

Value of IP for health and growth

The economic benefits of strengthening the environment for innovation in Argentina



PROJECT OBJECTIVES AND SCOPE

- INTERPAT asked Charles River Associates (CRA) to identify and quantify the economic benefits from strengthening the environment for innovation in Argentina.
- The objective of the study is to:
 - Set out the policy framework for supporting innovation in Argentina and the current state of innovative activity.
 - Undertake a case study analysis on countries with potential lessons for Argentina on how policies can improve innovation and related activities in countries.
 - Develop scenarios as to how innovative activity could change in Argentina, if policies adopted in other countries were pursued.



PROJECT STEPS

1

SET OUT INNOVATION IN ARGENTINA AND HOW IT COMPARES TO PEERS

- Review the current policy environment, resources and innovation and economic activity in Argentina and comparable markets.
- Undertake interviews with global and local experts on Argentina.

Stakeholder	Country	
Industry Experts	Global	
	Local	
	SMEs	
External (local policymakers/ experts)	IP expert	
	Researcher/ Academic	
	CRO	
Total	17	

2

ANALYSE CASE STUDY MARKETS AND SET OUT SCENARIOS

Choose case study markets that:

- Have shown a focus on strengthening innovative environment, particularly the IP protection.
- 2. Placed in similar income and development category as Argentina when started focusing on innovation.
- 3. Show an observable impact on innovative activity.

Analyse two case study markets:

- Changes in policies on innovation.
- Innovative environment and related economic activities pre and post policy changes.
- Any relationship between change in policy regime and innovative activity.

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APPLY SCENARIOS TO ARGENTINA AND REPORT PROJECT FINDINGS

- Statistical and impact analysis: Develop scenarios to assess potential gains in Argentina drawing on case studies and empirical analysis.
 - Innovative activity.
 - Economic activity.
- Reporting: Report out findings and implications for Argentina IP policy.
 - Draft results were presented at the LatAm conference and comments reflected.
 - INTERPAT white paper for publication being developed.

ASSESSING INDICATORS REFLECTING THE INNOVATIVE ENVIRONMENT – STRUCTURED AROUND FOUR AREAS



INNOVATION POLICIES AND IP RULES IN ARGENTINA

Drawing from the policy framework in Argentina, we note:

- A continuous and follow-on development of innovation plans that build from an initial focus on supporting science and technology through R&D investment in general, to more specific focus on some sectors (including healthcare) and key indicators towards a knowledge-intensive economy.
- However, at the same time separate incentives provide mixed support as R&D tax incentives and faster patent examination support innovative activities but rules on IP protection have become more restrictive.



ARGENTINA: ASSESSMENT OF PERFORMANCE

	INDICATORS	COMPARED TO LATAM	COMPARED TO OECD
HUMAN RESOURCES	Universities		
	Education attainment		
	Collaboration		
	Researchers		
HEALTHCARE SYSTEM	Infrastructure		
STRENGTH	Effective and safe care		
INVESTMENT IN INNOVATION	R&D investment		
	FDI		
INNOVATIVE ACTIVITY	Early research (publications)		
	Clinical trials		
	Patents		
ECONOMIC ACTIVITY	Employment		
	Taxes		
	Trade		

Improving performance



CASE STUDY ANALYSIS IMPACT ATTRIBUTABLE TO THE CHANGE IN REGULATION IN A 5-YEAR PERIOD

	SOUTH KOREA	TAIWAN
KEY INNOVATION POLICY CHANGES	"Bio-Vision 2016" Plan of 2007 "577 Initiative" of 2008	Biotech and New Pharmaceutical Development Act (2007)
KEY IP REGULATION CHANGES	Pharmaceutical Affairs Act of 2007: Grant of RDP	Revision of Pharmaceutical Affairs Law (2005): Grant of RDP
OTHER KEY REGULATION CHANGES		Biotech and Pharmaceutical Technology Island Plan (2005): Clinical trials database

		Change	Attributable to IP Regulation	Growth	Attributable to IP Regulation
Investment	BERD			5% increase*	
	Early research (publications)	49% increase**	\bigcirc	35% increase*	\bigcirc
Innovative Activity	Clinical trials	124% increase		61.2% increase	
	Patents (local residents)	101% increase		249% increase	
	Patents (local non- residents)	138% increase		23% increase*	
	Patents (USPTO)	250% increase		7.1% increase*	
Economic Activity	Employment in biotechnology and pharmaceuticals	47% increase		2.4% increase*	

Impact of the regulation

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Notes:

*Indicated increase in average YoY growth rate;

rather than absolute number

**Indicates an increase in the impact factor of publications

SCENARIOS: DEVELOPING THREE SCENARIOS ON IMPACT ON STRENGTHENING IP REGIME AND INNOVATION POLICY

Drawing from the case study analysis and the statistical analysis, we establish two scenarios:

- A scenario assuming an IP regime change in conjunction with other innovation policies (medium growth due to limited implementation).
- A scenario assuming an IP regime change in conjunction with other innovation policies (high growth with good policy implementation).

	SCENARIO DETAILS	R&D SPEND	CLINICAL TRIALS	PATENTS	EMPLOYMENT
IP REGIME AND INNOVATION POLICY – MID GROWTH	Paced growth scenario based on an improvement of the IP regime and other innovation incentives but with limitations in implementation (based on case study markets analysis)	Annual publications growth rate (of S&T publications) at 4.10%	Annual clinical trials approved growth rate at 4.40%	Annual patents granted growth rate (by local patent office to both pharma and biotech) at 14.9%	Annual employment growth rate in pharma at 3.97%
IP REGIME AND INNOVATION POLICY – HIGH GROWTH	Escalated growth scenario based on an improvement of the IP regime and other innovation incentives with good implementation (based on case study markets analysis)	Annual publications growth rate (of S&T publications) at 4.81%	Annual clinical trials approved growth rate at 7.40%	Annual patents granted growth rate (by local patent office to both pharma and biotech) at 17.9%	Annual employment growth rate in pharma at 8.10%



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ENABLERS OF INNOVATIVE ACTIVITY AND CHALLENGES IN ARGENTINA

- Drawing from the analysis on policies, innovation base and resulting activities and discussions with global and local experts in IP, research, academia, clinical research and industry, Argentina shows:
 - A good development in education base, infrastructure and market opportunity for innovations, but
 - Lags behind in investment in research, regulatory process, system predictability and strength of IP protection
- The rest of the analysis focuses on potential gains from improving the underdeveloped enablers and particularly the strength of the IP regime.

Enablers in Argentina

Low

	AREAS	DESCRIPTION IN ARGENTINA	
	Human capital and expertise	Good availability of top universities and education attainment to higher degrees and good standards	
	Infrastructure to undertake research	Good hospital infrastructure and collaboration for research	
	Market opportunity for innovations	Strong healthcare system with good coverage and generally good levels of access to innovation	
ENABLERS	Investment in research	Direct R&D spend and FDI are lagging behind case study countries but also leaders in LatAm	
	Regulatory methods and process	The regulatory process is regarded by local experts and researchers as a key flaw as agencies have not developed in line with LatAm peers (Invima vs ANVISA differences) ¹	
	Predictability of the system	Regarded highly unpredictable as the agenda on innovation and support for pharma and bio has had large shifts with government changes ¹	
	IP protection	Weakened protection due to recent rules and methodology changes, lack of RDP and slow and inefficient processes	

⁵Observations drawn from interviews with local experts

SCENARIO ANALYSIS ACROSS INNOVATIVE AND ECONOMIC ACTIVITY IN ARGENTINA: ABSOLUTE GAINS AND GROWTH POTENTIAL (ON AVERAGE)









Note: *From 2011 calculations

ILLUSTRATION OF GAINS FOR ARGENTINA (ABSOLUTE GAINS)

Drawing from the findings in the analysis, strengthening the IP environment in Argentina would lead to:

- *Significant gains* in areas such as clinical trials (that are strongly impacted by the level of protection of data generated) and patents granted (with the most direct impact from IP rules).
- *Moderate gains* in employment in pharma (as these are not only research-related employees) and publications (which are also S&T and would expect less impact).





Added benefit Argentina base

FINDINGS

1. ARGENTINA'S CURRENT INNOVATION AND POTENTIAL

Argentina lags behind LatAm and comparable OECD and Asia markets in innovation activities.

- This is noted both in the levels of activity and growth rates during the past 5 10 years.
- Particularly, Argentina performs below peers the clinical research outputs and patents issued locally.

However, in comparison it is a leading country in education, infrastructure and healthcare strength.

- This shows potential to unlock further value from existing resources in undertaking research activities and increasing the levels of investment, which remain suboptimal comparatively to other countries in LatAm.
- Also, the degree of development in capacity is similar to that of case study markets at the times of positive changes in innovation policy demonstrating a potential to drive a comparable growth.

An underdeveloped environment has led to a less dynamic industry with low and decreasing economic outputs.

• A decrease in growth and overall low levels of innovative activity lead to losses in employment, trade and taxes requiring a broader consideration in policy.

2. LESSONS FROM STATISTICAL ANALYSIS AND CASE STUDIES

The statistical analysis shows that a strong IP protection and patent regime leads to a positive impact across innovative and related economic activities.

• This in turn, incentivises more overall spend on research activities.

However, case studies show that a broader approach to support innovation is beneficial across activities and particularly clinical trials, patents issued and employees in research.

• This entails innovation plans in addition to strong rules on IP protection and economic incentives.

3. IMPLICATIONS FOR ARGENTINA INNOVATION AND ECONOMIC POLICY

Apply a suite of support mechanisms to unlock potential value of strong resources in Argentina and incentivise increased economic activity, that include:

Innovation plans.

- Issue *updated follow-on innovation plans* that include broad considerations on appropriate incentives for innovation activity including IP protection.
- Implement *monitoring mechanism on innovation plans* to improve accountability on implementation.

IP regime.

- Ensure the application of strong *IP rights* that allow appropriate rewards for innovation specific to pharmaceuticals and biotech.
- *Provide regulatory data protection* in line with countries of similar healthcare development and aspiration for innovation to support clinical research an area with significant potential gains.

Direct support for research.

- Increase levels of public spending on R&D activities in general and in pharma to provide support to early research and signal an enhanced focus in the sector.
- Encourage collaboration between public and private entities in conducting research.

Support for resources.

• Increase incentives for academics in biomedical sciences to stay or return to Argentina and engage in research activities.

Macro stability.

• Increase government accountability for support for innovation to create a more predictable and supportive environment for investment in innovation.



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