Examination: Argentina in Comparative Perspective[#]

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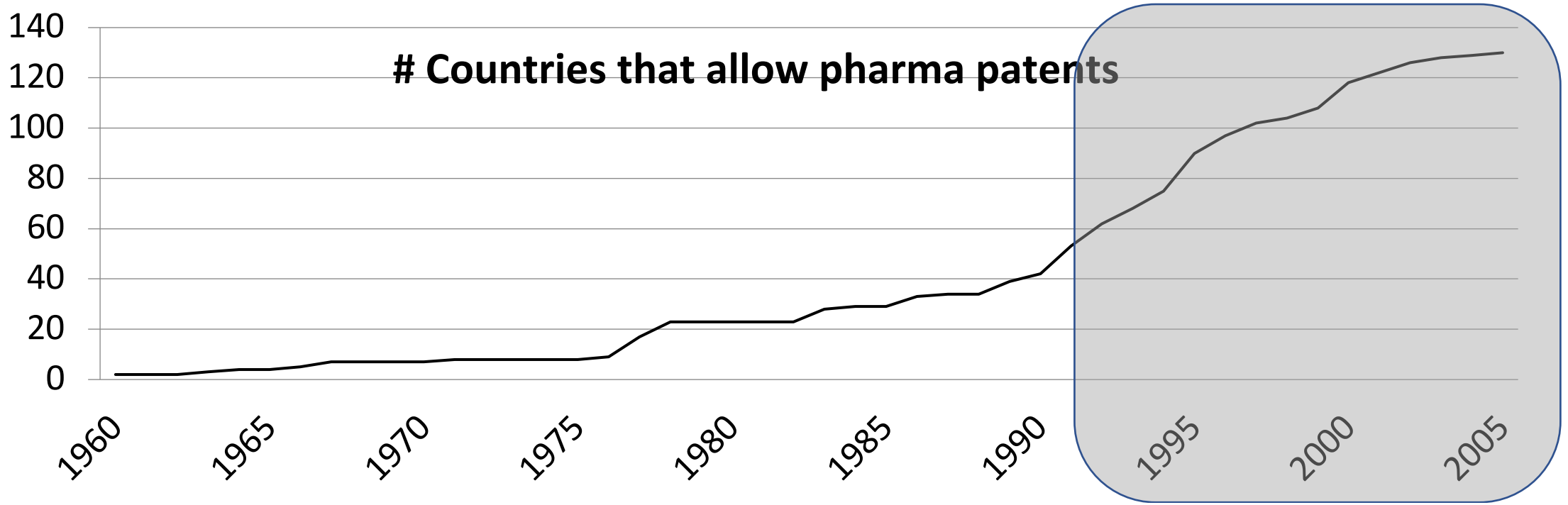
Background: Globalization of Pharmaceutical Patenting

"patents shall be available for any inventions, *whether products or processes, in all fields of technology,* provided that they are new, involve an inventive step and are capable of industrial application" (WTO, TRIPS: Art. 27).



Context and Focus

Variation in TRIPS implementation, in theory and in practice

- Not just what can countries do (law), but why countries respond as they do and how patent systems function (political economy)

Main areas of variation regarding TRIPS/pharmaceuticals

- Compulsory licenses
- ***Examination practices***

Argentina's 2012 Examination Guidelines

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PATENTES DE INVENCION Y MODELOS DE UTILIDAD

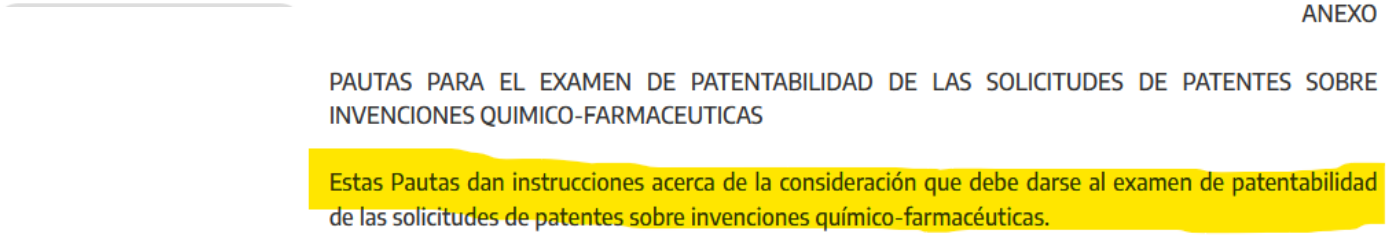
PAUTAS PARA EXAMEN DE PATENTABILIDAD DE SOLICITUDES DE PATENTES - APROBACION

Fecha de sanción **02-05-2012**
Publicada en el Boletín Nacional del 08-Mayo-2012

Resumen:

APRUEBANSE LAS PAUTAS PARA EL EXAMEN DE PATENTABILIDAD DE LAS SOLICITUDES DE PATENTES SOBRE INVENCIONES QUIMICO-FARMACEUTICAS.

- Modeled on UN Guidelines (Correa 2007)
- 13 different types of patents and patent claims for pharma-chemical products (not biologics)
- Instructions to examiners for what they should consider in examining applications (yellow)
- How to reject, using traditional patentability criteria
- Followed a study of granted patents by Arg academics and state officials (Correa et al 2011)
- Issued as Joint Resolution between 2 Ministries and the Patent Office
- Went into effect 8 May 2012 (clear before/after)
- Preceded by 2002 guidelines against 2nd medical use



ANEXO

PAUTAS PARA EL EXAMEN DE PATENTABILIDAD DE LAS SOLICITUDES DE PATENTES SOBRE INVENCIONES QUIMICO-FARMACEUTICAS

Estas Pautas dan instrucciones acerca de la consideración que debe darse al examen de patentabilidad de las solicitudes de patentes sobre invenciones químico-farmacéuticas.

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Primary vs. Secondary Patents

Compounds

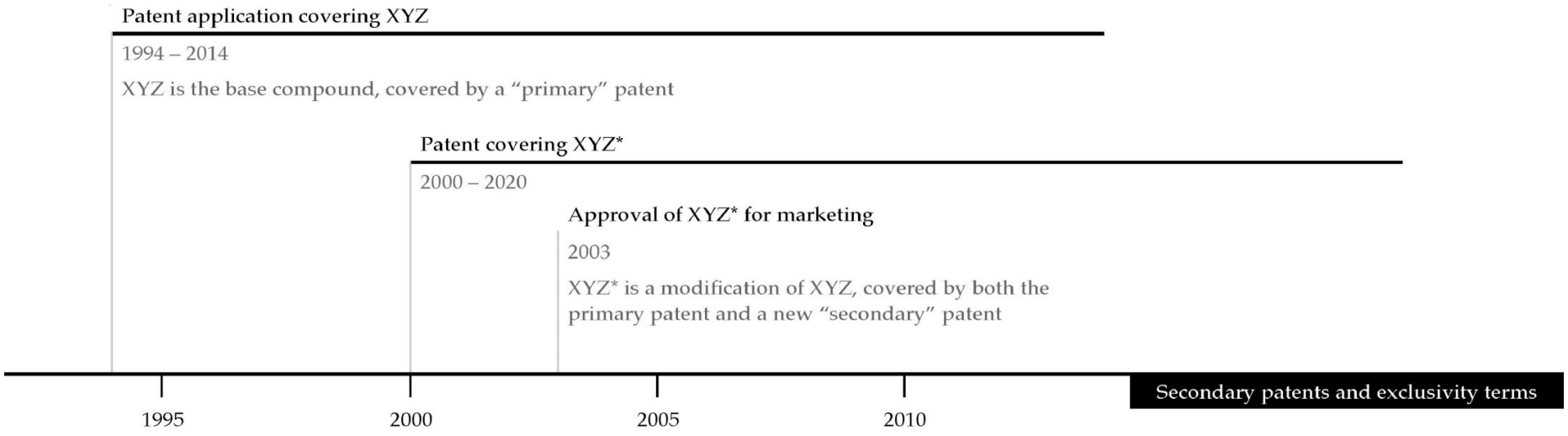
Alternative structural forms; formulations, compositions, dosages, combinations; uses

- *Product* patents (not processes)

Why Might Countries Try to Minimize the Grant of Secondary Patents?

To avoid extension of periods of patent protection

- Patents on alternative dimensions of existing molecules and drugs can extend periods of market exclusivity ("ever-greening" or "life-cycle management")
- Secondary patents: deposited later, expire later – *if granted*



Minimizing Secondary Patents via Examination: Previous Research

St Comp Int Dev (2015) 50:228–257
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TRIPS Implementation and Secondary Pharmaceutical Patenting in Brazil and India

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RESEARCH ARTICLE

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Basic approach

- Pharma patent applications filed in country
- Code primary vs secondary
- Study national prosecution histories and outcomes (data + in-country research)

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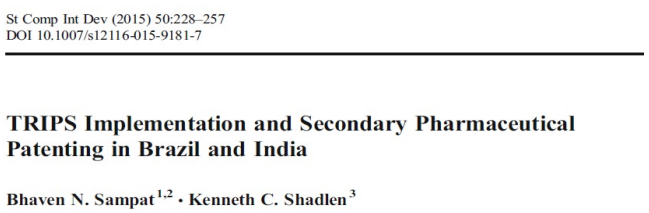
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Main findings

Brazil and India: Restrictions on secondary patents having minimal direct effects on patenting outcomes

- Gaps between "laws on the books" and "laws in practice"

Argentina: Examination guidelines *appeared* to be more effective in minimizing secondary patents

- Laws on the books and laws in practice *seemed* more aligned

Argentina findings in previous research only suggestive

- *Included in just 1 of the articles; small share of applications with final outcomes under new guidelines*
- *Additional research needed: longer time series; outcomes before and after guidelines introduced*

➔

Data and Research

1. Pharmaceutical Patent Applications in Argentina
    - All patent applications in all fields filed in Argentina 2000-2019 (PATSTAT)
    - Identify “pharma” applications (IPC+NACE correspondence; manual elimination)
    - Filters: (1) Triadic filings only (importance); (2) AR filings in 3 months per year (reduce workload); (3) Only applications with final outcomes
    - N=3,065

2. Distinguish Primary vs. Secondary Applications
    - Coding guide; expert consultant reads and code each claim of each application
        - Classification at application level (any “primary” = “primary”)
    - primary: 63%; secondary 37%

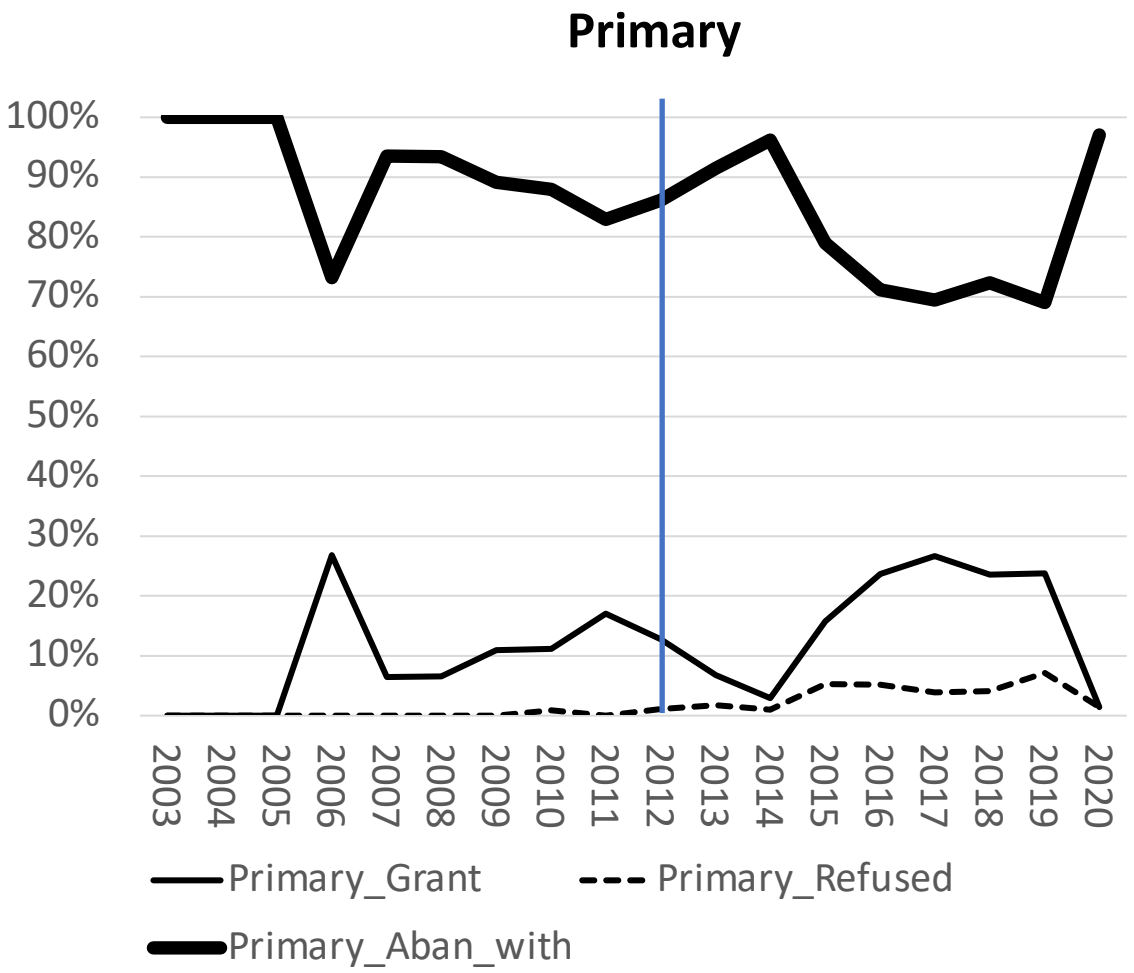
3. Identify Argentina outcomes (PATSTAT, and INPI-AR)
    - Outcomes: grants vs. refusals vs. abandoned/withdrawn (combining INPI’s 3 sub-categories)
    - Dates of decisions: before 8 May 2012 (“Old”) and after 8 May 2012 (“New”)

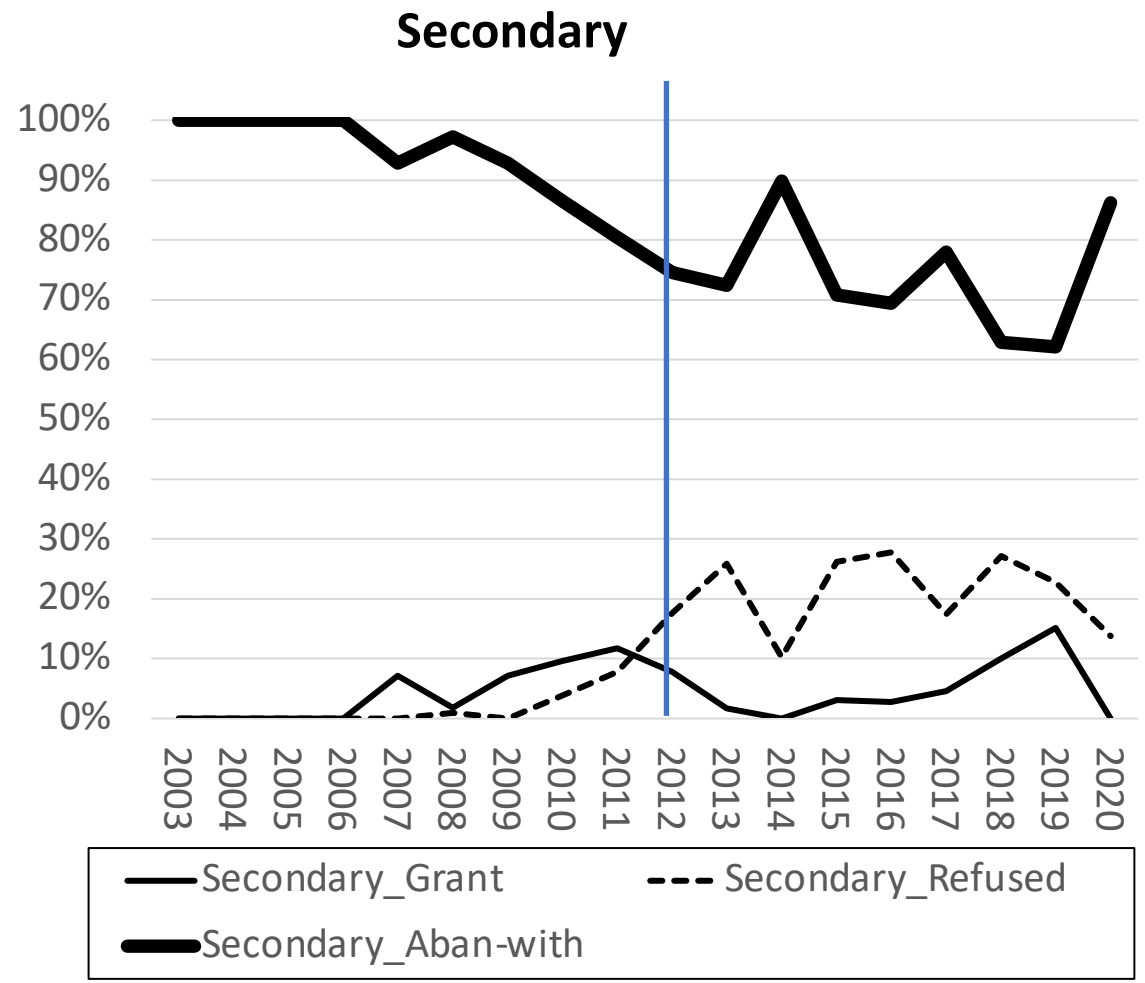
4. In-country research to understand processes (June 2022, November 2022, July 2023)
    - Presentation and discussion of preliminary findings with stakeholders (industry, lawyers, government, academics)
    - Building on previous research on pharmaceutical patents in Argentina (Shadlen 2017)

Before and After:
Final INPI Outcomes, by type of application and guidelines (%)

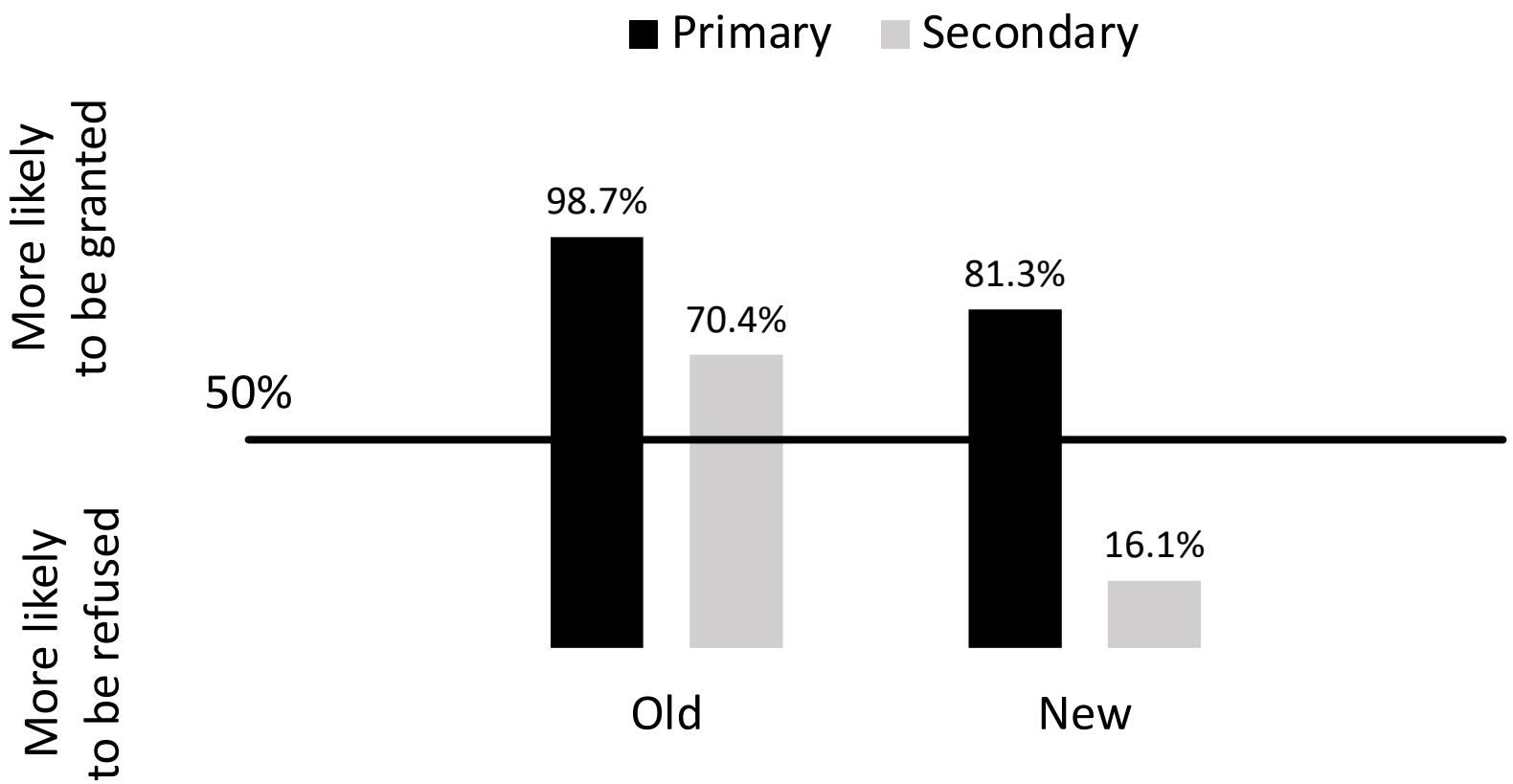
		Granted	Refused	Aban/With	Total
Primary	*Old*	10.56	.14	89.30	100.00
	New	12.28	2. 82	84.90	100.00
Secondary	*Old*	5.67	2.39	91.94	100.00
	New	3.56	18.53	77.91	100.00

Over Time:
Final INPI Outcomes, by type of application and year





Probability of Grant, by type of application and guidelines (conditional on Final INPI Outcome of grant or refuse)



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- Alternative codings of applications, e.g. Claim1 only
- Consider other characteristics of applications, e.g. family size, status of USPTO "twin"
- Conduct regression analyses with controls

➔ Main takeaway: "suggestive" findings from Sampat and Shadlen (2017) are supported by additional research

4 questions

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Why do they work? Why do they Persist?

	Institutional Design	Political Economy: State-Society Dynamics

Why do they work?	• Easy to use – instructions
	  • No inter-agency coordination
	  • Not reinventing patent law
	• Aided by not being in PCT
	  • Fewer apps to examine
	  • Apps don't arrive with preliminary reports	

Why do they persist?	• Hard to attack in courts (pautas not cited) • Coordination challenges for eliminating or revising (Joint Resolution)	

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		• Monitoring and oversight by local industry
		  • CILFA: preliminary examinations of published applications
		  • Works with member firms on "oppositions"
		  • Challenge granted patents
		• Informal "epistemic alliance" between industry, civil servants, academics (Drahos in Reverse)
		➔ Internalization of the guidelines by INPI

Why do they persist?	• Hard to attack in courts (pautas not cited) • Coordination challenges for eliminating or revising (Joint Resolution)	• National sector appears united in opposition to secondary patents and support of guidelines • Power of local pharma in political arena creates a "high price" for change ➔ Stability • Milei? USTR?

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Secondary Pharmaceutical Patents are Difficult to Obtain in Argentina: Implications for Access to Medicines

Pautas → lower likelihood of secondary patent. *Does the drug have a **primary** patent in Argentina?*

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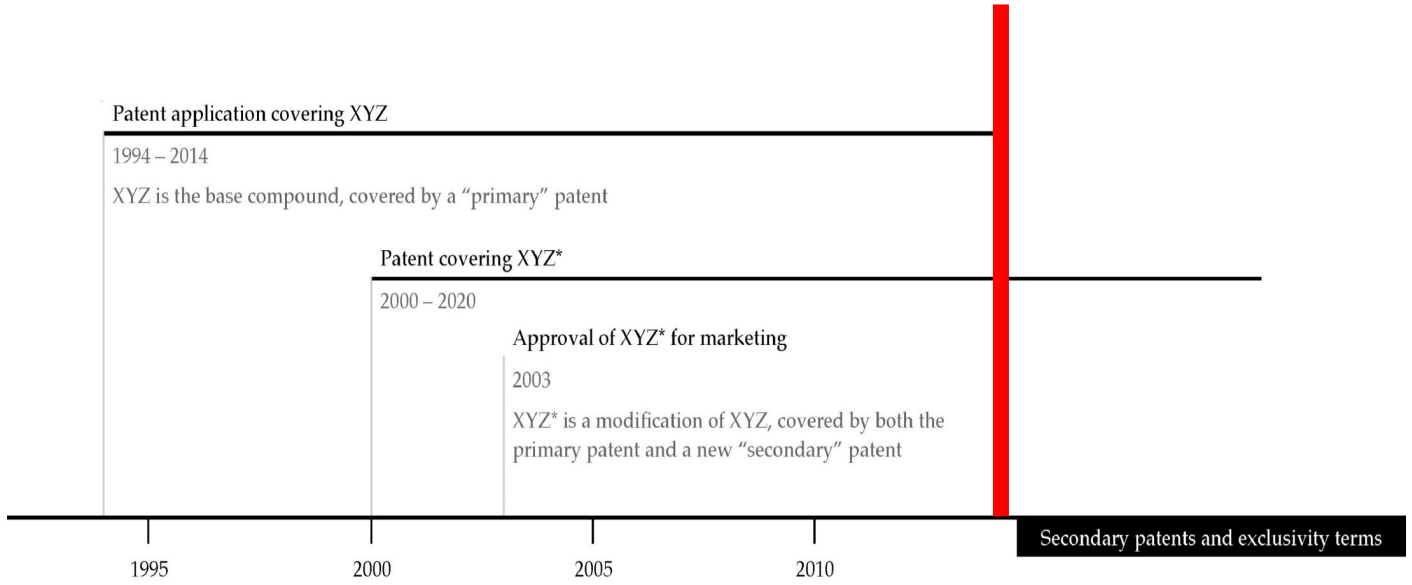
➔ Avoid extension of term, beyond the primary



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Pautas → lower likelihood of secondary patent. *Does the drug have a **primary** patent in Argentina?*

YES
➔ Avoid extension of term, beyond the primary

NO
➔ Early local availability of the drug, while still patented in other countries

(1) no AR application

(2) AR application, but patent not granted

(3) AR patent granted, but with claims that don't cover commercialized compound (Markush)

(4) AR patent covering commercialized compound granted, but not respected (launch at-risk)

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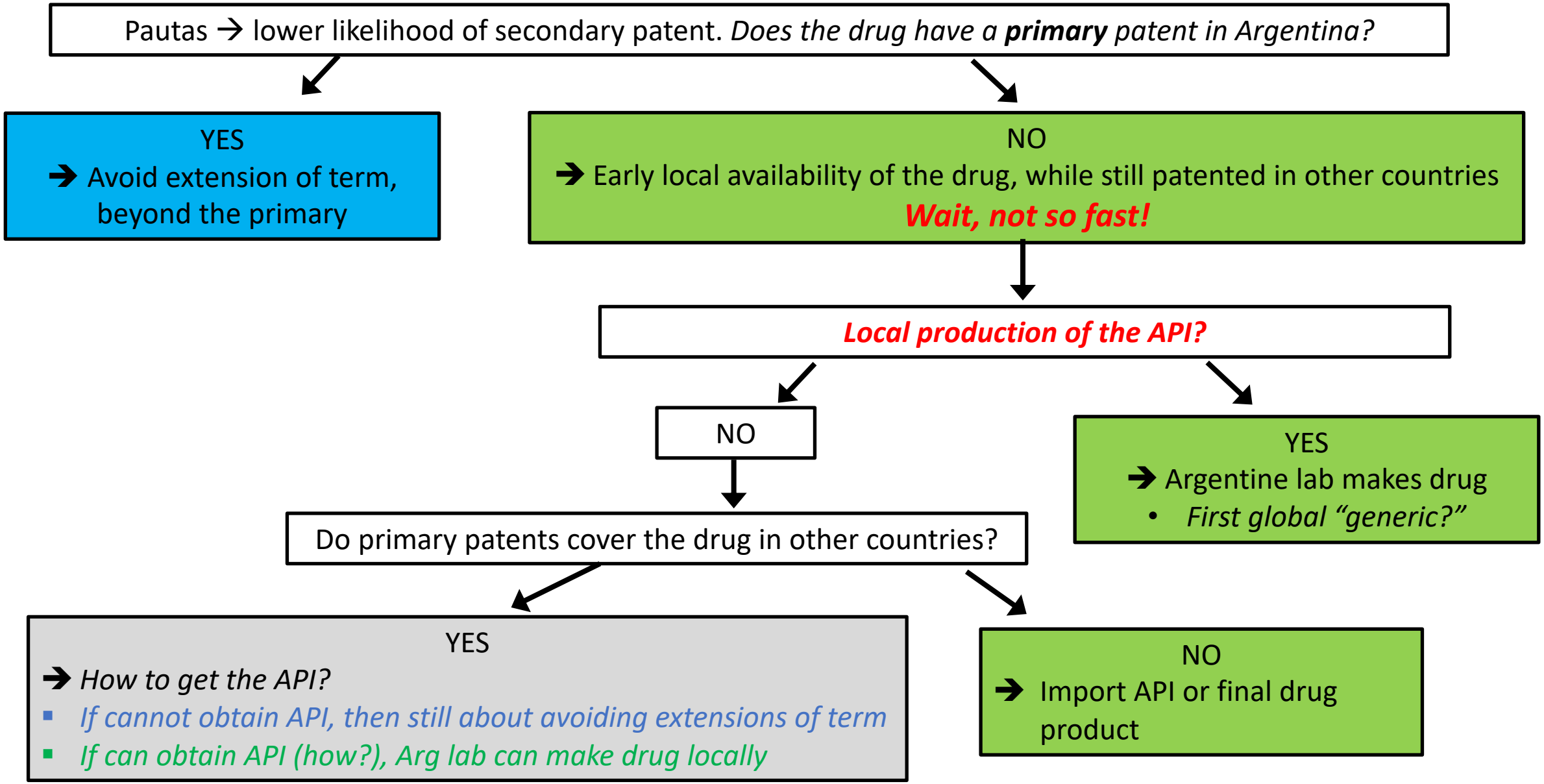

Argentina's 2012 Guidelines and Access to Medicines: Final Observations

As a mechanism to avoid the extension of periods of protection and facilitate the onset of ("generic") competition

- The 2012 guidelines function and can achieve this outcome
- Need to study market structure for drugs with granted primary patents, post-expiration (2015--)

As a mechanism to expedite early competition (i.e. recreate a "pre-TRIPS" world where new medicines are "multi-source")

- It might be that the 2012 guidelines – and the AR patent system more generally – enable this in part, but the effects on the market depend on access to API (local production or importation) for specific drugs
- Need more research on the global production and trade of API