

Ecosystems of Innovation: The Case of Biotechnology in Argentina



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Innovation is impacting every region and functional dimension of the global economy. It is an essential driver of economic productivity, social progress, and ultimately human achievement. Innovation is inextricably tied to success and profit, whether the enterprise is a tech giant like Microsoft, SAP, or Siemens; a natural resources firm like CVRD or BHP Billiton; a conglomerate like Samsung and GE; or a small or medium-size enterprise that is globally engaged.¹

This monograph addresses the emergence of ecosystems of innovation in emerging markets within the context of national policy, facilitating institutions, and the firm. It does so as a way of understanding the increasingly important, transformational industry of biotechnology in one of Latin America's most advanced nations in science and technology: Argentina. The study concludes with policy recommendations for other advanced emerging markets as they strive to build an ecosystem of innovation for biotechnology.

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INNOVATION IN LATIN AMERICA

Latin America is the second most entrepreneurial region in the world, according to the World Bank. Its Internet and mobile density are higher than the world average. However, the region ranks low on the 2016 Global Innovation Index. Chile is #1 in Latin America but #44 overall out of 128 countries worldwide.² This could well be changing, however. The accelerated pace of start-ups—both tech- and non-tech based—has been occurring irrespective of economic and political ups and downs in the region. In 2016 there were 1,333 start-ups in Latin America and 62 accelerators, with investment approaching \$32 million. Chile leads the way, with three times the investment of Brazil. In terms of numbers of start-ups, Chile had 442, Mexico 306, and Brazil 297.³ The scope and range of start-ups are impressive. To illustrate, Dev.F (Mexico) brings software development techniques to that nation; Platzi (Colombia) provides an online learning platform for IT and programming courses; HubUnitec (Honduras), Impact Hub (Guatemala), and Atom House (Colombia) provide co-working and meeting spaces for young techies; and initiatives like Laboratoria (Peru), Epic Queen, and WomenWhoCode assist female start-up entrepreneurs to achieve success.

Interestingly, facilitating institutions in the private sector are also producing significant impacts. Examples include Techstars, 500 Startups, Endeavor, Wayra, and NXTP Labs. As for financing, venture capital (VC) investments have been climbing over the past five years, with 2015 witnessing a deployment of \$594 million over 182 deals, an increase of 46 percent from the previous year.⁴ While funding resources are never sufficient to meet the needs of start-ups, the environment is improving with sources such as Venture Club (Panama), Kaszek Ventures, Guadalajara Angel Investors, and Ideame, a crowdsourcing financing platform.

The outlook for innovation in Latin America is positive, despite a scarcity of resources and low R&D intensity. Latin American governments are leading the way, with improved collaboration between universities, research institutions, and the private sector. According to Marc Nager, Chief Community Officer at Techstars, "... [Latin America's] ecosystem of startups is one of the most dynamic and with the highest potential on the planet."⁵ He argues that this development is being shaped by culture, density, capital, talent, and the regulatory environment.

In essence, innovation is the single most powerful force for driving economic evolution and progress globally, but particularly in the emerging market context where it is critical in driving job creation and income growth. Innovation holds this elevated economic importance for a number of reasons.

First, innovation is key to sustainability and progress. Second, this impact is magnified because innovation is occurring in every region around the world, at every link in the economic value chain, and at every organizational level. Finally, innovation provides the opportunity for market disruption and "leapfrogging" progress, which could help frontier markets "equalize" or even pass developed markets on a number of fronts.

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The most dynamic arenas of innovation are science- and technology-related; and within that realm, one of the most promising is biotechnology.

THE BIOTECHNOLOGY INDUSTRY

With population increases, it becomes more difficult for each country to meet today's energy, food, and environmental needs. Biotechnology has been the leading innovative solution that emerging markets are turning to in order to tackle these needs. The Organization for Economic Cooperation and Development (OECD) defines biotechnology as "the application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services."⁶ Biotechnology has allowed countries not only to tackle threats facing their countries, but also to contribute to accelerated economic growth, development, and human welfare.

Biotechnology as a science was born in the United Kingdom and the United States in the 1950s.⁷ In the years following, thousands of biotech firms have been established throughout the world, while the United States continues to lead in scientific publication and commercial application.⁸ Australia, Canada, Israel, Europe, and Japan are striving to catch up. In addition, a series of emerging countries in Africa, Asia, and Latin America are entering the market.

Since the 1950s, biotech applications have drastically advanced. Genetic engineering has dominated the biotech industry for more than a decade by splicing a gene for a useful protein into production cells—such as yeast, bacteria, or mammalian cells—into culture, which begins to produce the protein in volume.⁹ In the 1980s the U.S. Supreme Court authorized a live human-made microorganism to be a patentable subject matter.¹⁰ Since then, dozens of genetically-engineered protein medications have been commercialized around the world.¹¹ The main achievement of biotechnology in the medical field is its capability to develop traditional pharmaceuticals that can stop the progress of diseases and/or produce



Source: Shutterstock



generic pharmaceuticals that lower the cost of medical drugs. Within the agricultural sector, applications of biotechnology have caused controversy surrounding genetically-modified organisms (GMOs). In 1993, the United States introduced GMOs into agriculture when the FDA approved a growth hormone that boosts milk production in dairy cows.¹² Developing countries have adopted GMOs in their agricultural sectors by creating specific herbicides to prevent weeds and increase production.¹³ These advances have drastically increased agricultural yields in many developing countries, allowing emerging markets to increase agricultural export sales.

A 2013 study analyzed small and medium-sized enterprises (SMEs) in emerging markets dedicated to R&D and biotechnology. Based on the study, dedicated biotech firms tend to cluster in large metropolitan areas and around research universities, in order to forge a close relationship with institutions where new knowledge is generated.¹⁴ Of the sample size, all companies conducted R&D, yet the amount of expenditures on average was very low, roughly \$0.9 million, indicating that government incentives were modest and public financial support was low to nonexistent.¹⁵ Despite the low support, in the last decade, SME biotech companies in emerging markets have begun to make headway in productivity, which has not only changed government perceptions of the industry but also begun to increase government and private investments and has altered governmental policies to create incentives.

Biotech has already started changing traditional industries and given rise to new technology for production of hormones, antibiotics and other chemicals, food, and energy sources. Over the past century, biotech has successfully transformed sectors in improving production in the fields of agriculture, health care, and industry. The application of biotechnology has improved the agricultural sector through increased production of crops, pest control, and plant and animal disease control. In the health care industry, biotechnology has improved drugs, vaccines, gene therapy, and tissue replacements. In industrial use, biotechnology has improved oil/mineral recovery, environmental protection, waste reduction, and improved detergents and chemicals. The improvement and sustainability of these sectors have transformed emerging markets into globally competitive players in the areas of food production, accessible and cost-effective pharmaceuticals, and renewable energy.

With any new advancement, challenges and opportunities will always arise. Biotechnology has its fair share of challenges and opportunities, which vary by country and industry. The biggest challenge in the field of agriculture will continue to be how to meet the needs of a growing population and the conflicting political perceptions society has of the ability to increase harvests in a country. Some overarching challenges that emerging markets experience are the lack of governmental policies that create incentives for innovations and for public and private financial support. In Argentina, for instance, academic salaries are mediocre in a discipline that aims to attract the best and brightest. Research funds are increasing but still insufficient, and industrial incentives for R&D are minimal compared not only with the United States and Western Europe, but also with emerging Asian countries such as China, India, Singapore, South Korea, and Taiwan.¹⁶

Challenges create room for advancement and opportunity. The overall advances in biotechnology include the potential to reduce hunger and starvation through increasing yields and eliminating weeds and other sources that harm each harvest. In Brazil, for example, the U.S. Department of Agriculture (USDA) forecasts an increase of over five percent in the area planted with biotech crops during the 2016-2017 Brazilian crop year, with the increase mostly attributed to the greater use of biotech soybeans and corn.¹⁷ As of November 1, 2016, there were 58 genetically-engineered events approved for commercial cultivation, of which 34 events were for corn, 12 for cotton, 10 for soybeans, one for dry edible beans, and most recently, one for eucalyptus.¹⁸ In addition, the total area planted for genetically-engineered crops during the 2015-2016 crop season in Brazil reached 43 hectares, making Brazil the second largest producer of genetically-engineered crops in the world.¹⁹ The pharmaceutical market poses a great opportunity for biotechnology in emerging markets, as they represent a third of the global pharmaceutical market²⁰ and where aging populations will seek improved care for a variety of diseases and medical conditions.

Overall, the field of biotechnology is becoming more and more accepted as its opportunities outweigh its challenges. Governmental institutions are relying on biotech advances for cost-effective production increases. In order to continue advancing in biotechnology, countries must create incentives for improvements in human capital formation. The United States and some developing countries have taken advantage of this opportunity by providing scholarships to research facilities and universities and competitive grant opportunities. The more public and private support these institutions receive, the easier innovative applications can enter the market.

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BIOTECHNOLOGY IN ARGENTINA

Commodities have been and continue to be the economic anchor of South American countries. While it is not feasible for Latin America to free itself altogether from dependence on commodities, what the big regional emerging markets of Argentina, Brazil, Chile, Colombia, and Peru can do is boost their knowledge-based industries and value-added services sectors. Argentina illustrates, in the first instance, how economic diversification can do precisely that while transforming the very commodities from which to lessen its dependence.

A key component of technological expansion, biotechnology is experiencing dynamic growth throughout the world, including many parts of Latin America. From 2005 to 2015, R&D investment in Latin America doubled, with Argentina, Brazil, and Mexico accounting for 91 percent of the total. A combination of trade and investment liberalization, improved regulations, better intellectual property protection, national policies and increased resources



Source: Shutterstock

Argentina, Brazil, and Mexico have all expanded educational opportunities in biotechnology fields.

in support of science and engineering, and expanded post-graduate programs in scientific fields, have resulted in the blossoming of the biotechnology sector. Argentina, Brazil, and Mexico—regional leaders in biotech—have all been expanding their activities in the three main application areas of biotech: health, agriculture and food, and the environment.

In the case of Argentina, despite modest budgets, the science sector has garnered worldwide respect. Argentina is the Latin American nation with the most Nobel Prize laureates and has made notable contributions to the Human Genome Project, nanotech, biotech, defense systems, and space research. Argentina continues to be the third largest producer of biotech crops after the United States and Brazil, producing 14 percent of the world's total.

Argentina has over 200 biotech firms earning well over \$2 billion, across multiple sectors such as human health, animal health, food processing, and agriculture. Firms such as Bioceres (dedicated to agro biotechnology) as well as Biocientifica (focused on human, animal, and vegetable health) are on the cutting edge of biotechnological development. Through the advancement of biotechnology varieties, Argentina has increased its crop yields by 140,000 hectares between 2015 and 2016.²¹ Almost all soybean area is planted with biotech seed varieties, while 95 percent of corn area and 100 percent of cotton area are biotech varieties. Despite the economic and political volatility in Argentina in recent decades, biotech firms have suffered very few failures and have attracted interest from the leading investment groups in the country. An interesting feature of biotech firms is that they have comparatively very low rates (if any) of bankruptcies, closures, and reduction in business activity.

In international rankings in science and technology, Argentine institutions jumped from 144th place in 2009 to 79th place in 2014 among the 5000 most important entities in that

sphere, according to the Organization for Economic Cooperation and Development (OECD). The country was named one of three institutions only outside Germany to be a locale for a branch of the Max Planck Institute.²² Argentina's R&D expenditures (public and private) exceed \$80 million, ranking 18th in the world in biotech and compatible with countries of intermediate economic development, many of which have a per capita GDP above that of Argentina.²³ Additionally, Argentina is the country with the highest number of researchers per active person in Latin America (3.06/1,000 active) and has internationally renowned scientific capabilities and a pioneering spirit.²⁴

STRUCTURE AND ORGANIZATION OF THE BIOTECH SECTOR

The Argentine biotechnology sector encompasses a broad range of activities, from human and animal health to the development of inputs for industry. Biotech companies in Argentina are of three kinds: (1) firms that are engaged in the whole process, from R&D through final product for the market; (2) private companies that sell products and inputs to other firms; and (3) companies involved in product or process development for their own use.

The areas in which Argentina's 200+ biotech firms operate consist of human health, inoculants, animal reproduction, industrial inputs, seeds, fertility, animal health, and micro-propagation of plants. Relatively recent firms are the most competitive in international markets. Of these firms, nearly half were founded in the last decade, and nearly 90 percent funded by domestic capital.

In terms of sectors of activity, Graph I illustrates that a little more than 20 percent is dedicated to human health and 17 percent to animal reproduction. Agroindustry accounts for a large number of firms producing inoculants (13 percent), seeds (9 percent), animal health (8 percent), and vegetal micro-propagation (6 percent). Human fertilization makes up 11 percent and industrial inputs (such as enzymes and food additives) account for 10 percent.²⁵

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In the economic domain, the total sales of biotechnological products and services exceeded \$15 billion in 2014. Animal health, inoculants, and human health accounted for the bulk of biotechnology sales (see Table III).

As illustrated in Graph II, seeds are clearly the most important component of the biotech sector, accounting for over 70 percent, followed by human health at 12.2 percent. Together these two make up over 80 percent of biotechnology sales. Industrial inputs stand at 6.2 percent and animal health at approximately 6 percent in third and fourth place, respectively, in sales.

R&D activity is becoming increasingly important to the biotechnology sector, with respect to new products and methods of production. At present, biotechnology firms invest over \$90 million in their activities, with 65 percent destined for seeds, 20 percent for human health, and 15 percent for other activities. Nearly 2,700 researchers are employed in R&D, with the seed sector accounting for the largest share.

GRAPH I

**DISTRIBUTION OF COMPANIES BY SECTOR
(IN ABSOLUTE VALUE AND PERCENTAGES)**

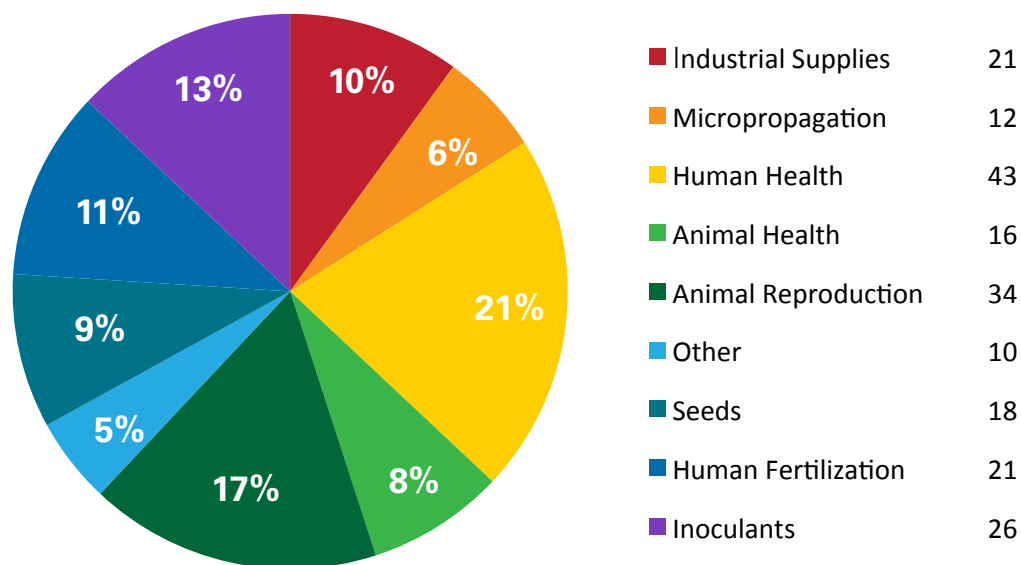


TABLE I**BIOTECHNOLOGY SALES (IN U.S. DOLLARS), INCLUDING EXPORTS**

Sector	# of Companies	Total Sales		Biotechnology Sales		Biotechnology Export Products
		(ARS Thousand)	(USD Thousand)*	(ARS Thousand)	(USD Thousand)*	(USD Thousand)*
Seeds	18	77,626,638	9,607,257	12,181,997	1,507,673	278,342
Human Health	43	8,870,583	1,097,844	2,110,045	261,144	120,084
Industrial Supplies	21	27,088,316	3,352,514	1,070,033	132,430	4,053
Animal Health	16	1,890,768	234,006	965,271	119,464	80
Inoculants	26	1,426,427	176,538	667,399	82,599	884
Animal Reproduction	34	550,652	68,150	107,009	13,244	36
Micro-propagation	12	3,218,914	398,380	102,680	12,708	-
Human Fertility	21	262,977	32,547	54,201	6,708	-
Other	10	99,748	12,345	3,519	435	-
Total	201	121,035,023	14,979,582	17,262,153	2,136,405	403,480

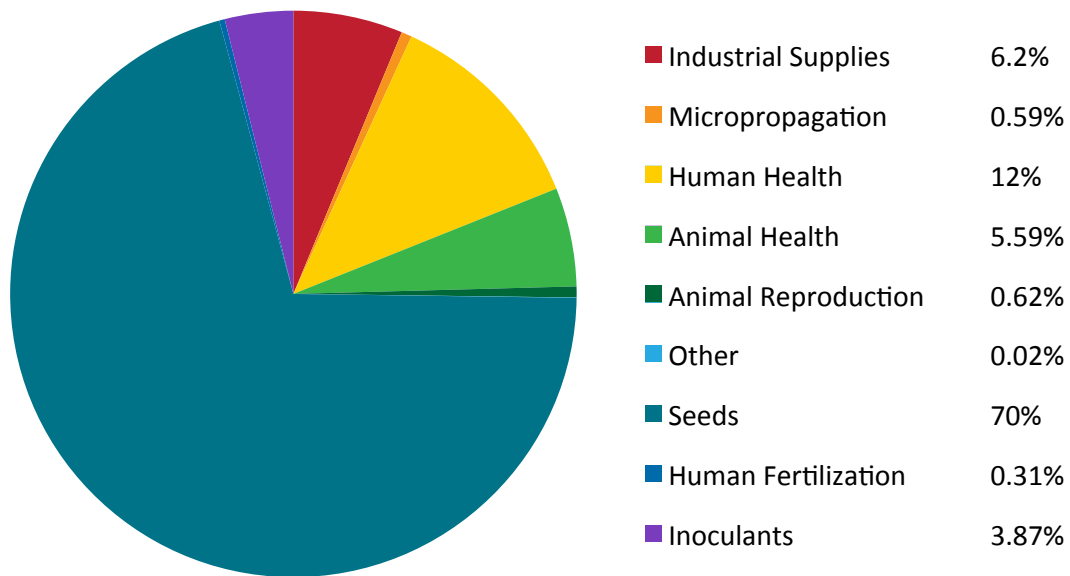
*Note: The 2014 exchange rate was 8.08 pesos per US dollar (in 2017 it is approximately 15-1)

Ordered according to biotech sales in thousands of \$

Source: *National Survey of Biotechnology Companies (DNIC-MINCYT, 2015) and other sources*

GRAPH II

BIOTECHNOLOGY SALES BY SECTOR



THE BIOTECHNOLOGY ECOSYSTEM

The ecosystem of biotechnology in Argentina is composed of government (federal, provincial, and municipal); facilitators (industrial parks, R&D labs, incubators and accelerators, business organizations, NGOs, and cluster organizations); and companies (local and multinational).

THE ROLE OF GOVERNMENT

Governments play a critical role in enhancing competitiveness by directly encouraging innovation, through establishing an environment for firm innovation and technology-based entrepreneurship, and by providing complementary public goods such as scientific knowledge and advanced human capital.²⁶

Argentina's worst recession in 2001 inhibited the economy. However, over the past decade and a half the increase in innovation and biotechnology has been significant and a boon to the economy. That said, it wasn't until President Mauricio Macri took office in December 2015 that Argentina's agricultural sector experienced a spur of optimism through his implementation of rapid policy changes. These included the elimination of all export taxes except on soybeans (which themselves were reduced by 5 percent), the removal of export restrictions (primarily for corn and wheat), and a 45 percent devaluation of the local currency.²⁷

Government financing plays an outsized role in Argentine science and technology. Of total R&D spending, the government accounts for 65 percent, with 43 percent destined for public entities and 22 percent for public universities. The role of the state has been and will continue to be dominant. During the administrations of Presidents Néstor Kirchner and Cristina Fernández de Kirchner between 2003 and 2015, the state increased the budgets of universities and the National Scientific and Technical Research Council (CONICET) by a factor of 7; created the Ministry of Science, Technology, and Productive Innovation (MINCyT); increased the support for researchers from 3,500 in 2003 to 9,000 in 2015 as well as scholarship recipients from 1,800 to 10,000; boosted joint CONICET-University research centers from 100 to 230; and constructed more than 150,000 square meters of laboratories for research.²⁸

The key government entities involved with biotechnology are as follows:

INTA—National Institute for Agricultural Technology

INTA operates under the Argentine Secretary of Agriculture and focuses on generating and structuring innovative groups and promoting technological spillovers. Unlike other agencies, INTA takes a vertical policy approach and directly works with firms to produce new technological innovations on a product or process. INTA provides technological and R&D services to advance firms' capabilities of producing new innovations. These technological R&D and marketing agreements have had a positive impact on the accumulation of human capital and the improvement of R&D in Argentina.

INTA has been at the forefront of the development of new herbicides and transgenic materials that have technologically revolutionized the agricultural sector. INTA has played a significant role in industry successes, including the development of new varieties of grains, inoculants, and farm machinery.

MINCyT—Ministry of Science, Technology, and Productive Innovation

MINCyT was established in 2007 to reflect the importance of innovation in Argentina's economic development. MINCyT is responsible for formulating innovative policies as well as for supervising agencies responsible for financing and implementing them.

FONTAR—Argentine Technology Fund

In the early 1990s FONTAR was established to support the advancement of Argentina's technology and innovation sector by financing and subsidizing technological innovation, R&D, and the technological advancement of small and medium-sized enterprises (SMEs). FONTAR has collaborated with the Inter-American Development Bank (IDB), the National Agency on Scientific and Technological Promotion (ANPCyT), and the World Bank (WB) to implement the Technological Modernization Program (PMT).

Other institutions that support biotechnology are:

AGENCIA—Agency for Scientific and Technical Promotion

AGENCIA awards scholarships and financially supports those who seek a career in research.

FONCyT—Fund for Scientific and Technological Research

This fund supports research projects targeted at generating new scientific and technological knowledge.

ANPCyT—National Agency for Scientific and Technological Promotion

This agency encourages scientific, technological and innovation-related activities in SMEs, with resources coming from contributions from the national budget (FONTAR) and the Inter-American Development Bank. Through the Argentine Sector Fund (FONARSEC), ANPCyT supports projects and activities designed to develop critical skills in areas of high potential impact and permanent transfer to the productive sector. The aim is to accelerate the development of public-private projects, create or expand the research-oriented manufacturing sector, and develop a strong local platform that can be shared by several companies and/or institutions.

BIOTECOSUR

This is the first MERCOSUR platform of biotechnology, created to establish a long-term shared vision for the development and application of new technologies within the trade bloc. Biotecosur promotes a regulatory environment favorable to the development of public policies that stimulate investment in biotechnology.

Although not an institution, MAIZALL also deserves mention; it is a multinational agreement among the corn exporting countries of Argentina, Brazil, and the United States. These countries, work together on: (1) the synchronization of global approvals of biotechnology products; (2) the harmonization of regulatory policies in the Americas; and (3) the provision of better consumer information about agricultural production.

FACILITATORS

Among the many facilitating institutions and organizations within economic development ecosystems, clusters are particularly significant. This is true throughout Argentina. For example, Córdoba has created clusters in petroleum supplies, furniture, food, craft beer, and technology (the oldest cluster, accounting for 175 firms). Metal mechanic clusters are prominent in Olavarría; forest products in Misiones and Corrientes; wine and olives in Mendoza; and honey cultivation in Tucumán and Salta.²⁹ Buenos Aires province is, expectedly, the home to the most advanced clusters as well as to industry-themed neighborhoods. More than seven such clusters, including ones for technology, design, arts, audiovisual production, logistics, pharmaceuticals, and entertainment/sports, cover more than 7,500 acres and employ over 150,000 people. The Parque Patricios technology district is the most prominent



among them.³⁰

Clusters are but one component of Argentina's facilitating institutions. Relevant to biotech is the fact that the nation has over 120 research institutes within firms and universities and is especially strong in genetically modified crop use. Argentina is fortunate to be home to numerous science and technology parks³¹ and clusters such as the Rosario Biotechnological Pole in the province of Santa Fe. One of the most prominent is Parque Austral, launched by the Universidad Austral and located within the University's campus in Pilar, in close proximity to the IAE Business School. Other notable parques are Tecnópolis, located in Villa Partelli, within one of the main polos (centers) in Buenos Aires Province for scientific and technological development, and the Coastal Technological Park of SAPEM Center, a technological park in the city of Santa Fe, comprising several universities and municipalities.

As for the research community and their facilitating role, the rate of growth of scientific researchers climbed 77 percent between 2004 and 2012, more than Chile, Colombia, and Mexico. However, although the amount of scientific research output has grown considerably in recent years, its productivity (actual application) has not increased. There are other problems as well. The topics and themes for research and for awarding scholarships are suggested by the candidates but all too often are unrelated to the policy priorities of MINCyT. Still another impediment is that while CONICET and ANPCyT do conduct evaluations of projects, it is not clear that these evaluations have any impact on future support of projects. There is also a tendency to parcel out research support to less developed regions in the country irrespective of capabilities. The contribution of the private sector to financing and executing scientific research is scarce. Not surprisingly, the impact and visibility of Argentine research publications are sparse. On a positive note, MINCyT has followed the global trend of supporting applied research much more than basic research.³²

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THE PRIVATE SECTOR

Agribusiness and pharmaceuticals are the two principal sectors that are directly relevant to biotechnology. In the first instance, Argentina's crop potential is substantial and is estimated to rise by 79 percent by 2020, in a best-case scenario laid out by Argentina's Ministry of Agriculture.³³ Joint research by the OECD and United Nations Food and Agriculture Organization (FAO) more conservatively estimates the country's crop potential to rise by 41 percent by 2020. Over the next ten years grain production is expected to leap from 100 million tons today to 145 million, and total arable farmland will increase to 35 million acres from 30 million today. Argentina is expected to see a shift away from soy and back towards

corn and wheat, with the former increasing by 63 percent and the latter by 43 percent, compared to just 12 percent for soy.³⁴ These estimates reflect the supportive measures introduced by the Macri government, particularly a 5 percent reduction in the soybean export tax rate and the removal of export quotas for agricultural exports.

Argentina has been front and center in the controversy over GMOs because, along with the United States, Canada, and Brazil, the four countries produce 90 percent of the planet's GM crops. Mixing plant species has had undeniable benefits, producing papayas free of viruses, corn plants that survive drought, and crops that overall yield more and cost less. The vast majority of scientific research concludes that the benefits of GM crops far outweigh health risks. However, despite the fact that in almost 20 years there have been no clear impacts on human health reported or confirmed in professional journals, eight nations of the European Union have banned them and India and China have yet to approve them. Large segments of the public in the United States and Europe appear fearful of what health impacts GMOs might cause in years to come.³⁵

In the case of Argentina, the country has not only one of the major land areas devoted to transgenic (GMO) agriculture but also one of the first regulatory agencies in the region. The country's approach towards GMOs is based on a cost-benefit analysis and the argument that the country's evaluation procedures guarantee the safety of agricultural biotech developments. Regulatory costs to developers are high; and for transgenic crops to be locally approved, they must also have been previously approved in the country to which the exports are destined.³⁶

In the realm of pharma, Argentina is one of the few nations of the world whose domestic pharma sector accounts for more revenue than do foreign pharma multinationals. Of the top ten international pharma firms, seven are Argentine and 60 percent of the market value is sold by Argentine laboratories. These companies are not domestic but regional or mini-multinationals, exporting worldwide with strong brands such as Roemmers.³⁷ Annual retail spending on pharmaceuticals in Argentina is approaching \$7 billion, and the compound annual growth rate is expected to exceed 7.1 percent in dollar terms over the next five years. Given the significance of brands to Argentine consumers, it is difficult for foreign multinational corporations (MNCs) to penetrate the market on their own. Therefore, joint ventures through licensing and co-marketing agreements are the mechanism of choice.

Tables II and III list, respectively, the multinational companies in the biotech arena in Argentina and local firms with international growth potential.³⁸

TABLE II

MULTINATIONAL COMPANIES IN BIOTECHNOLOGY IN ARGENTINA

1. Eli Lilly
2. BASF (health)
3. Bayer (health)
4. Crop Science
5. Dow Agrosciences
6. Monsanto
7. Pioneer
8. Pfizer (health)

TABLE III

LOCAL COMPANIES IN BIOTECHNOLOGY WITH INTERNATIONAL GROWTH POTENTIAL

- | | |
|--------------------|-------------------------|
| 1. AMEGA Biotech | 6. Gador |
| 2. Bioceres | 7. Indear |
| 3. Biogenesis-Bagó | 8. PharmADN |
| 4. BioSidus | 9. Rizobacter |
| 5. Cassara | 10. Wiener Laboratorios |

Following the 2001 Argentine economic crisis, pharma MNCs began to sell their production facilities. Local investors bought these high-tech manufacturing facilities at bargain prices. Today, of the 110 plants, only 17 are foreign. However, price controls on pharma products have made it difficult for these companies to maximize their profitability.

Both agricultural and pharmaceutical proponents and producers have lobbied the government that biotech is an essential component of state economic strategy.³⁹ After all, half of the top-selling drugs in the world are of biotech origin; and although regulatory standards have increased significantly even in the most unregulated markets, the upside potential is enormous. For example, Amega Biotech is working hard to enter the U.S. and European markets while BioSidus's core objective is to become the leading bio-similars producer in emerging markets. State-owned laboratory Hemoderivados, part of the National University of Córdoba, is one of the



Significant strides in research have been accomplished in the last decade

Source: Shutterstock

most advanced institutions in Argentina. Hemoderivados currently has several bio-protein products in the pipeline. Its aim is to produce expensive medicines at a more affordable price and to produce medications that are not currently being manufactured by anyone in Argentina or the region.

Taking advantage of a low-cost base and high-quality professionals in the biotechnology sector, Argentina has over 130 biotechnology companies; most are small and medium-sized enterprises with an average of 25 employees. More than half are involved in the development and commercialization of human healthcare products. Geographically, most are found in Buenos Aires, Santa Fe and Rosario.

Argentina's main biotechnology companies have achieved significant success in R&D. To illustrate, Sidus has garnered international attention for its work on developing human insulin from transgenic cattle through its biotechnology subsidiary, BioSidus. Currently, the company has seven biosimilar recombinant therapeutic proteins in its product portfolio, and its strategy is based on the export of cost-effective, high-quality products tailored to meet the demands in markets with flexible regulations and intellectual property regimes.⁴⁰

During the past twenty years, the government and private sector have forged a closer, more cooperative relationship regarding the biotechnology sector. Law No. 26270 of 2007 established a range of measures designed to foster the development of biotechnology, through incentives related to workforce and expenditure on capital goods during the different phases of R&D and technology development. Another law (Law No. 270/07) of 2007 contains incentives to boost public and private investment in the biotechnology sector along with tax benefits to R&D projects.⁴¹ There are several public agencies, credit stimuli, and programs that serve as sources of funding for the Argentine R&D sector.⁴²

In recent times, Argentina has devoted attention to the public sector incubation of new technology-based companies with local research institutions such as the University of Buenos Aires and the National University of La Plata. MINCyT also supports public-private partnerships in biotechnology. For example, Biomatter benefited from a \$300,000 investment from FONARSEC, complemented by private sector funding and was based on a consortium among universities, research agencies, and the Argentine company Medipharma. Bio-matter developed bioengineering products for dermal regeneration in severely burned patients. The firm Raomed was involved in a public-private partnership for the development of biocompatible materials for cranial reconstruction.

In addition to private sector companies in agribusiness and pharmaceuticals, there are a growing number of business associations and non-governmental organizations that champion the biotechnology sector in Argentina. The most prominent is CAB (Argentine Chamber of Biotechnology), the leading business organization that educates and advocates for biotechnology in the country and proactively searches for national and international financing programs to support Argentine biotech.⁴³ Other groups are FAB (Argentina Forum on Biotechnology), ASA (Argentine Association of Seed Traders), and RedBio, a cooperation network on plant biotechnology, in association with the UN's Food and Agricultural Organization.

MULTILATERAL FINANCIAL INSTITUTIONS

These institutions play a supportive role in the ecosystem of innovation in biotechnology. For example, the World Bank funds over 19 projects related to biotechnology, mainly in the agricultural sector in Latin America—three of which are in Argentina.⁴⁴ The Inter-American Development Bank has funded biotechnology related to agriculture, with most funding going to Brazil, but it has not been a significant player in financing biotechnology in the region

THE ROLES OF TAX AND REGULATORY POLICY AND ACCESS TO CREDIT

Taxation, regulations including intellectual property right (IPR) protection, and the availability and accessibility of credit all have a significant impact on Argentina's innovation ecosystem in biotechnology.

In terms of *regulatory policies*, the Macri administration changed agricultural and trade policies from the previous administration to improve agricultural production and trade. The policies implemented were: (1) the elimination of a 23 percent of export tax on wheat and 20 per cent tax on corn; (2) elimination of export limitations through the Registry of Export Operation System (which in many cases made producers receive up to \$60 less per ton); (3) the devaluation of the peso; (4) retention of a 30 percent export tax for soybeans (reduced from 35 percent); and (5) removal of foreign exchange restrictions. Agricultural commodities with a new zero percent export tax include meat products, grains, fruits, and vegetables. As for impacts on wheat and corn, the former is expected to achieve its highest production levels in the past 5 years and exports to be the highest since 2011; corn will also surpass recent records.⁴⁵

While it is premature to assess the long-term impacts of President Macri's new policies, there has been a marked increase in production and exports, and Argentina is currently negotiating with 33 countries about improving market access.⁴⁶

With respect to *tax incentive* programs, in addition to FONTAR and FONCyT, there is the Argentine Sector Fund (FONASERC) that supports projects and activities aimed at developing critical capacities in potentially high-impact areas and permanent transfer to the productive sector. Potential areas include health, energy, agroindustry, social development, nanotechnology, biotechnology, environment, and climate change.⁴⁷

Of special importance is Law 26270⁴⁸ of July 27, 2007, that offers the following incentives on the research, development, and production of biotechnology applicable to certain production processes:

- Accelerated depreciation of capital goods, equipment, parts, and components;
- Early reimbursement of VAT paid on the purchase of capital goods, equipment, parts, and components;
- Exemption from taxation of listed under the minimum presumed income tax;
- Fiscal credit on employer's social security contributions paid (up to 50%);
- Fiscal credit for purchases of research and development services from institutions under the science, technology, and innovation national public system (up to 50%).

Additionally, the National Science and Technology Council (COFECYT) promotes the development of technological, innovative, and scientific activities throughout the country. Projects and programs financed by COFECYT include national projects for productive innovation and municipal technological development projects.⁴⁹ Finally, there is the Promotion and Encouragement of Technological Innovation (Law No. 23877), the purpose of which is to promote and encourage research and development, technology transfer, and technical assistance. The benefits are that the executive branch sets an annual quota of tax credits that may be offset against the payment of national taxes (income taxes) in an amount not in excess of 50 percent of the total value of the project. These tax credits must be used in equal parts within a three-year period.⁵⁰

In terms of *intellectual property rights*, Argentina is a land of contradictions. To encourage patenting, Law 25,859, implemented January 14, 2014, protects a patent holder by preventing third parties from using the holder's patented procedure. The law validates international research and technical examinations made by certain international patent offices. Patents are granted for 20 years from the date of publication. The owner of a patent has the right to prevent third parties from using, offering, or selling the patent without his/her consent.⁵¹ On the other hand, Argentina's patent application backlog, especially related to biotechnological and pharmaceutical inventions, continues to grow and is estimated to be approximately



Source: Shutterstock

21,000 applications. The processing time may take as long as 8 to 10 years. Argentina’s law does not provide provisional protection rights to applicants during the pending period and does not grant patent term adjustment to compensate for the delays during patent examination. As Nicolás Nobile of Janssen Pharmaceutical notes: “Today it is very difficult to obtain patent protection for a biotechnology primary compound, although there are some exceptions.”⁵²

Argentina has not ratified the Patent Cooperation Treaty (PCT) of the World Intellectual Property Organization (WIPO). Argentina does not have an effective patent enforcement and resolution mechanism. Lack of data protection has hindered some companies from introducing new technological innovations into the Argentine market.⁵³ Argentina’s own Resolution 283/2015 of September 2015 limits the ability to patent biotechnological innovations based on living matter and natural substances, including biologics.

Argentine intellectual property laws are based on UPOV-78, the International Convention for the Protection of New Varieties of Plants. This law provides strong protection for the right of farmers to save and replant seeds and exempts them from providing explanations on how selected seeds were used. The lack of effective enforcement options for plant variety rights, combined with the absence of patent protection for a significant range of biotech inventions, renders Argentina’s intellectual property system inadequate from the perspective of the biotechnology industry.⁵⁴

Deficiencies persist within the Argentine patent and regulatory data protection regimes that continue to be problematic for U.S. exporters of intellectual property to Argentina, especially pharmaceutical, biotechnology, and software firms. These industries consider delays and restrictions in the approval of patents as indicators of Argentina’s lack of commitment to protect their intellectual property.⁵⁵ It is not uncommon for a firm to pay a licensing fee for a patented technology for a short period of time (e.g., one year), then copy it and fail to pay the licensor in subsequent years. Not surprisingly, due to enforcement challenges, theft of IPR, and other obstacles, the U.S. government continues to place Argentina along with 10 other nations on the Priority Watch List in its 2016 Special 301 Report.⁵⁶

Finally, in terms of *access to credit*, the Argentine government has put in place subsidized rates for loans to micro, small, and medium-sized enterprises (MiSMEs). The aim is to facilitate MiSMEs' access to credit and cover part of the financial costs of bank loans. The benefit is that these credit facilities are slated for the acquisition of new capital goods via loans or capital leases, working capital, pre-financing and financing exports of goods and services, creation and development of new enterprises, industrialization of goods and services developed through technological innovation, and scientific and technological research activities, productive modernization, and innovation.⁵⁷

Additionally, there is the National Development Fund for MiSMEs (FONAPyME) that makes capital contributions and provides financing to micro, small, and medium-sized enterprises to carry out projects focused on the domestic market with an emphasis on import substitution, added value generation, job creation, and regional development promotion. These loans are offered to finance investments in fixed assets and working capital.⁵⁸

Still another mechanism is the Investment Bank for Foreign Commerce (BICE). This entity offers a range of financing lines in both pesos and U.S. dollars.⁵⁹ Its credit lines for development aim to finance the purchase of capital goods and investment projects in goods and services. BICE's program for financing of investments for SMEs and cooperatives has the purpose of financing investment projects and purchasing new capital goods. The Argentine government also finances technological innovation and modernization through project financing to improve the competitiveness of goods-producing companies through the technological modernization of products or processes

THE DYNAMICS OF ARGENTINA'S BIOTECHNOLOGY ECOSYSTEM

The interaction of the various features of Argentina's biotechnology ecosystem has shaped and continues to shape the landscape for growth and development of this important sector. Public institutions, facilitators, and the private sector interact at times in a coordinated fashion, other times independently, and sometimes at cross-purposes. They possess strengths that allow them to compete effectively, opportunities based on many of those strengths, weaknesses in their factor endowments, and threats from other competitors in the region—namely Brazil and Mexico.

Argentina's research and partnering capabilities in biotechnology are, along with Brazil's, among the most advanced in the Americas. A well-developed network fuels this biotech ecosystem through synergies among the various entities previously cited.⁶⁰ The dynamism of Argentina's biotechnology ecosystem evolves from the interplay of public policy, financial mechanisms to fund R&D, the regulatory policies in place, and the interaction among universities, research institutes, and the private sector. On the public investment side, biotechnology has been financed through R&D outlays by the federal government, with

human health being financed principally via ANPCyT. However, the amount of public funding devoted to supporting private investment in biotechnology R&D has been very limited.

A key shaper of the biotechnology ecosystem is the regulatory framework. Argentina has issued soft regulations with fewer constraints than many other countries. Only efficacy and safety need to be demonstrated. As most other countries have more stringent approval processes, Argentina's biotech drugs can only be exported to other countries with similar soft regulation. In the agriculture domain, the regulatory system is governed by the National Commission for Agricultural Biotechnology (CONBABIA). This entity studies the effects of new GMOs on the environment. Another organization, the National Service for Health and Agricultural Quality (SENASA) evaluates food characteristics of any new GMO before it is released.

Finally, there is technology transfer—a process that is indispensable to the biotechnology ecosystem. This occurs through various channels: local academic research, the acquisition of technology and GM seeds from foreign private firms, foreign direct investment, the acquisition or establishment of dedicated biotech firms, R&D collaboration between the industry and research organizations, and the hiring of university graduates by local firms.⁶¹

STRENGTHS AND WEAKNESSES

The biotechnology ecosystem has a number of notable strengths. These include: an educated population, talent, resources, clusters, local science entrepreneurs, tradition, and an installed base for pharma and agriculture, as well as interaction with multinationals and industrial nations. Unquestionably, biotechnology will become a greater priority as more and more Argentines move into the middle class, urbanize, and seek improved health care, and as the search intensifies to increase energy efficiency and alternatives to fossil fuels and boost the quality and resilience of plants and crops. South American countries in general are advantaged in this regard, endowed with biodiversity, an abundance of fertile lands for biomass production, and steady growth.⁶² The use of GMOs has grown substantially and boosted productivity in the agricultural sector.

Biotech firms located in close proximity to other research centers and infrastructure facilitate easy access to centers of technological know-how.⁶³ There are usually excellent universities in the locale, providing access to highly qualified personnel and research infrastructure such as laboratories. Research has shown that knowledge transfer is geographically limited; therefore, it is important for companies to be near the source of innovation.⁶⁴

The high political priority assigned to biotech by MINCyT and other governmental entities are reflected in the National Plan of Science, Technology, and Innovation known as "Argentina Innovadora 2020". Additional strengths are a panoply of governmental programs to support biotechnology, from ANPCyT, CONICET, the national universities, INTI, and INTA. International cooperative agreements, excellent human resources in the sciences, and well-developed

R&D networks are notable assets as well. Other strengths are the strong presence of companies funded with national capital, many of them small and medium sized enterprises, although in recent years, larger local firms and foreign multinationals have expanded their presence. Finally, national legislation has been approved for partial exemption from taxes for R&D and the expansion of national and provincial credit expanded for biotech companies. Beyond patents, technology, and early stage research, public organizations also provide private companies with human resources in many cases. Amega Biotech works with the National University of Litoral and the National University of Córdoba on projects. As noted by Dr. Ignacio Demarco, Program Manager at Insud, a leading biotechnology firm, it is the collective strength of human and financial capital (mainly national), strong basic research, significant government support, and dominance in agricultural biotechnology that position Argentina to excel.⁶⁵

It is the collective strength of human and financial capital, strong basic research, significant government support, and dominance in agricultural biotechnology that position Argentina to excel.

Counterbalancing the strengths in Argentina's biotechnology ecosystem are a number of weaknesses. To begin with, the priorities of the scientific sector are not mainly oriented to produce innovations of a defined commercial use. Additionally, there are excessively bureaucratic procedures for evaluating R&D, and it is often difficult to incorporate into these evaluations the needs of the private sector. Despite the growth of R&D in biotechnology, research groups are small as are the size of projects. There is also a lack of equipment and other resources to scale up each stage of research in both research centers and companies. Additionally, there are no incentives for the scientific-technological community to render services to private enterprises, nor are there best practice protocols for laboratories. The number of biotech firms, across a spectrum of specialties, is limited; and the linkage between R&D institutions and companies is poor, as is public-private cooperation. Moreover, there is no prioritization in the R&D global strategies of firms with respect to private investment. Even more importantly, there are the shortcomings of inadequate IPR protection, a lack of incubators and major biotech clusters, and an inadequate level of seed capital for start-ups and as well as long-term credit for later-stage firms.

Argentina's biggest barrier to innovation is inadequate capital to invest in R&D that avoids taking unreasonable levels of risk. According to investment banker Ken Sawyer of Saints Capital: "Argentina has significantly underinvested in biotechnology compared with many other nations."⁶⁶ While that observation may be true when Argentina is compared with industrialized nations alone, Argentina ranks 16th on a worldwide basis and is the only developing nation in OECD rankings. In terms of investment in biotechnology R&D in PPP terms (\$154 million), Argentina ranks 20th; and with respect to biotechnology R&D as a percentage of total investment in R&D of companies, Argentina places 4th, with 13.5 percent.⁶⁷

And as noted by Felix Rozanski, Coordinator of CEDIQUIFA (Center for Studies of the Development of the Argentine Chemical-Pharmaceutical Industry), the operating environment for biotechnology firms in Argentina is a very reasonable one.⁶⁸ According to Fabiana Dircie of Novartis, there are more and more start-ups dotting the landscape and new regulations in place to support entrepreneurial efforts.⁶⁹ Nevertheless, in the words of Dr. Ignacio Demarco of Insud, “There is much more the government needs to do to create incentives for angel investors to invest in biotech start-ups and facilitate long-term credit access for research and development.”⁷⁰

The research capacity exists, however. Local laboratories face these same risks and are relatively conservative in all their investment projects. Even two of the most innovative firms in the country, Gador and Bagó, invest only 4-5 percent of their revenue in R&D. The public sector—mainly MINCyT—has filled the gap in terms of providing research funding, through CONICET and government grants. (CONICET employs 8,000 researchers and has filed 26% of all patents in health.)

Argentina has strong agricultural and pharmaceutical industries able to demand services in bioinformatics, genomics, and R&D services and products. However, there is a lack of continuity in policy, reinforced by inadequate funds and idiosyncratic academic practices. With mediocre salaries in a discipline that is known globally for good wages, the best and brightest often do not choose the profession of biotech researchers.⁷¹

As one of the first Latin American countries to emphasize biotechnology, Argentina has received a stream of support from the public sector; however, it still lacks sufficient government resources. FONTAR acknowledges these challenges and aims to focus increasing attention on coordination among SMEs and private agencies to foster innovation.⁷²

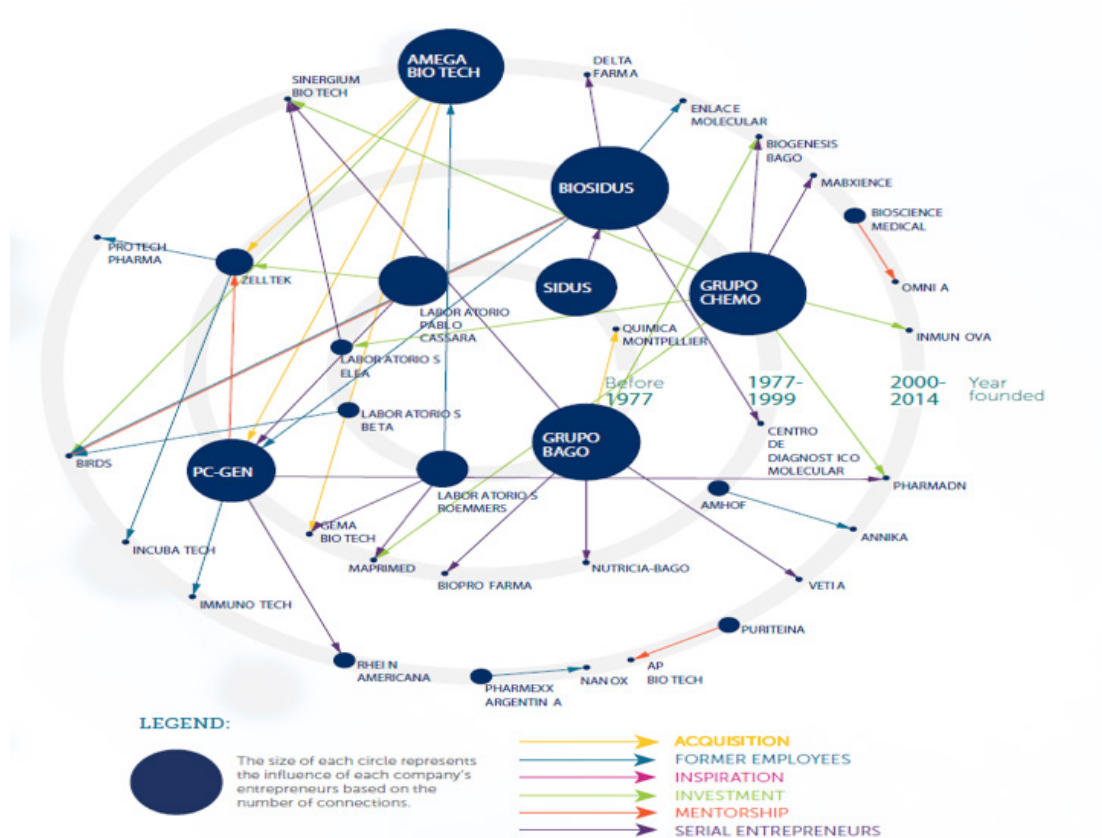
The productive development policies of FONTAR and INTA are small vis-à-vis other support programs aimed at financing SMEs, promoting exports, and financing investment, but are more successful. Additionally, their impacts are often limited by lack of coordination with other public agencies that matter for the supported sector or activity and by government failures.⁷³ Research finds that productive development policies succeed when they are flexible and varied enough to adapt to the needs of different types of firms and different classes of projects, as in the case of FONTAR’s instruments, which also facilitates the formation of platforms. In many cases the presence of committed stakeholders that break the status quo or that manage to maintain and upgrade policies in an unstable policymaking scenario is crucial.

LOOKING AHEAD

Argentina has achieved significant progress in developing its biotechnology capabilities. It has been an early adopter of biotechnology and is a regional leader through domestic sales and exports, currently exporting to over 100 countries.⁷⁴

GRAPH III

NETWORK MAP OF THE BIOTECHNOLOGY INDUSTRY IN BUENOS AIRES



Source: Endeavor Insight, *The Growth of Biotechnology Entrepreneurship in Buenos Aires*, New York, 2016.

It is evident that Argentina is championing the introduction of innovative technologies to farmers through its active involvement in genetically engineered plants, herbicides, and transgenic materials, especially in crops such as soybeans, corn, cotton, and wheat. Argentina continues to be the third largest producer of biotech crops after the United States and Brazil, producing 14 percent of the world's total.⁷⁵ However, compared to the United States and Brazil, Argentina has had slower production growth in the industry due to the lack of policy regulations in support of technology and innovation. However, Argentina has made strides in closing the innovation gap between it and the United States and Brazil.

Argentina's continued policy support for biotechnology, irrespective of the political party in power and its regulatory framework, contributes to the diffusion of advanced technologies. Government programs including FONCYT, FONTAR, and FONARSEC are dedicated to collaborative research and have improved university-industry technology transfer. As

public investment has been limited, it has been the private sector that has invested in the development of biotech capabilities. Since Argentina's biotech industry is the result of imitative innovation processes, the pharmaceutical industry must compete on the basis of price rather than novelty. Nonetheless, as the share of biotechnologies within the global innovative pharmaceutical market increases, Argentina's highly developed and lower-cost biotechnology industry is poised for increased investments over the medium to long term.⁷⁶

The fulcrum of the biotechnology ecosystem is networks; and while cities outside the capital are engaged in biotechnology development, it is Buenos Aires where the largest and most dynamic features of the biotechnology ecosystem occur (see Graph III).

Buenos Aires is the principal hub for competitive biotech firms such as BioSidus and Grupo Chemo.⁷⁷ Companies in the hub have built on the low-margin business models of the pharma manufacturing industry to create an industry that leverages greater innovation to utilize higher-margin business models. As a result, they have increased the supply of local innovation and found ways to effectively compete in global markets.⁷⁸

This agglomeration—clusters and networks—has proven effective across nations, regions, sectors, and industries as drivers of performance and competitive advantage.⁷⁹ And while Buenos Aires is the principal hub of clusters, as cited earlier, there are locales elsewhere in the country that are upgrading their cluster and networking capabilities.⁸⁰

CONCLUSION

Looking to the future, the growth, development, and competitiveness of Argentina's biotechnology will be shaped largely by six factors: (1) scientific capital, consisting of scientists along with their special knowledge and creativity; (2) scientific institutions; (3) human capital, including scientific and managerial personnel along with entrepreneurs; (4) access to technology and patents; (5) financial capital; and (6) clusters, accelerators, and incubators within those clusters.⁸¹

Following international trends, the industry is moving towards big biotech "molecules" (large-scale pharma-biotech collaboration). In October 2016, IndieBio, the first biotechnology accelerator in Silicon Valley, announced that it would select 5-10 biotech companies in Argentina to enter its accelerator program—a four-month instructional/mentoring program along with a \$200,000 investment. Founded in 2014, IndieBio has a portfolio of 30 start-ups.⁸²

On a cautionary note, one needs to be realistic about biotech costs. It takes \$200-\$500 million or more to build a large biotech facility, compared with similar scale small-molecule facilities that can cost far less (\$30 million to \$100 million). These large facilities can take four to five years to build, and are also costly to run.⁸³ Additionally, it is one thing to have technology available, but quite challenging to incorporate it into the productive process. Adopting and absorbing

technological innovations is uncertain and risky, not to mention costly for firms, requiring access and assimilation of physical and human capital.⁸⁴

One of the most auspicious developments going forward in the biotechnology ecosystem is the growing presence of start-ups. There is a new generation of young scientists and technologists that have a market-oriented vision towards biotech with a focus on health and agribusiness. Grupo Sancor Seguros in Sunchales in Santa Fe province funds CITES, the first technology incubator in Latin America that works with many start-ups. In fact, emerging firms such as Keclon, Unleash, Phylumtech, and start-ups of CITES and GRID can become “champions” of biotech innovation and serve as models for others. Venture capital will increase, as well. For example, Axia Ventures is raising funds for a VC fund to finance food science ventures, including those based on new foods as one of its verticals.⁸⁵

Biotechnology is widely believed to be “the next technological frontier.” According to Dr. Federico Prada, Biotechnology Program Director at Fundación UADE’s School of Engineering in Buenos Aires, Argentina’s best prospects in biotechnology in the long term are in human health, and agro and industrial biotechnology in the short to medium term.⁸⁶

How Argentina crosses the next technological frontier will depend upon its success in strengthening, deepening, and expanding its current ecosystem of innovation for both agribusiness and pharmaceuticals. In the opinion of a number of experts in biotechnology, such as Dr. Andrés A. Poeylout-Palena, Manager of Innovation, Research, and Development at Wiener Lab Group, it is imperative that Argentina support institutes of applied research—not just basic research—and that the government creates incentives for private biotechnology firms to interact closely with these institutes.⁸⁷

As Argentina addresses its ecosystem of innovation in biotechnology, it should:

- Focus on the urgent need to upgrade (tighten) its regulatory approval system;
- Strengthen its IPR regime;
- Increase public funding for biotechnology, including human capital;
- Devote more attention to new drug creation rather than to generics; and
- Adopt a code of business ethics similar to APEC’s for SMEs in the biopharmaceutical sector.⁸⁸

Such actions will provide sustainable benefits not just for Argentina’s biotechnology sector but for the nation’s competitiveness overall.

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