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The economic impact of changing the environment for innovation in Argentina—Applying the lessons of Asia to Latin America

Tim Wilsdon | **Artes Haderi** | **Zlatina Dobreva** | **Giuliano Ricciardi**

Life Sciences, Charles River Associates International Inc., London, UK

Correspondence
Zlatina Dobreva, Life Sciences, Charles River Associates International Inc., 8 Finsbury Circus, EC2M 7EA London, UK.
Email: zdobreva@crai.com

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Abstract

This article discusses the potential impact of reforming Argentina's innovation policy on innovative and economic activity, drawing from evidence of case study markets. We review existing evidence on the relationship between changes in innovation policy and innovative activities to develop an analytical framework. Using the framework, we compare innovative activity in Argentina to other Latin American markets and case-study markets in Asia that have experimented with innovation policy. Drawing on a statistical analysis of the impact of these policies on innovative and economic activity in the case-study markets, we develop a scenario-based model on the potential innovative growth in Argentina, focusing on the pharmaceutical industry. These results are particularly relevant for Argentina, as a market with a strong resource base to undertake innovation, but which has underperformed in terms of innovative activity. Strengthening the policy environment could unlock Argentina's potential and support a step change in innovative activity and the transition to a more knowledge-intensive pharmaceutical industry. This could be achieved by strengthening intellectual property rights relevant to the pharmaceutical and biotech industry and by providing regulatory data protection.

1 | INTRODUCTION

Over the last 20 years, considerable changes have taken place in the location and structure of innovative activity in the life sciences sector. There has been increasing fragmentation in the value chain, with a proliferation of partnerships between research institutions and smaller and larger companies. The globalisation of research and development (R&D) has resulted in the formation of new research hubs in emerging markets and closer collaboration between academia and commercial companies—with the literature often focusing on the trend toward Asian markets and the importance of China (Capo, Brunetta, & Boccardelli, 2014; Frew et al., 2008). To capture some of the value, many countries have developed innovation plans to encourage innovative activity and foreign direct investment (FDI; Guimón, 2009; Khorsheed, 2017).

In the context of this study, we broadly define innovation as "a multiphase process, beginning with lab-based research leading to patentable inventions, moving into the stages of clinical research, which are then translated into safe, effective and commercially viable products from which society gains a benefit in terms of improved health" (Wilsdon, Attridge, Fiz, & Ginoza, 2012). We also distinguish between measures of innovation that focus on inputs (e.g., R&D investment or the number of people employed in different activities) and those that focus on outputs (patents, products in development, or products ultimately commercialised).

Extensive research has examined the characteristics that make countries attractive locations of innovative activity. However, the literature has rarely focused on quantifying the impact of a more favourable innovation environment (with some exceptions such as Wilsdon, Attridge, Haderi, & Estus, 2016). The aim of this study is to contribute to the debate by examining the potential impact of changing the environment for innovation in Latin America (LatAm), using Argentina as an example. We seek to develop concrete evidence on the magnitude and speed of the impact across a range of measures of innovative and economic activity. To achieve this, we first identify common policy priorities and then use the experience of Asian countries who have adopted policy solutions to quantify the impact.

In the next section, we provide a description of the approach, data and methods used for the analysis. Section 3 includes the framework we have used and provides an overview of the environment for innovation in Argentina compared to other countries in Latin America and the OECD. In Section 4, we review the experience of the case study countries on the impact of changing the environment for innovation and the results of the analysis and quantification of the impact on Argentina are presented. Section 5 sets out a discussion of the results and draws conclusions.

2 | DATA AND METHODS

In this study, we apply a three-step approach, namely we (a) conducted interviews and reviewed the literature to develop an analytical framework of indicators; (b) assessed the current performance of Argentina against OECD countries and identified its strengths and weaknesses; and (c) projected the impact of innovation policy changes in selected case study countries in terms of innovative and economic activity to Argentina's baseline performance.

2.1 | Developing an analytical framework of indicators

First, we conducted interviews to understand the relationship between the policy environment for innovation and its impact on innovative and economic activity in the biopharmaceutical space. In total, we held discussions with 19 stakeholders from the pharmaceutical industry, both local in Argentina and international, and innovation and policy researchers and academics as set out in Table 1. These took place between September and November 2018.

TABLE 1 Composition of the interview program

	Interviewee type	Number of interviews
Industry	Multinational companies	9
	Local and SMEs	3
External (local policymakers and innovation experts)	CROs	2
	Researchers and academics	5
Total		19

Abbreviations: CRO, Clinical Research Organisation; SME, small and medium sized enterprise.

Findings from the interviews were supplemented with evidence from a targeted literature review on the changing environment for innovation and the resulting impact on health technologies, the biopharmaceutical industry, and the economy. The literature review targeted studies investigating the relationship between policy environment and the location of innovative activity, focusing on LatAm and Argentina in particular. Studies published between 2010 and 2018 were prioritised for review, both in English and local languages. A combination of search terms were used to capture: (a) the policy environment: "innovation policy," "intellectual property protection," "intellectual property regime," "innovation plans," "innovation regulation," "regulatory data protection," "patent regime"; and (b) the impact on innovation: "innovative activity," "basic research," "R&D investment," "clinical trials," "patents," "foreign direct investment," "tax," and "education." The research was conducted in PubMed, Google Scholar, and grey literature. This yielded over 65 articles with more than 30 international economic theoretical or empirical studies and around 15 specifically focused on Argentina.

Based on the findings from the interviews and the literature, we developed an analytical framework of indicators (Figure 1), to characterise a country's policy environment, the available resources for innovation and the resulting biopharmaceutical innovative and economic activity. These were used as the basis for an impact assessment of improving the policy environment in Argentina.

2.2 | Applying the analytical framework to Argentina compared to the OECD, Latin American, and case study countries in Asia

We undertook a quantitative comparison of Argentina to other Latin American and OECD countries to identify the areas of underperformance (Section 3.3), followed by a comparison to selected case study countries (Section 4). Drawing from the literature and public databases, we compared the countries' performance against the innovative and economic activity indicators in the framework, while also taking into account environmental factors affecting innovation including economic development, political stability, innovation policy, skilled labour, and scientific infrastructure.

We selected the appropriate case study countries based on whether (a) they had instituted changes in their innovation policy that would address the existing gaps in Argentina, (b) this change occurred in a relevant time period so that we could observe the outcome, and (c) present a relatively comparable environment, economic situation, political commitment to innovation, and educational attainment. We focused on:

- **South Korea**: developed local innovation through the "biotech plan" in 1994 and the "557 plan" in 2008. In 2007, regulatory data protection (RDP) for new medicines was also implemented. South Korea is a slightly larger market (population of 51 million compared to 44 million in Argentina) with higher income level (GDP per capita of $29,000 compared to around $14,000 in Argentina).

- **Taiwan**: strengthened the environment for pharmaceutical innovation through the introduction of RDP for medicines in 2005 and through two successive industrial innovation policies in 2005 and 2007. We need to take into account that Taiwan is a smaller market (population of 23 million compared to 44 million in Argentina) and higher income level (GDP per capita of $25,000 compared to around $14,000 in Argentina).

Recognising the challenge of quantitatively accounting for the impact of the differences between Argentina and the case study countries in their availability of resources and investment in innovation, we sought to allow for these qualitatively based on the literature.

2.3 | Estimating the potential impact of policy changes on innovative and economic activity in Argentina

We estimated the potential gains in Argentina's innovative (such as research outputs in the form of publications, clinical trials and patents), and economic (such as the number of biopharmaceutical employees) activity based on the impact of the innovation policy changes in the case study countries that is South Korea and Taiwan (Section 5). Data was retrieved from the literature review and from international and local databases such as WIPO, the World Bank and each country's Ministry of Health website. The impact of the innovation policies was measured using the average year-on-year (YOY) growth across the indicators over 5 years starting from the second year since the introduction of the earliest policy change. The 2-year gap is somewhat arbitrary but allows for the effect of a regulation to start to materialise and a sufficient period of time to estimate its magnitude. To the extent other changes occurred in the 5-year period we have attempted to account qualitatively for these. Finally, the gains on average in the YOY growth were applied to the indicators in Argentina using the 2011 level of activity as a baseline and projecting the growth over a 5-year period in two scenarios of medium and high growth.[1]

3 | BACKGROUND AND REVIEW OF EVIDENCE

In this section, we discuss the current literature examining the relationship between the environment for innovation and the resulting innovative and economic activity, which enabled us to develop an analytical framework (Figure 1) and apply this framework in comparing Argentina to other countries.

3.1 | The relationship between policy and innovation

Prior theoretical and empirical studies have investigated the relationship between changes to or strengthening of the policy framework, specifically for pharmaceuticals, and the level of innovative (pharmaceutical) activity across developed and developing countries. In one of the earlier studies, Aubert (2005) provides a conceptual framework for promoting technological innovation and its diffusion in developing countries. It argues that promoting innovation requires the provision of the necessary package of support (including technical, financial, commercial, legal) and flexible, autonomous agencies adapting their support and operations to the different types of concerned enterprises. It finds that intellectual property rights (IPR) are vital as patents provide protection for the invention, enabling the investor to regain investments in R&D. Otherwise, companies or investors will not risk capital to discover or develop a drug and as a result will not focus their R&D efforts in a country with weak intellectual property (IP) protection. Alongside proposing a framework, Aubert (2005) outlines proxy variables which can be used to measure the level of innovation in a country.

More recently, Charles River Associates (2013, 2016) analysed the conditions for encouraging innovation in emerging markets across different regions. The reports find that a jigsaw of policies is needed to develop the range of innovative activities from basic research to clinical development. They note that this would take considerable time and that the key components are to have a consistent policy framework, a coordinated industrial and health policy, strong IPR and an environment that encourages partnerships between the different stakeholders.

Other studies have looked at distinct policy instruments, particularly IP protection. The relationship between IP and innovative activity found in these studies varies depending on each study's methodology. Whereas some papers have shown a positive relationship between IPRs and patenting activity by innovators in developing countries (Chen & Puttitanun, 2005), others have found a nonlinear U-shaped relationship that is dependent on the level of economic development of a country (Allred & Park, 2007). Similar is the case for private-sector R&D spending (Laforgia, Montobbio, & Orsenigo, 2007).

However, in the case of pharmaceutical patents, a positive relationship between the level of pharmaceutical patent protection and the number of filed biopharmaceutical patents is broadly documented (Laforgia et al., 2007; Dutz, Dutta & Orszag, 2009). The literature further shows that there is a positive relationship between the strength of IP and clinical trial activity, FDI from multinational companies (MNCs), and the number of collaborations between foreign companies and local researchers, institutes and companies in developing countries (Dutz, Dutta, & Orszag, 2009).

A significant portion of the literature documents a positive relationship between strong IPRs and wider economic indicators such as economic development (measured by GDP per capita), jobs created, and the balance of imports and exports (Pham, Pelzman, Badlam, & Sarda, 2016). For example, in a review of close to 200 studies on IPRs and economic growth, Falvey, Foster, and Memedovic (2006) find that strong IP protection generates economic growth. Improvement in the level of IP protection can also result in greater trade (imports and exports), particularly in the trade of knowledge-intensive goods, such as pharmaceutical products (Falvey et al., 2006). Delgado, Kyle, and McGahan (2013) investigated the change in imports and exports in developing and developed countries following the implementation of The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and found a positive impact of the agreement on IP-dependent products represented largely in the biopharmaceutical, information, and communications technology sectors (Delgado et al., 2013).

There is a consensus that IPR policies are necessary but insufficient to spur innovation and that the wider innovation ecosystem is important. Several studies show that the impact of strong IPRs varies with the level of economic development in a country and the extent to which other factors such as skilled labour and scientific infrastructure are available, illustrating the compound relationship between IPRs and domestic innovation (Kumar, 1996; Qian, 2007).

In terms of approach, many analyses focus on case studies but a few use statistical approaches to quantify the relationship between IPRs and domestic innovation. A World Bank analysis (2004) of the relationship between knowledge, domestic innovation and economic development across 92 countries during 1960–2000 finds that domestic innovation, as measured by the number of patents granted by the US Patent and Trademark Office (USPTO), is positive and highly statistically significant (Chen, Derek & Dahlman, 2004). The World Bank (2004) regression analysis suggests that a 1% increase in the number of patents granted by the USPTO is associated with an increase in the average economic growth of 0.19%. In another study, Berndt, Cockburn, and Thiers (2006) conducted an econometric analysis and found that the rising number of clinical trials conducted in emerging economies at the beginning of the century is due to changes in the strength of patent protection for biomedical inventions. This activity is primarily driven by Phase III clinical trials (Berndt et al., 2006). Similar approaches have been applied to FDI (Lesser, 2002).

To unpick the impact of different approaches, studies have used a wider set of controls. Qian (2007) evaluated the effects of patent protection on the pharmaceutical innovation for 26 countries with patent laws issued during 1978–2002. The analysis finds that national patent protection alone does not stimulate domestic innovation. However, domestic innovation accelerates in countries with higher levels of economic development, educational

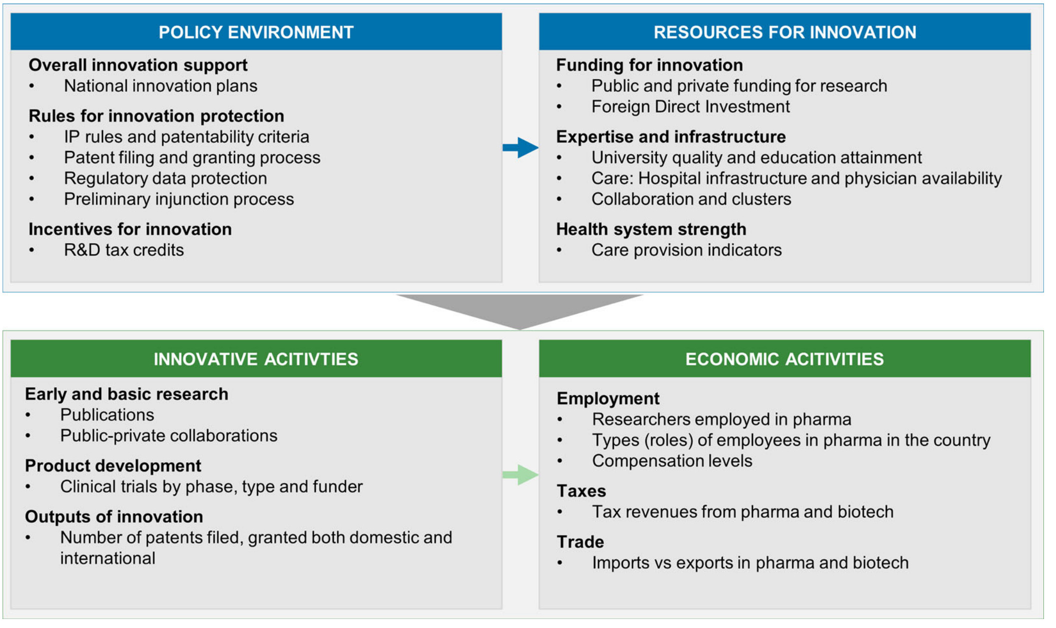

FIGURE 1 The relationship between policy framework and innovative environment. *Source:* Authors' analysis [Color figure can be viewed at wileyonlinelibrary.com]

attainment, and economic freedom (Qian, 2007). Similar is the argument outlined by Kumar (1996), who finds that while the available infrastructure and local capabilities influence the probability of attracting R&D investments from MNCs, the overall strength of IP protection also contributes to attracting foreign R&D investments in a sample of industrialised countries at the time (including Argentina, Brazil, Mexico, Hong Kong, Singapore, Taiwan and Israel). Finally, a number of papers attempt to holistically look at policy development. These find that long-term government strategies and coherent industrial policies can lead to local capacity development and encourage the sustainable development of the pharmaceutical industry and thus local innovation (Aubert, 2005; Chataway, Tait, & Wield, 2006; Kuruvilla, 1996).

The insights from the interviews and the literature review findings led to an analytical framework that associates the policy environment (overall innovation support, rules for innovation protection, incentives for innovation) and the resources for innovation (funding, expertise, and infrastructure) to metrics of innovative (research, development, and innovative outputs) and economic activities (employment, trade, and taxes) focusing on the biopharmaceutical space (Figure 1). The framework allows to assess the current policy and resources environment in Argentina as well as the level of innovative and economic activities, focusing on the pharmaceutical industry, where this information was available, and to systematically compare it to other countries in the OECD and Latin America to identify areas of underperformance.

3.2 | The policy environment for innovation in Argentina

Other studies have assessed the relationship between the IP environment in Argentina and the level of local innovation and indicators of biopharmaceutical activity (Biopharmaceutical Competitiveness & Investment Survey, 2017; Haar, 2017; Thorn, 2005; Wu & Ezell, 2016). In the most comprehensive review, Thorn (2005) examines the strengths and weaknesses of Argentina's national innovation system and proposes policies that will help address these challenges. Though outdated, the paper finds that Argentina underinvests in R&D in terms of national spending, but also in terms of private sector involvement in R&D. The paper highlights low collaboration between private companies, universities, and government research institutions, which are particularly strong in basic research but face insufficient levels of R&D personnel with advanced degrees to fill the future demand for researchers. The paper argues that a strong IPR regime should be in place to complement national policies to provide enterprises with a strong incentive to undertake R&D and commercialise innovations. It further argues that economic growth is to a large extent driven by innovation and that the ability to create knowledge and innovate is essential for gains in productivity and global competitiveness, giving South Korea, Singapore, and Taiwan as examples.

A more recent assessment of the current innovation environment in Argentina was completed in the Pugatch Consilium's Biopharmaceutical Competitiveness Investment Survey (LatAm Special Report) in 2017. According to the authors, Argentina is among the countries least likely to attract foreign investment (through basic research, clinical development, manufacturing or commercialisation efforts), lagging behind Chile, Costa Rica, and Mexico, despite its strong potential due to local human capabilities and available infrastructure, similar to those countries. Key reasons for this are inappropriate leveraging of opportunities for collaborative R&D and technology transfer in biopharmaceuticals, long clinical trial approval delays, red tape and gaps in technical capacity as well as constraints in market access and lack of effective IP protections (The Biopharmaceutical Competitiveness & Investment Survey, 2017).

3.2.1 | Overall innovation support and incentives for innovation

Argentina is characterised by a complex science, technology, and innovation system at the level of the national government. Multiple agencies with overlapping responsibilities feed into the Ministry of Education, Science, and Technology, which is seen as a potential weakness (Cabinet for Science and Technology, the Federal Council for Science and Technology, and the Interagency Council on Science and Technology; Thorn, 2005; Ministry of Science, Technology and Productive Innovation, 2015). Despite the complexity, Argentina has historically focused strongly on innovation. The Argentine government approved the first national multiyear science and technology (S&T) plan in 1997 and since then has shown a strong commitment to encouraging innovation in the country through a series of innovation plans and R&D tax incentives (Figure 2). These interventions aimed to

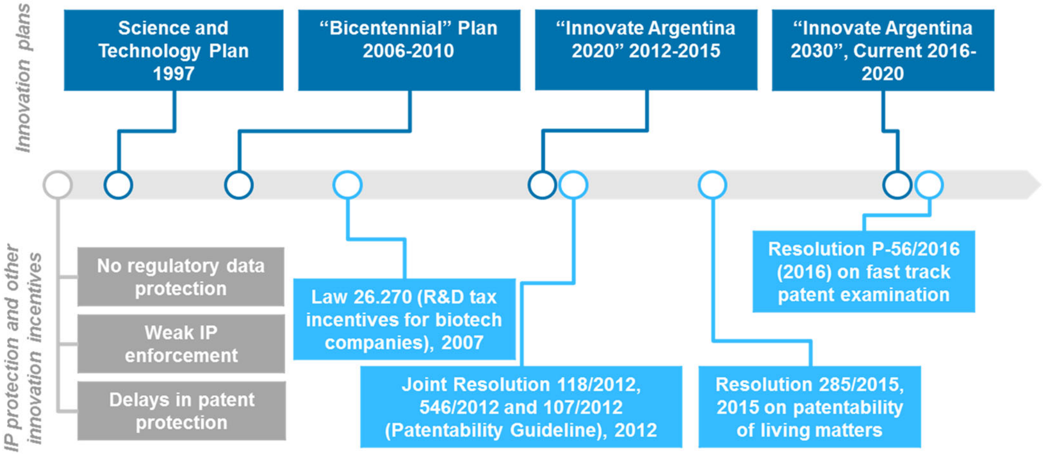

FIGURE 2 Innovation policies and IP rules in Argentina. *Source:* Authors' analysis [Color figure can be viewed at wileyonlinelibrary.com]

expand the scientific and technological capabilities in the country and grow public and private investments in R&D as well as the number of researchers in basic research to transform Argentina into a knowledge-intensive economy (Ministry of Science, Technology and Productive Innovation, 2015). Additionally, in 2007 the Promotion of the Development and Production of Modern Biotechnology Law 26.270 (2007) made R&D tax incentives available to biotechnology companies in the form of tax relief. The law also made available seed capital and early-stage funding to further incentivise R&D. Being part of the government's long-term strategy and industrial vision, these interventions, if implemented consistently, have the potential to incentivise innovation over time, from basic research to clinical development.

3.2.2 | Rules governing IP protection

However, the current IP protection provisions are a potential weakness when compared to other countries. Argentina was included in the Office of the United States Trade Representative (USTR) Special 301 report, comprising a list of countries with IP and market access challenges (Office of the United States Trade Representative USTR, 2017). One of the key issues identified was the lack of RDP for pharmaceuticals.[2] RDP provides additional incentives to companies by ensuring the protection of the clinical trial data required for regulatory approval.

USTR identified other IP challenges including (a) the weak enforcement of IP rules by the national agency that has led to a burdensome and lengthy process of seeking a preliminary injunction to prevent the sale of an infringing product during patent litigation, (b) the existing backlog of patent applications, and (c) a series of issued resolutions that implemented restrictive criteria for the patenting of pharmaceutical inventions. The latter include:

- *Joint Resolutions 118/2012*, *546/2012*, and *107/2012* (collectively known as "*The Guideline on Patentability*") issued in 2012 by the Argentinian government and followed by the Argentinian Patent Office (INPI). The guideline restricts the patentability criteria for new products that are an innovation on existing products (e.g., new formulations, combinations, and dosage) and their use for new indications. Given that the process of innovation is often iterative, this restricts the ability of manufacturers to patent new inventions and method of use to address new areas of unmet need (WIPO Lex, 2018).
- *Resolution 283/2015*, passed in 2015, which leads to a more restrictive interpretation and application regarding the prohibition of patentability of every living matter pre-existing in nature (including biologics) set forth in Section 6 of the Argentine Patents Law (Schmukler, 2018, para 2). This may limit the ability of manufacturers to obtain a patent on potentially life-saving medicines based on components of living organisms (e.g., vaccines, blood components, cells, and recombinant antibodies).

The Argentinian government has taken steps to address some of the current limitations and to improve the current IP framework, particularly relating to the backlog of patent applications. For example, *Resolution P-56/2016* states that patent applications with claims that are the same as for patents granted abroad can be considered through a fast-track process, though the *Guideline on Patentability* and the *Resolution 2835/2015* take precedence when considering patent applications (Moeller, 2016). This may facilitate the application review process and tackle some of the backlog. We have focused on these remaining gaps.

To identify the innovation areas of underperformance from the perspective of the biopharmaceutical sector and assess the potential impact of improving the innovation and IP policies, we review the available data across indicators comparing Argentina to other Latin American and OECD countries, followed by a comparison to selected case-study countries.

3.3 | The resources for innovation and innovative and economic activity in Argentina compared to OECD and other Latin American countries

Based on the framework of indicators, we characterise and compare Argentina's resources for innovation and innovative and economic performance to OECD and Latin American countries. We are able to highlight the areas where Argentina performs strongly today and where there is the potential for improvement given the right policy intervention.

3.3.1 | Investment in research and development

Argentina has a high investment in R&D compared to the region, but it is four times lower than that of OECD countries. Argentina invests 0.5% of its gross domestic product (GDP) compared to 2.0% in the OECD (Figure 3). There is a gap in the private sector's investment in R&D. The private sector investment in R&D is lowest in the Latin American region, comprising 21% of the total expenditure on innovation compared to 36% on across Peru, Mexico, Colombia, Chile, Costa Rica, Ecuador, and Brazil and 47% in the OECD (World Bank Innovation Policy Platform, "BERD", Ibero-American Network of Science and Technology Indicators, 2018c). The pharmaceutical industry in

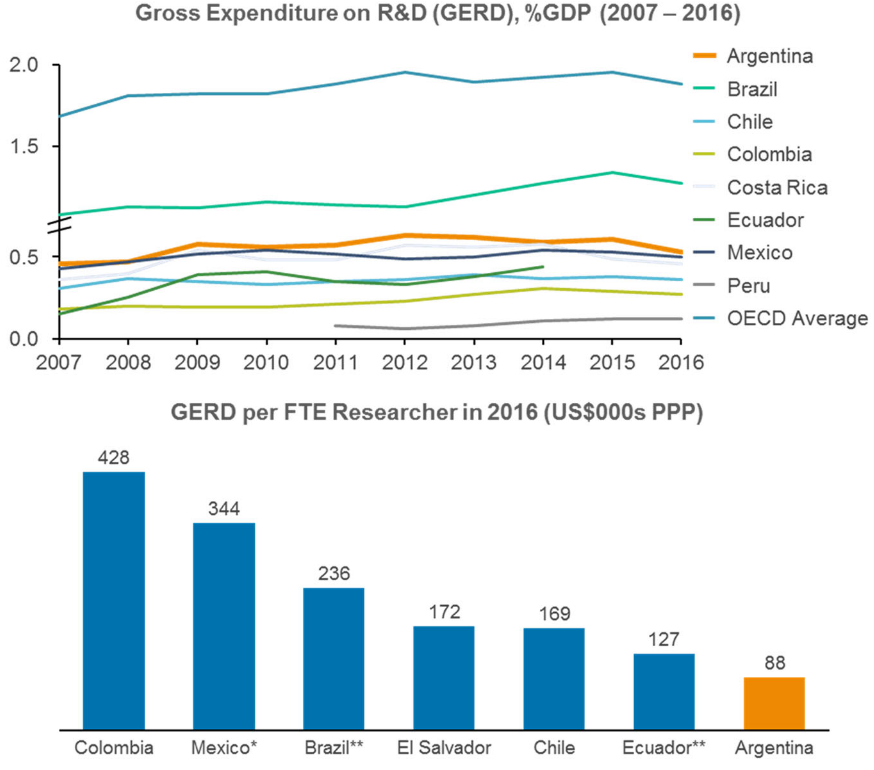

FIGURE 3 Gross R&D expenditure as a percentage of GDP (GERD) and per researcher. *Latest data from 2013, **Latest data from 2014. *Source:* Authors' analysis based on Ibero-American Network of Science and Technology Indicators (2018a) and Ibero-American Network of Science and Technology Indicators (2018b); OECD, "Main Science and Technology Indicators." FTE, full-time equivalent, GDP, gross domestic product; PPP, purchasing power parity [Color figure can be viewed at wileyonlinelibrary.com]

Argentina reinvested only 2% of its sales in R&D in 2013 (KPMG, 2014) compared to 14% by global companies (Guevara et al., 2015).

The inflow of FDI, another form of investment in R&D, is on a downward trajectory and lags behind the OECD countries and the region. FDI inflow in Argentina decreased from around 2.5% of GDP in 2010 to 1.8% in 2017, compared to 2.8% on average for Brazil, Mexico, and Chile and of 2.1% in the OECD (World Bank, "Foreign direct investment").

As a result, scientific researchers are underfunded compared to countries in the region and the OECD. Argentina invested only US$87,670 per researcher in 2016 compared to US$220,000 across Latin America and US$243,362 across the OECD (Figure 3), resulting in an apparent "brain drain" from Argentina to Europe and the United States.

3.3.2 | Availability of skilled workforce and local infrastructure

Argentina has a strong education foundation compared to the region and the OECD. In 2017, the percentage of the population engaged in upper secondary or tertiary education was 40% and 21%, compared to 43% and 37% in the OECD and 25% and 20% in Colombia, Costa Rica, Mexico, and Brazil (OECD, "Adult Education Level").

Argentina has three times the number of researchers in the region, but 90% are employed by public institutions. There were 4.7 researchers per 1,000 in employment compared to 1.7 in the region (Ibero-American Network of Science and Technology Indicators, 2018e, OECD, 2018d). Argentinian academics participate in fewer international collaborations with nearly two times fewer coauthored articles (5,400) than Brazil, Mexico, and Chile (average of 12,100) and nearly six times fewer than the OECD (32,100) in 2016.

With more than double the available hospital beds and physicians across the region, Argentina has a strong healthcare infrastructure. There were 5.0 hospital beds per 1,000 population compared to 1.9 on average in Brazil, Chile, Ecuador and Mexico in 2012. There were also 4.0 physicians per 1,000 people compared to 1.9 on average in Brazil, Chile, Colombia, and Mexico in 2017/2016 (World Health Organization, 2018).

3.3.3 | Scientific publications

Argentina's research productivity is one of the lowest in Latin America—20.7 publications per researcher compared to a regional average of 42.3 in 2016 (Figure 4). Nevertheless, academic research remains of high quality and significance relative to the region and the OECD. Argentina's share of publications in the top 1% most cited articles in the Scopus database was 1.19%, greater than that of Mexico (0.79%) and Brazil (0.65%), though lower than of the OECD counties (1.79%; National Center for Science & Engineering Statistics, 2018).

3.3.4 | Number of clinical trials

Even though a significant number of clinical trials are located in Argentina, these have decreased in number. Based on an analysis of the clinicaltrials.gov database and World Bank Indicators (2018), Argentina hosted just under double the number of clinical trials in the region in 2017—2.9 per million compared to 1.6 across Colombia, Chile, Brazil, Ecuador, Mexico, and Peru. However, the absolute number decreased from 157 in 2012 to 129 in 2017. The local pharmaceutical sector's investment in clinical trials is also low—the percentage of Phase I, II, and III clinical trials it funded declined from 40% to less than 5% between 2002 and 2017.

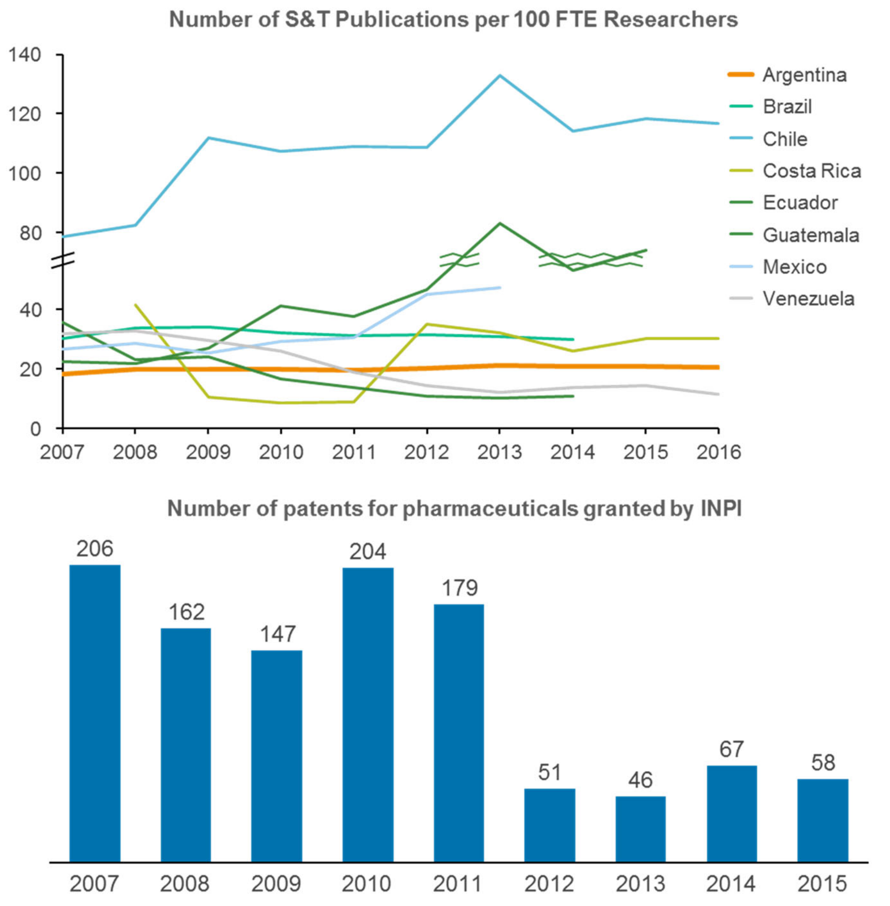

FIGURE 4 S&T publications and pharmaceutical patents granted. *Source:* Author's analysis based on Ibero-American Network of Science and Technology Indicators (2018d) and Bein & Asociados (2017). FTE, full-time equivalent; S&T, science & technology [Color figure can be viewed at wileyonlinelibrary.com]

3.3.5 | Number of pharmaceutical patents

The number of pharmaceutical patents granted by the U.S. Patent and Trademark Office to Argentinian nationals is more than double that of the region but is significantly less than the OECD. In 2015, a total of 8.2 pharmaceutical patents were granted to Argentinian nationals compared to an average of 3.2 across Brazil, Chile, Cuba, and Mexico and 91.4 for the OECD (OECD, "Patents by technology"). The number of pharmaceutical patents granted by the Argentinian patent office, INPI, decreased between by 72% 2011 and 2012 reaching 58 in 2015 (Figure 4).

3.3.6 | Employment, trade, and taxes in the biopharmaceutical sector

The biopharmaceutical sector in Argentina has grown in the past and is a significant employer when compared to other countries. Employment increased by more than 20% between 2007 (34,000) and 2017 (41,800). Expert interviews underscored the strength and size of the Argentinian pharmaceutical sector but highlighted that it focused on producing low-cost generics, given that less than 10% are employed to undertake R&D (Ministerio de Hacienda Presidencia de la Nación, 2018).

TABLE 2 Comparison of Argentina to Latin America and the OECD

	Indicators	Compared to Latin America	Compared to the OECD
Human resources	Universities	●	◑
	Education attainment	◕	◕
	Collaborations	◑	◔
	Researchers	●	◔
Healthcare system strength	Infrastructure	●	◑
	Effective and safe care	◑	◔
Investment in innovation	Gross Expenditure on R&D (GERD)	◑	◔
	Foreign Direct Investment (FDI)	◑	◔
Innovative activity	Early research (publications)	◑	◔
	Clinical trials	◔	◔
	Patents	◔	◔
Economic activity	Employment	◑	◔
	Taxes	◔	◔
	Trade	◔	◔

Legend: ○ ◔ ◑ ◕ ● → Increasing performance

Note: Economic activity concerns indicators of performance in the pharmaceutical sector. *Source*: Authors' analysis.

Economic activity as measured by tax receipts and trade surplus in the pharmaceutical sector has remained weak. Pharmaceutical tax receipts increased from US$556 million in 2012 to US$1,247 million in 2015, but in latest years these have constituted a smaller proportion of overall tax revenue (1.05% in 2015), suggesting a significantly higher increase in tax collection in other industries. Growth in the level of exports over the past 10 years was offset by an increase in imports leading to consistent trade deficits—from US$1.7 billion in 2012 to US$2.0 billion in 2015 (Ministerio de Hacienda Presidencia de la Nación, 2018), compared to a deficit of US$2.4 billion in Brazil (UNCTADstat, 2018).

Table 2 provides a summary of the comparative analysis. This highlights Argentina's strong performance in terms of educational attainment, healthcare, and academic infrastructure and skilled workforce but also its underperformance in terms of innovative activity (as represented by the low number of publications, clinical research, and number of patents granted). This suggests that with the correct policy intervention there is a significant opportunity in Argentina.

4 | THE IMPACT OF POLICY CHANGES ON INNOVATION IN TAIWAN AND SOUTH KOREA

We identified two OECD countries—South Korea and Taiwan—that in the past faced similar policy challenges to Argentina and implemented policies in line with the current gaps in the innovation and IP regime in Argentina. In the following section, we compare them to Argentina in terms of the analytical framework of indicators and quantify the impact of the policy changes relevant to Argentina.

Comparing Taiwan and South Korea to Argentina, there are clearly some areas of alignment (in terms of resources: the local levels of education and quality of research) but also differences (in terms of the level of investment for innovation and other innovative outputs such as pharmaceutical patents and clinical trials):

- *Investment in R&D*: South Korea and Taiwan invest significantly more in R&D than Argentina. South Korea's GERD doubled from 2% in 2000 to 4% in 2016. In Taiwan, it increased from 1.9% in 2000 to 3.2% in 2016. In contrast to Argentina, the main source of funding for research in South Korea and Taiwan is the private sector, with its percentage contribution to GERD standing at 95% and 78% in 2015, respectively.
- *Educational attainment*: Argentina performs comparably to South Korea and Taiwan in terms of the level of education of its workforce. In Argentina, 95% of the higher education graduates (130,000) had an undergraduate degree, 3% had a master's degree and 2% had a doctorate degree (Ministry of Science, Technology & Productive Innovation, 2015). The same year data for South Korea are similar—87% of graduates had an undergraduate degree, 10% had a master's degree-, and 3% had a doctorate degree in 2016 (Korea Institute of S&T Evaluation and Planning, 2018).
- *Number of scientific researchers*: In line with the higher spending on R&D, South Korea and Taiwan had more researchers available in 2016. Compared to 4.7 per 1,000 in employment in Argentina, South Korea, and Taiwan had available 13.8 and 13.1 in 2016, respectively.
- *Number of scientific collaborations*: Colocalisation can help enhance the number of collaborations and transfer of knowledge between academia and the private sector (Baptista, 2001). Both South Korea and Taiwan have gradually established science and technology clusters or parks located in strategically selected cities, where a number of companies and universities are colocalised and compare favourably to Argentina.
- *Number of scientific publications*: Biological sciences publications in South Korea and Taiwan were greater than in Argentina—about 9,000 and 3,400 in 2016, respectively (National Center for Science & Engineering Statistics, 2018). Nevertheless, as already observed, Argentina has a high quality of the research output, whereby Argentinian articles took 1.19% of the share of top 1% most cited science and engineering publications, compared to 1.01% in South Korea and 0.79 in Taiwan (National Center for Science & Engineering Statistics, 2018).
- *Number of clinical trials*: Despite the available skilled workforce and good healthcare infrastructure compared to South Korea and Taiwan, Argentina was the chosen location for significantly fewer clinical trials (2.9 clinical trials per million of population) than Taiwan (10.2) and South Korea (172.2) in 2017.
- *Number of pharmaceutical patents*: Pharmaceutical patents granted by the South Korean (2,100) and the Taiwanese (511) IP Offices exceeded those granted by INPI (58) in 2015 (Ministry of Science and ICT, South Korea, 2018; Taiwan Intellectual Property Office, 2017). In terms of the internationalisation of local research, nationals from South Korea and Taiwan patented a greater number of pharmaceutical inventions with the USPTO in 2016 (2,200 and 440, respectively, compared to only about 11 in Argentina), highlighting the lack of focus on pharmaceutical innovation and the challenge of translating early research into inventions.
- *Employment in the biopharmaceutical sector*: Despite the apparent lack of focus on innovative activities, the local biopharmaceutical sector remains a significant economic force in Argentina employing a greater number of people than that in the two case study countries. The number of employees in the biopharmaceutical sector in South Korea was about 20,818 in 2015 (Ministry of Science and ICT, South Korea, 2018) and in Taiwan was around 20,000 in 2015, which nearly tripled since 2004 when there were around 7,700 employees (Ministry of Economic Affairs, R.O.C., 2018).

However, the policies introduced closely align with those suggested for Argentina. As illustrated in Figure 5, South Korea introduced successive national science and technology plans and RDP in 2007 (Erstling & Strom, 2009):

- The 577 Initiative, launched in 2008, outlined three overarching objectives: (1) invest 5% of GDP into R&D, (2) focus on seven key S&T areas, and (3) become one of the seven major S&T powers. The focus on seven S&T areas is divided between seven R&D topics (key industrial technologies, emerging industrial technologies, knowledge-based service technologies, state-led technologies, national issues-related technologies, global issues-related technologies, and basic & convergent technologies) and seven systems (world-class human resources, basic and fundamental research, small and medium enterprise (SME) innovation, S&T globalisation, regional innovation,

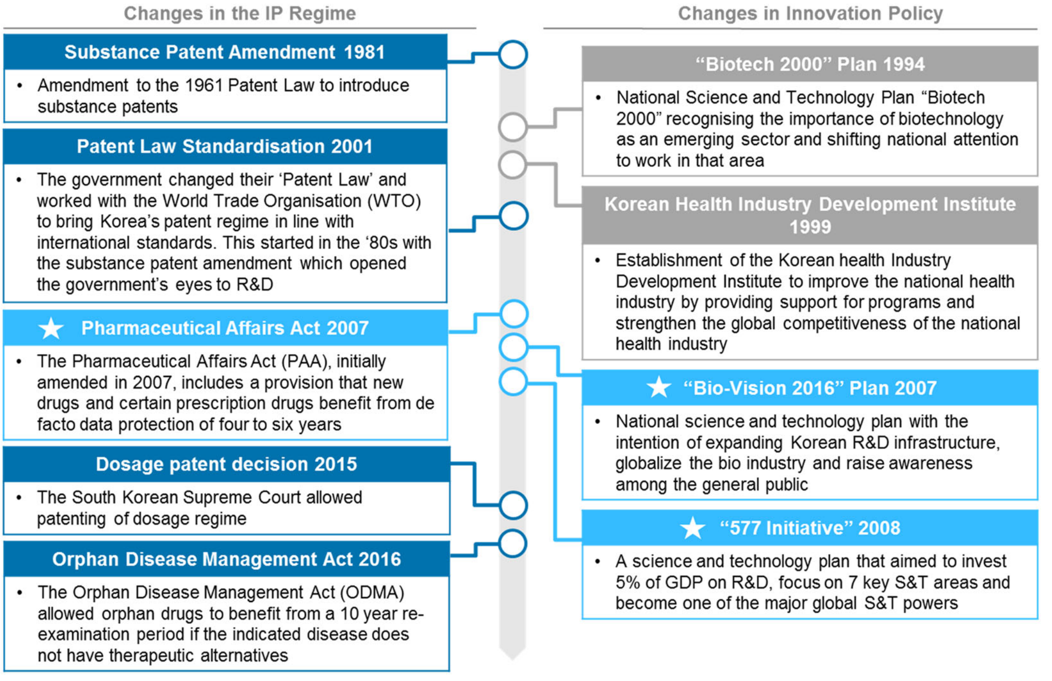

FIGURE 5 Innovation policies and IP rules in South Korea. *Key events considered in the analysis.
Source: Authors' analysis [Color figure can be viewed at wileyonlinelibrary.com]

S&T infrastructure and S&T culture). As a continuation of the progress made with Biotech 2000 initiative, in 2007 South Korea embarked on Bio-Vision 2016, the second phase of their biotechnology promotion plans.

- Parallel changes to regulatory data protection were introduced under the Pharmaceutical Affairs Act (PAA) launched in 2007. Following the harmonisation of Korea's IP system with members of the World Trade Organisation (WTO) in 2001, Korea adopted the Pharmaceutical Affairs Act in 2007 which introduced RDP during the first 4 or 6 years of market entry for new and certain other prescription medicines. All biologic drugs also benefit from de facto data protection (Korea Development Institute, 2012).

Taiwan complemented IP incentives with a robust biopharmaceutical industrial strategy to develop an overall strong and innovative sector (Figure 6):

- To establish Taiwan as a centre for genomic research and a leading location for clinical trials, and the most vibrant biotech-focused venture capital industry in Asia Pacific (Chen, 2007), Taiwan implemented the Biotech and Pharmaceutical Technology Island Plan consisting of three major projects: (a) the National Health Information Infrastructure Plan, (b) building Taiwan's Biobank database, and (c) establishing a clinical trial and research system (Chen, 2007). In 2007, Taiwan implemented regulations to facilitate knowledge transfer from academia into industry with the Biotech and New Pharmaceutical Development Act.
- While pharmaceutical inventions have been patentable in Taiwan since the introduction of a law in 1968 (Lo, 2011), additional IP incentives for pharmaceutical products were adopted in 1997 (Yeh, 2009) and following its accession to the WTO in 2002. Taiwan introduced a 5-year RDP in 2005, contingent upon filing for marketing approval in Taiwan within 3 years of obtaining marketing authorisation in a different country (Centre for Drug Evaluation, 2018) and which did not apply to new dosages, formulations, indications, and combinations (Centre

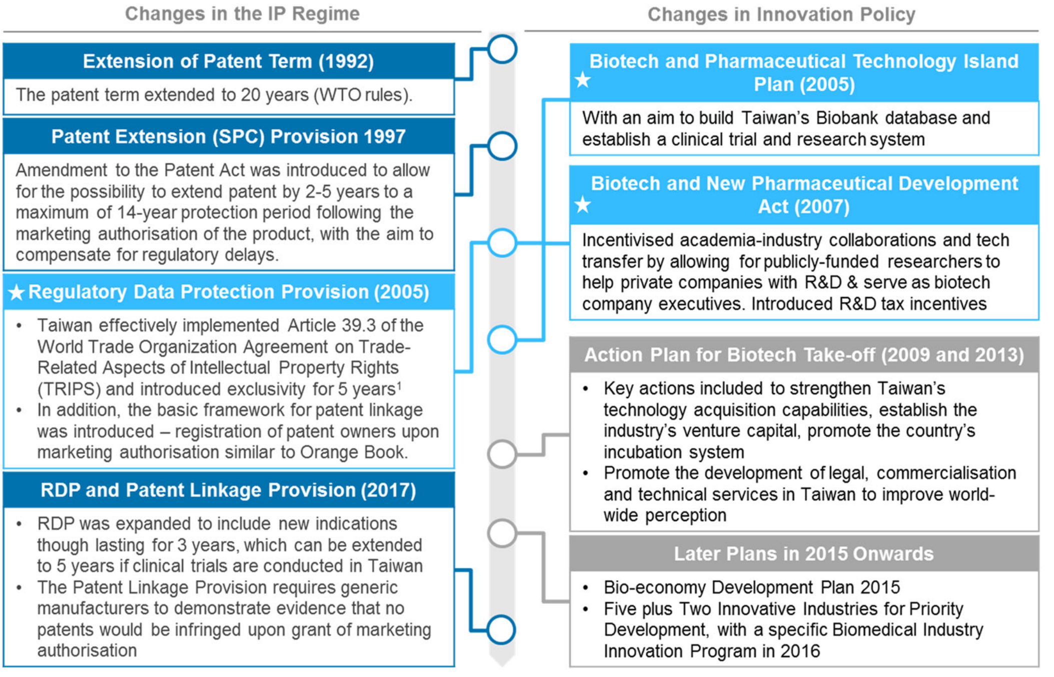

FIGURE 6 Innovation policies and IP rules in Taiwan.*Key events considered in the analysis. *Source:* Authors' analysis [Color figure can be viewed at wileyonlinelibrary.com]

for Drug Evaluation, 2018). It was not until 2017 that Taiwan adopted RDP for new indications, though this measure is out of the scope of this study.

If we look at the experience of South Korea and Taiwan before and after regulatory change we can consider if this would be applicable for Argentina. Table 3 illustrates our analysis of the YOY growth from 2007 for the following 5 years across the different indicators based on available data from international databases such as the World Intellectual Property Office and the OECD Innovation Indicators. Overall, we find:

- The policy changes have had the strongest impact on the number of patents (between 15% and 29% increase).
- Relatively weaker growth in employment (4.0% and 8.1% in South Korea and Taiwan, respectively) and private sector investment in R&D (6.5% and 11.0% in South Korea and Taiwan, respectively).
- A less pronounced impact on other outputs of innovation such as clinical trials 7.4% and 4.4%, respectively) followed by scientific publications (4.8% and 4.1% in South Korea and Taiwan, respectively).
- Clinical trials are more strongly impacted by improvements in the innovation and IP policies targeting primarily the pharmaceutical sector but can also be impacted by the cost of conducting those in a particular market (Berndt et al., 2006).
- In contrast, the number of scientific publications is affected to a lesser degree by wider innovation policies being a more direct output of early academic research.

To substantiate this analysis, we reviewed the government, academic and grey literature to understand the impact of policy changes on innovative and economic activity in Taiwan and South Korea. While the literature examining their impact is scarce, two notable exceptions support our findings:

- The progressive changes in the protection provided in South Korea are seen as an important component in incentivising innovative activity. Before this, most pharmaceutical companies in South Korea did not conduct large amounts of innovative R&D, but an industry-wide shift occurred whereby the industry began to conduct innovative R&D (Korea Development Institute, 2012). One of the major achievements of Biotech 2000 was increased South Korean competitiveness from a publication and patent standpoint. South Korea moved from 29th in 1994 in SCIE study rankings to 13th in 2005. With regard to patents, South Korea increased in the US Technical Strength rankings from 21st in 1994–1996 to 14th in 2003 to 2005 and since 1998 the number of filed Korean domestic patents far outstripped the number of filed foreign patents (Hyeon et al., 2008).
- In Taiwan, it was reported that despite opposition from the local pharmaceutical associations, a consensus was reached that RDP would stimulate innovative activities and amendments to the Pharmaceutical Affairs Law were introduced in February 2005 (Centre for Drug Evaluation, 2018).

TABLE 3 Relationship between innovation policy and innovative and economic activity

		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	
		Growth	**Link to Policies**	**Growth**	**Link to Policies**
Innovative Activity	BERD	6.5%	◑	11.0%	◕
	Early research (publications)	4.8%	◔	4.1%	◔
	Clinical trials	7.4%	◕	4.4%	◕
	Patents (residents)	20.9%	◕	26.3%	◕
	Patents (non-residents)	15.0%	◕	16.4%	◕
	Patents (USPTO)	29.0%	◑	17.8%	◑
Economic Activity	Employment in biopharmaceuticals	4.0%	◕	8.1%	◕

Legend: ○ ◔ ◑ ◕ ● → Increasing relative impact

Abbreviations: FTE, full-time equivalent; GDP, gross domestic product; PPP, purchasing power parity.
Source: Authors' analysis based on Ibero-American Network of Science and Technology Indicators, "Expenditure on R&D" and "Expenditure on R&D perper researcher" (2019); OECD, "Main Science and Technology Indicators."

5 | APPLYING THE LEARNINGS TO ARGENTINA

Drawing from the impact analysis described above, we then developed growth scenarios in Argentina to quantify the impact of similar innovation and IP policy changes being introduced and the Patentability Guideline repealed. The quantification of benefits is based on the following four key indicators:

- *Innovative activity—early research*: proxied by the number of scientific publications.
- *Innovative activity—clinical research*: proxied by the number of clinical trials including Phase I, II, and III.
- *Innovative activity—output, that is patents*: proxied by the number of pharmaceutical patents issued by the local patent office.
- *Economic activity—employment*: proxied by the number of employees working in the biopharmaceutical sector.

We understand that there are important caveats to this approach. The case study countries share similarities with Argentina in the local resource environment for innovation but also many differences, most importantly the per capita level of income, which itself can lead to more investment in and resources for innovation (Raghupathi & Raghupathi, 2017). Ideally, this analysis would take into account these and other socioeconomic factors and this is an area for future research.

Using the maximum of the average YOY growth rates in Table 3 as our high growth assumption and the minimum as the medium growth assumption, the average YOY growth rate is then applied to the Argentina baseline. As reported in Section 3, the baseline—the final year before the introduction of the patentability guideline implemented in 2012, that is 2011—is extrapolated to the latest year for which data are available across indicators (illustrated as an average annual growth on Figure 7 and the 5-year gains on Figure 8). The analysis shows an expected increase in all innovative and economic activity indicators due to improved innovation policy and IP system (Figure 7). The greatest impact would be on the number of pharmaceutical patents, followed by clinical trials, employment gains and publications. There would be on average between 201 and 219 more pharmaceutical patents granted per year leading to a total of 380–398 and on average 61–86 more clinical trials up to a total between 259 and 284. More important, it is expected that the policies would contribute towards 2,675 to 9,294 more people being employed in the pharmaceutical industry. A timeline illustrating the change in activity across the indicators for the two growth scenarios as compared to the actual activity is shown in Figure 8.

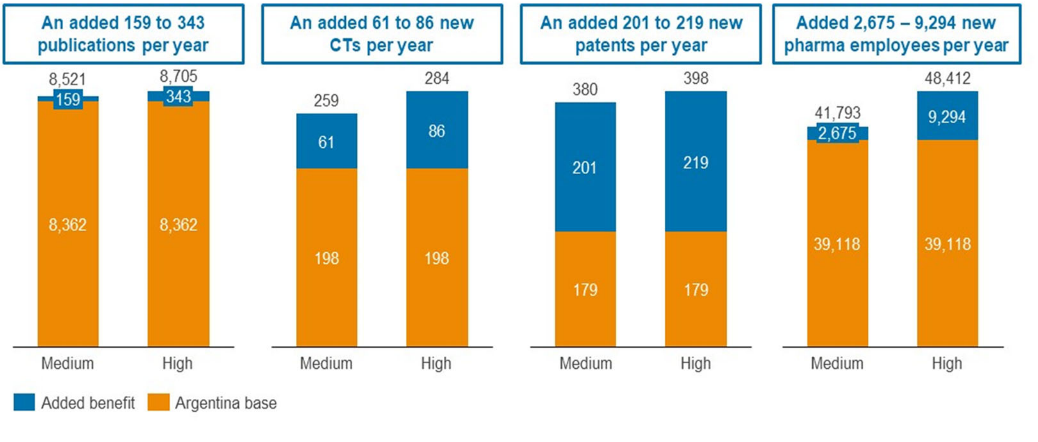

FIGURE 7 Annual gains in Argentina from changes in the environment for innovation. *Source:* Authors' analysis [Color figure can be viewed at wileyonlinelibrary.com]

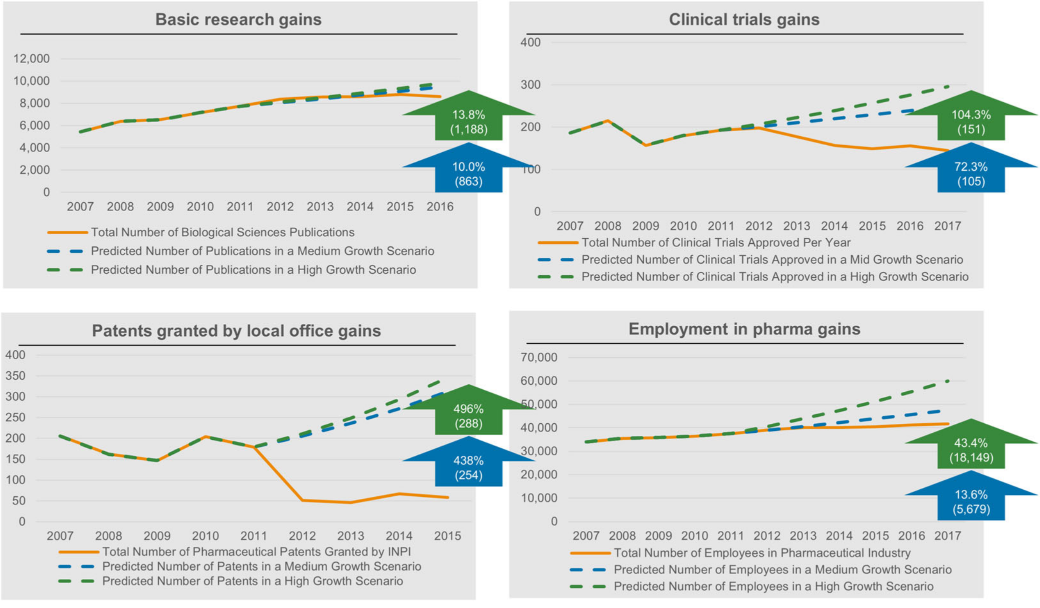

FIGURE 8 Scenario analysis across innovative and economic activity in Argentina: Absolute gains and growth potential (final year). *Source:* Authors' analysis [Color figure can be viewed at wileyonlinelibrary.com]

Although the similarity between our medium and high scenarios provides some reassurance on the accuracy of our estimates, we understand that differences between Argentina and our case study countries mean the results should be treated cautiously. The interviews were used to discuss the magnitude of the results and remaining caveats. The main concern is regarding the employment estimation. The structure of the off-patent market in Argentina is larger than that in Taiwan or South Korea. The off-patent market is an exporter of medicines and significantly contributes to the employment by the industry, as the figures show employment exceeds the levels reported in Taiwan and South Korea. Thus, the extent to which changes in innovation policies and RDP translate into more employment may be limited compared to the case studies. However, in both Taiwan and South Korea we found a positive impact of employment throughout the period and any impact will be transitional (medicines will lose data protection and there are likely to be more innovative products being launched in Argentina). Therefore, we conclude that this may alter the path of the changes (as set out in Figure 8) but not the magnitude of the changes after a five-year period.

6 | DISCUSSION AND CONCLUSIONS

It is clear from our assessment that Argentina lags behind comparable markets in terms of innovative activity, but it has significant capabilities for undertaking these activities. We find that while Argentina has lower levels of private investment in R&D, lower number of clinical trials and patents, it also has a higher or similar level of human capital (and quality education) available, the healthcare infrastructure needed to research and launch innovations and a generally developed healthcare system. The literature also identifies gaps in the innovation policy regime including the lack of RDP for pharmaceuticals, the application of restrictive patentability rules, and the backlog of patent applications gradually being addressed. These could partly explain Argentina's current underperformance against other OECD countries. Addressing these policy gaps, would unlock potential value from the existing resources in undertaking research activities and increasing levels of investment in R&D leading to further economic gains.

To illustrate the potential impact of implementing these changes, we conducted a case study analysis of Taiwan and South Korea, countries with comparable economic situation, political commitment to innovation and educational attainment, and with the innovation policies required in Argentina. The YOY analysis of key innovative and economic activity indicators showed that in the presence of strong capacity to sustain innovative activity, a more favourable innovation policy regime can result in improvements in innovative activity (the number of research publications, patents granted, and clinical trials implemented) leading to further economic benefits (mainly employment in the biopharmaceutical sector) over a period of 5-10 years.

The gains observed in YOY growth were applied to Argentina's baseline (the level of activity in 2011 before the introduction of the 2012 *Patentability Guideline*). Recognising the differences in income levels between Taiwan, South Korea, and Argentina, which could lead to higher investment in research, as well as other socioeconomic differences that might be having a compound effect on the YOY growth across indicators, we found that the most significant positive impact from improved regulation in Argentina would occur in clinical research activities (the number of clinical trials could increase by 72.3% or 104.3% in the medium and high growth scenarios over 5 years) and patents issued locally (patents could increase by 438% and 496% in the medium and high growth scenarios over 4 years). The number of basic research publications and employees in the pharmaceutical sector was less strongly impacted (with 10.0% and 13.6% growth in the medium growth case, respectively, and 13.8% and 43.4% growth in the high growth case, respectively). While the past literature has recognised the positive impact of improved regulation support and patent protection, our literature review did not identify any comparable studies in the context of Argentina.

It is prudent to note that the analysis assumes the patentability rules in Argentina would not have changed in 2012, so preventing the significant drop observed in the number of patents issued from 2012 onwards and leading to a considerable increase in the patents issued per year compared to the rest of the indicators. Second, we have incorporated the impact of enforcing regulatory data protection (based on the experience of Taiwan and South Korea) on clinical research. With respect to early research and employment in the sector, the impact observed is smaller but positive compared to the number of clinical trials and patents per year. This is due to three reasons: (a) changes in basic research only occur slowly over time, (b) Argentina is performing well in these metrics and (c) the impact of these changes in regulation only indirectly contributes to changes in these activities. For example, early research highly depends on the support for academic capacity building and funding, whereas employment relies heavily on other economic factors and social policies.

We conclude that some key changes in the innovation policy and IP regime are required to enable Argentina to leverage its existing strong capacity and resources for innovation. Learning from the experience in Taiwan and South Korea, IP rights could overall be brought in line with those in other OECD countries through the introduction of regulatory data protection for new medicines and indications. This could make Argentina more attractive for manufacturers to conduct clinical trials compared to other countries in the region, boosting foreign investment and improving local capabilities. In addition, broadening the types of new molecules that can be patented to include new indications, combinations, and formulations, and thus repealing the restrictive 2012 *Patentability Guideline* could promote the transfer of early-stage research into patentable inventions and overall boost innovative outputs in terms of the number of patents granted and products commercialised. Updating and implementing more coherent innovation and biopharmaceutical plans, with the appropriate incentives for R&D could further underscore the government's commitment to innovation, boost local resources available for research and incentivise innovators to invest in and conduct research. These changes combined with Argentina's current efforts to address the patent backlog would overall boost innovative outputs and economic activity.

As with any scenario analysis, there are some significant caveats. Given the complexity of the environment, it is difficult to draw lessons from one market and apply to another. Despite the aim for comparability of the countries and control for elements such as income levels, there are other key differences between the Argentinian economy and those of the chosen case studies. These include healthcare sector structure, the strength of the economy, and social and cultural issues attached to innovation. Second, it is important to recognise that national activities can be subject to regional forces, as investment has shifted towards Asia in recent years, independently of the policy framework in these countries (also largely driven by the Chinese economy).

However, we conclude that a strengthened policy environment for innovation would lead to a more dynamic biopharmaceutical industry and increase innovative and economic activity. Indeed, it appears an ideal time to strengthen the environment, building on the recent modest improvements in innovation-friendly policies. This would lead to a compelling increase in levels of innovative activity across innovation inputs and outputs (clinical trials, patents) and lead to economic gains through higher sector employment, trade, and taxes.

ENDNOTES

[1] A draft of this report was presented at the 9th Latin America Seminar in Rio, Brazil on the November 29, 2018. The comments and suggestions have been incorporated into this report.

[2] RDP is the period during which data from clinical trials of a drug's toxicology and efficacy submitted to regulatory agencies cannot be relied upon to evaluate applications for marketing approval by generic entrants, also termed market exclusivity.

ORCID

Zlatina Dobreva http://orcid.org/0000-0003-2212-4314

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AUTHOR BIOGRAPHIES

Tim Wilsdon is a Vice President in CRA's Life Sciences Practice in London, England and is responsible for leading the policy sector in the global life sciences practice. He commonly talks at international conferences on issues to do with health technology assessment and pricing and reimbursement and the economics of innovation for pharmaceutical products and diagnostics. He has also acted as an expert in international arbitrations involving multinational pharmaceutical companies and was EFPIA and PhRMA's economic expert during the DG Competition's Sector Inquiry. Mr. Wilsdon has completed studies for the European Commission (including DG GROW and TRADE) and the pharmaceutical industry (through EFPIA, PhRMA, and country associations such as Innovative Medicines Canada, ABPI, LIF, and IPASA) on how healthcare markets could be reformed for efficiency. He was responsible for leading an assignment for the European Commission determining whether there was a global crisis in innovation and the risks of importation. For the industry, he has undertaken assessments of health technology assessments, international reference pricing, early access agreements, managed entry agreements and many other issues.

Artes Haderi is a pharmaceutical policy expert in the Life Sciences Practice at Charles River Associates (CRA). In her role, she provides support to leading pharmaceutical and biotech companies and trade associations in analysing, devising solutions and responding to key challenges in the life sciences industry. Through her extensive work, she has gained deep insights into global intellectual property rights and regulatory, access and pricing and reimbursement trends and the distinct challenges of novel treatments and care models. Some of her recent work has focused on indication and combination-based pricing approaches for immune-oncology treatments, ensuring access to orphan drugs and curative therapies and addressing antimicrobial resistance by improving the incentives for research and innovation. Artes holds an MSc in Management and Strategy from the London School of Economics and Political Sciences and a BSc (Hons.) in Economics from Utrecht University.

Zlatina Dobreva is a Consulting Associate in CRA's Life Sciences Practice in London. She has experience working on innovation, healthcare, and pharmaceutical policy projects, where she provides support with primary and secondary research and analysis drawing on health economics principles. In the past, she worked on public health related topics while briefly at the Policy and Strategy office at UNAIDS in Geneva. She holds a M.A. (Hons.) in Natural Sciences from the University of Cambridge.

Giuliano Ricciardi is an Associate in CRA's Life Sciences Practice focusing on a range of strategy and policy projects for a range of corporate clients and trade organisations. He holds a dual MSc in Management from the London School of Economics and Copenhagen Business School as well as a BSc in Pharmacology and Molecular Genetics from King's College London.

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