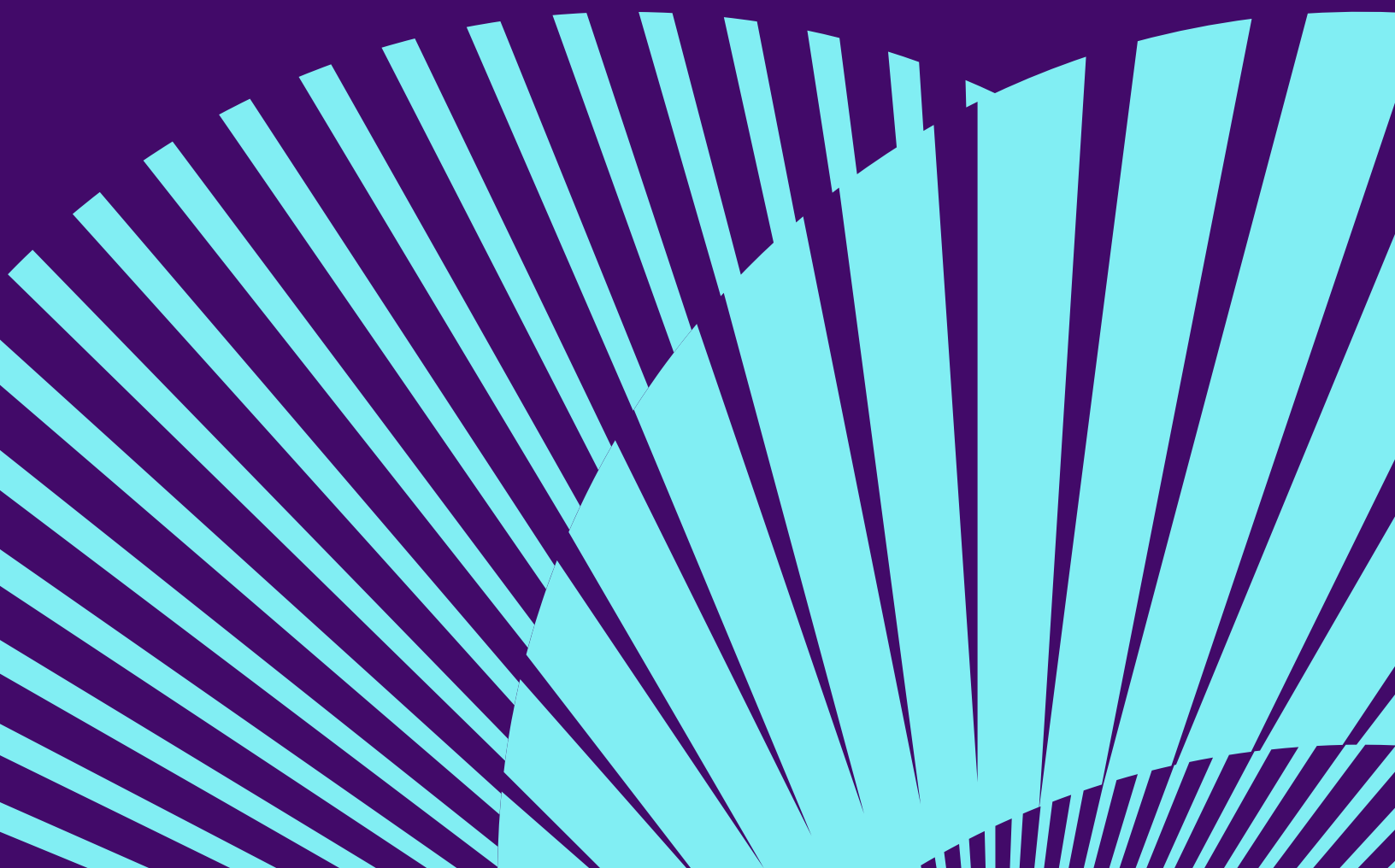
Unleashing the Post-COVID Potential of Argentina's Innovation System



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The U.S. Chamber of Commerce's U.S.-Argentina Business Council (USABC) is dedicated to strengthening the economic and commercial relationship between the U.S. and Argentina. The USABC pursues its mission by identifying challenges and proposing solutions to issues hindering the commercial relationship, advancing trade and investment opportunities for USABC members, and supporting economic growth in Argentina and the U.S., with an emphasis on supporting Argentina's economic reform efforts.

Argentina has excellent baseline conditions to develop innovative industries like biotechnology, which has already proven its potential in the development of medicines and seeds. However, insofar as innovative companies or researchers lack the necessary enabling conditions to invest in R&D, Argentina will remain below its potential as a regional—or even global—leader for high value-added activities like clinical trials or genetic engineering of seeds. The USABC developed this policy paper to raise the visibility of Argentina's underutilized potential for biotechnology innovation and to put forward recommendations to unleash this potential.

This paper makes the case for promoting innovation and examines the connections between economic development, innovation, and intellectual property (IP) protections, as well as their overall positive impact on public health. It describes indicators that demonstrate Argentina's potential for innovation, both in regional and absolute terms. It also provides recommendations to realize this potential by implementing concrete policies to strengthen Argentina's IP framework.

Introduction: The Untapped Potential of Biotechnology Innovation in Argentina

Comparable to other developing countries, one of the greatest challenges Argentina faces is a need to make a qualitative leap in the competitiveness of its industries, which would allow the economy to expand above the rate of population growth. Literature on economic development has increasingly assigned a more prominent role to innovation as the main driver of competitiveness. Indeed, developing new and specialized products and more efficient production methods is what allows an economy to capture a greater share of the value of the goods and services it produces.

Argentina has the enabling factors for innovation: a skilled labor force, a diversified industrial base, and a fixed investment in higher education and basic research. In particular, Argentina has great potential for biotechnology development across two main areas: pharmaceutical and agricultural. Two recent developments illustrate Argentina's enormous potential for biotechnology in these two industries. When the COVID-19 pandemic started in December 2019, Argentina became one of the few developing countries where clinical trials for vaccine development were conducted, with almost 70 trials. This included tests for Gilead's Remdesivir, Pfizer's Comirnaty and Ritonavir. Second, and more recently, Argentina authorized the sale of HB4 wheat, the first genetically modified wheat variant in the world, developed by domestic biotech company Bioceres with two national research institutions.

Despite these success stories, Argentina is not achieving its potential for innovation. Only 25% of all R&D that takes place in the country is conducted by the private sector, a figure well below international and regional benchmarks. Although Argentina has three times the regional average in qualified human resources employed in R&D, it ranks below other countries in Latin America in patent applications by national residents (442 in 2019), barely above similar-size Colombia (422) or smaller Chile (438) and considerably below Brazil (5,464) and Mexico (1,305).

One of the key reasons for this disconnect between Argentina's potential and the current reality is the country's weak patent protection. Without a robust IP framework that allows innovative individuals and corporations to recoup their investment in cutting-edge innovation, the framework to facilitate R&D investment in Argentina disappears as innovations are typically public goods. They require major investment in R&D but can easily be replicated once they are put on the market. Therefore, absent adequate regulations and streamlined procedures to register patents, inventors will be less likely to invest in innovation in Argentina.

Innovation, Economic Development, and the IP System

More than ever, innovation has become crucial to long-term economic growth. In a globalized world—with blurred barriers in the movement of goods, capital, skilled labor, technology, and ideas—the innovation capability of a country is the key driver to capture the value added of global production and consumption.[1] In fact, 85% of the long-term economic growth of developed countries is explained by the increased productivity that comes from innovation, which lies behind the GDP per capita gap between rich and developing countries today.[2] But beyond economic growth, innovation also confers substantial benefits to public health. Now, more relevant than ever, an innovative life sciences industry can also be more prepared to tackle the global health challenges of today, such as potential new pandemics, chronic disease, or population ageing. A more innovative country will have a more resilient health system and better access to high-quality medicine and biotechnology.

As a result, governments worldwide and in the region see innovation as a critical target for improved public policy. A country can support innovation by encouraging investment in that area through a solid legal framework. While universities have a critical role as they typically invest in basic research that often spills over to other areas, the private sector is also crucial as it complements basic research through applied research, testing, and commercialization of new technologies that can be enjoyed by a wider public. For this innovation ecosystem to thrive, governments must adopt policies that encourage private sector innovation by guaranteeing effective IP protection and enforcement mechanisms that ensure innovation is adequately protected.

The U.S. Chamber's 2022 International IP Index, which ranks the IP framework in 55 global markets, shows the vast disparities in IP protection around the world. In Latin America, Mexico, Costa Rica, and the Dominican Republic score in the top half of the economies benchmarked in the report, while other economies in the region have greater room for improvement, such as Argentina which ranks below the Latin American average. The Index illustrates how economies with the most effective IP frameworks are more likely to receive a range of socioeconomic benefits that all countries strive to achieve. In the life sciences sector, economies with robust IP protection are more likely to see increased innovative output, greater clinical trial activity, and more private sector investment in R&D. According to the World Economic Forum's Global Competitiveness Report, when measuring IP protection, developed countries average 5.6 points out of 7 (higher protection) and developing countries average 3.0, almost half of developed ones, which highlights the correlation between development and IP protection.

Around the globe, effective IP protection enables innovators to make high-risk, high-capital investments to discover the next generation of innovative solutions. Under a scenario of a lack of intellectual property rights (IPRs) or low IPR enforcement, innovators will be less likely to invest large amounts of time and resources in the development of new products and services, resulting in a production of innovations lower than the socially optimal amount. Thus, effective and predictable IP systems provide an important framework for investing in innovation and enabling innovative ideas to be commercialized and scaled.[3] In particular, a strong system of IPRs does the following:

- **Promotes the generation of local innovation:** Effective IP regimes bring clarity and certainty to the market, encouraging the introduction of technology to new places and enabling innovative ideas to be scaled locally.

- **Facilitates contract research and license-based production collaborations:** For instance, pharmaceutical IPRs allow innovators and producers, both local and foreign, to use license agreements in which rights holders can manage the exchange of know-how and the transfer of technology, as well as production and distribution rights.[4]

- **Fosters foreign direct investment (FDI) in innovative sectors**: Countries with higher levels of pharmaceutical IP protection and enforcement tend to show a higher level of FDI, especially in developing countries.

The positive impact of a strong IP system on innovation is more pronounced in knowledge-intensive sectors, like the health industry, which implies risks associated with the large costs of R&D with highly uncertain results. The development, production, and distribution of medicines are subject to heavy government regulation. Once approved, it typically takes years for companies to recoup the investment needed to bring just one new medicine to market. Further, research has shown that countries with a more robust level of pharmaceutical IP protection tend to enjoy a greater level of clinical trial activity by multinational research-based companies.[5]

A strong patent protection system may be instrumental for innovative firms to strengthen their position when obtaining financing, scale up their production, and internationalize. Indeed, patents or other IPRs have been increasingly used as a collateral for debt or to attract venture capital at an initial stage and could serve as a key tool to obtain financing at an attractive rate in a country where capital is scarce like Argentina.

Argentina's Underdeveloped Potential for Innovation in the Biotech Sector: The Case for Strengthening its IPR System

Argentina ranks remarkably high in most indicators generally used to measure a country's potential to innovate. Argentina is, after Brazil, the country that invested the most in R&D in the region: an average of 0.56% of GDP, considerably above the regional figure of 0.32%. In addition, Argentina claims 17 patent applications by nationals per million inhabitants yearly, ranking third after Brazil and Chile. Still, both Argentina and the rest of the Latin America region lag far behind the average of OECD countries in these indicators, which allocate 2.5% of GDP in R&D and claim 152 patents per million inhabitants every year. Argentina's availability of skilled human capital also stands out, being the only country in Latin America with more than 1,000 researchers per million inhabitants employed in R&D activities. This figure, which is more than triple the regional average (1,207 vs. 391), is explained by high investment in education, which reaches 5.5% of GDP and is the third largest in the region after Brazil and Costa Rica.

Figure 1: Research and Development in Latin American Countries

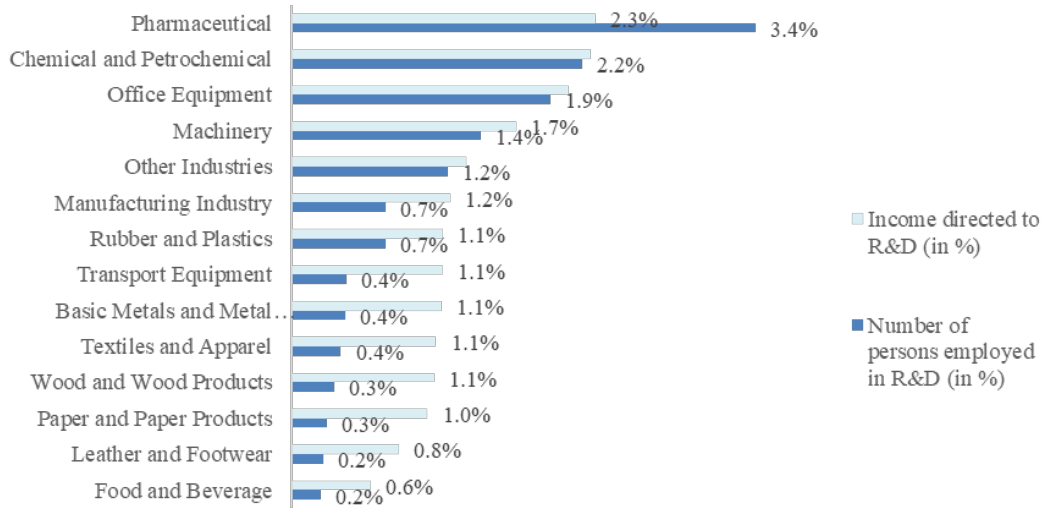
Country	R&D/GDP	Researchers in R&D per million persons
Brazil	1.09%	887.7
Argentina	0.56%	1,206.9
Uruguay	0.48%	642.9
Costa Rica	0.44%	568.5
Chile	0.36%	427.1
Mexico	0.33%	260.2
Colombia	0.24%	58.3
El Salvador	0.18%	NA
Paraguay	0.15%	152.2
Panama	0.15%	39.1
Peru	0.12%	NA
Honduras	0.04%	NA
Guatemala	0.03%	20.3

Source: USABC based on the World Bank Development Indicators

The pharmaceutical industry is one of the main engines of innovation in Argentina. Between 2014 and 2016, the industry invested more than 2% of its revenue in innovation activities, double the average of the manufacturing industry. Eight out of 10 firms in the pharmaceutical industry carried out at least one innovation activity. In terms of skilled human resources, more than 3 of every 100 employees in the sector were employed in innovation activities, five times the manufacturing industry average. In Argentina, 1 out of 6 researchers are employed by the pharmaceutical sector.

The same applies to the chemical and petrochemical sector, which encompasses the big players in genetically modified seeds. Companies in the sector direct 2.2% of their revenues to R&D, and 2.1% of their personnel is employed in these activities. Given the considerable size of the sector, it hosts the largest number of researchers in the manufacturing sector.

Figure 2: Resource Implications in R&D by Sector Argentina, 2014–2016 Period

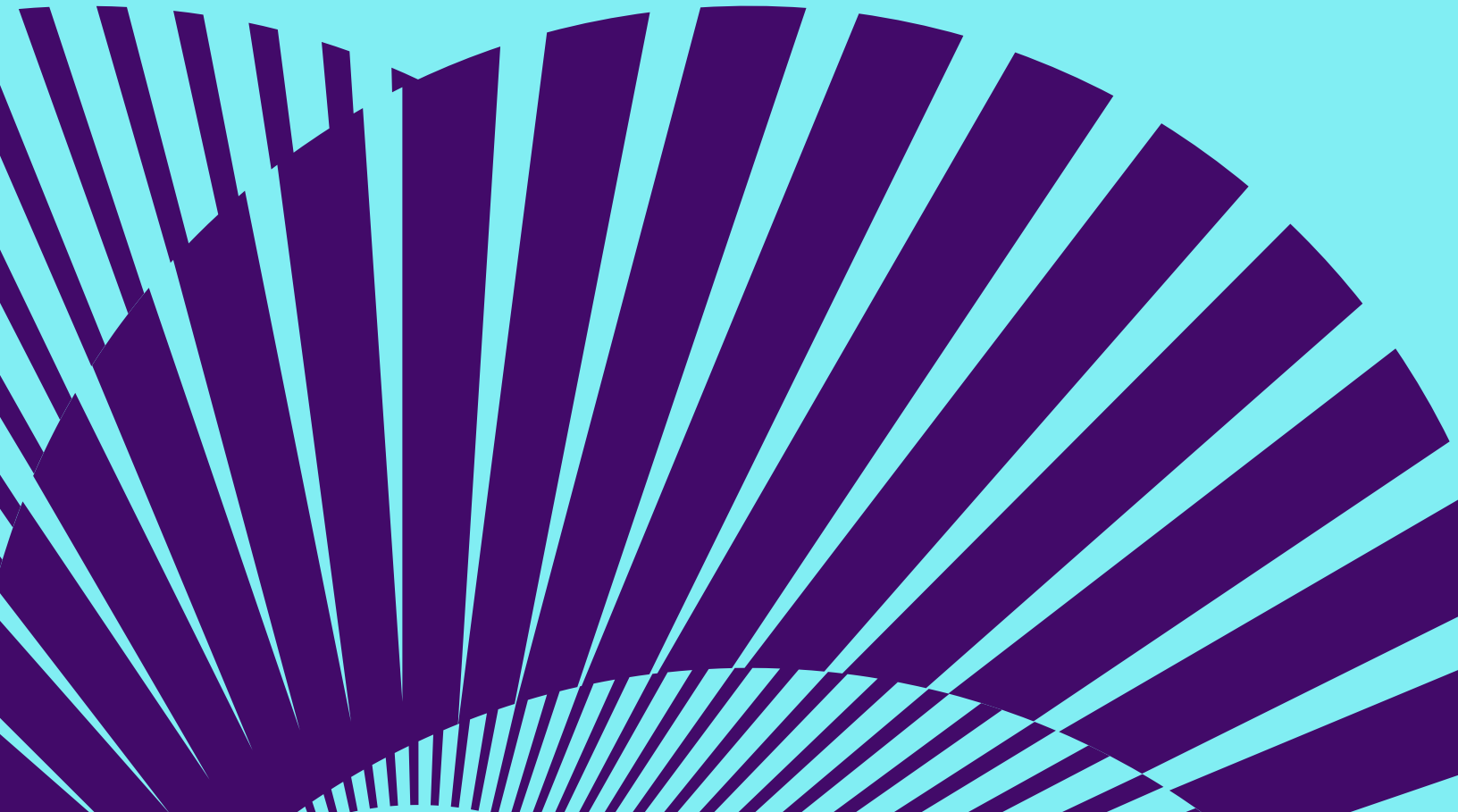


Source: USABC based on National Innovation Survey

The large number of researchers per capita is combined in the medical and genetic engineering sectors, with a solid institutional framework where these scientists can develop their skills and careers. Indeed, Argentina has a major infrastructure of research institutes that underpin innovation efforts.[6] In addition, it has world-renowned supervisory agencies for medicines and food—*Administración Nacional de Medicamentos, Alimentos y Tecnología Médica* (ANMAT), and *Servicio Nacional de Sanidad y Calidad Agroalimentaria* (SENASA)—which have similar standards to the agencies of developed countries. Argentina's hospital system and the number and quality of medical professionals are also considerably higher than the regional average and the average for developing countries. In 2017, Argentina had 3.9 medical doctors per 1,000 inhabitants, above the regional average of 2.9 and well above the average for medium income countries (1.5).

These outstanding baseline conditions allow Argentina to be in a position to readily boost innovation in the medical and pharmaceutical sectors to unprecedented levels in the developing world by supporting innovation through public policies. Moreover, Argentina's population has a very diverse genetic makeup, with a strong prevalence of European genetics, which positions the country as an attractive destination in Latin America to develop clinical trials for some of the largest medicine markets in the world where the populations have a similar genetic makeup.

Regarding the private sector, Argentina has an unusually developed pharmaceutical industry for its development level both for traditional medicines, based on chemical synthesis, and biologics. Domestic pharma companies have a very strong presence well above foreign companies. Unlike other Latin American countries, almost 80% of the pharma companies in Argentina are national, much higher, for example, than in Brazil (49%), Uruguay (26%), and Mexico (34%). With regard to revenue, around 70% of the sales by pharma companies in Argentina are from companies with Argentine capital, which is above the trends in Brazil (59%), Mexico (66%), and Uruguay (63%). Among the 20 pharma companies with the highest revenues, the top eight have Argentine capital.



Argentina's Potential for Innovation: The Cases of COVID-19 Clinical Trials and Vaccines and HB4 Transgenic Wheat

Two paradigmatic cases illustrate Argentina's strong potential to develop and attract innovation-driven technology industries: the exponential increase of clinical trials during the last four years and the successful development of transgenic wheat.

Argentina has managed to enter global value chains as a hub for research, development, and manufacturing of vaccines in the context of the COVID-19 pandemic. During the pandemic, Argentina became a global focal point for clinical trials. In total, 13 vaccine and 66 medicine trials were conducted across the country, making a significant contribution to scientific research on COVID-19 treatment and prevention, providing high-quality employment opportunities, building confidence in the safety and effectiveness of the vaccine data for the Latin American population, and providing early access to vaccines and treatment compared to other countries in the region. In 2021, the country reached the highest rate of clinical trials per million inhabitants in Latin America and saw an increase from 118 to 210 total studies between 2017 and 2021—a rise of 70%. This outstanding growth included activities in Argentina by AstraZeneca, Pfizer, and Sinopharm.[7]

Some of the main features that enabled Argentina to become a key player in the clinical trials sector in the context of the health crisis include the exceptional quality of human capital in the scientific research and medical industries, as well as Argentina's vast trajectory in clinical research and its commitment to good clinical practices and scientific development. The significant reduction of regulatory deadlines and the digitalization of procedures in the years prior to the pandemic also proved to be decisive in making Argentina an ideal setting for COVID-19 studies.[8]

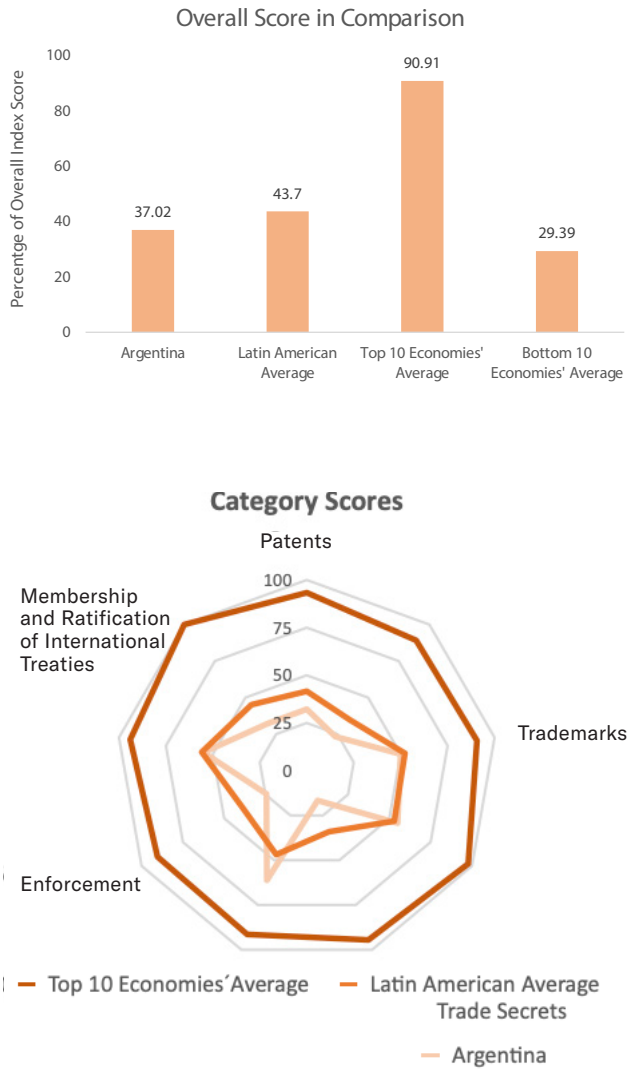
The case of transgenic wheat exemplifies Argentina's potential to spearhead innovation in the agribusiness sector. The development of wheat with drought-resistant technology known as HB4 is an unprecedented breakthrough for agriculture in an era in which climate change constitutes the main challenge. This research project was led by a public-private partnership between a team of experts at *Instituto de Agrobiotecnología del Litoral* (IAL), a research lab dedicated to technological innovation related to agriculture; CONICET, the main public organization dedicated to the promotion of science and technology; and Bioceres, an Argentine agricultural biotechnology company. HB4 is the first event of drought and salinity tolerance in Latin America applicable to both wheat and soy seeds. Previously, all events involving grains had been generated by multinational companies and related to herbicide and insect resistance.

All these characteristics afford Argentina the opportunity to become a true regional—or even global—innovation hub for the pharmaceutical and agribusiness industries. In particular, Argentina could become a center for clinical trials and seed development.

Notwithstanding these remarkable baseline conditions, Argentina's potential for innovation seems to be underdeveloped, chiefly in the private sector. More than 75% of R&D is carried out by public agencies. This figure should be contrasted not only with OECD countries but with other countries in the region. In developed countries, the public sector only accounts for 39.6% of total R&D, while in Brazil, Colombia, and Chile the average is 57.0%. Moreover, the fraction of total R&D carried out by foreign firms in the country is unsurprisingly low, less than 1%. In Chile, this figure goes up to 14%; in Costa Rica, 6%; and in Colombia, 2.5%. Among OECD countries, cross-country flow of innovation is as high as 9% of total R&D.

One of the reasons that may explain this blunt predominance of public over private investment in R&D in Argentina is the weakness of its IPR system, specifically its patent system. In the WEF GCI, Argentina at 3.9 ranks better than developing countries on average (3.0), but it is behind leading countries in the region such as Uruguay (4.73), Mexico (4.1), and Chile (4.7). A similar conclusion can be drawn from the U.S. Chamber of Commerce 2022 International IP Indexwhere Argentina receives 37.02% of the overall score and ranks 46 out of 55 countries, far from the average of the top 10 economies (90.91) and considerably lower than the average for Latin America (43.7). The country also ranks poorly across various categories of IP protection in the Index, which measures specific aspects of the IP system, such as the strength of an economy's environment for patents, trademarks, or copyrights; IP rights enforcement; and membership and ratification of international treaties.

Argentina IP Index (2022). Overall Score and Category Scores



Source: U.S. Chamber of Commerce, 2022 International IP Index Report (10th edition).

Main Conclusions and Recommendations: Toward a Regulatory Framework for Innovation in Biotechnology in Argentina

Argentina has enormous potential to develop and attract groundbreaking technology industries. The country has a solid scientific base and produces quality knowledge and skilled resources, but the processes that would allow this knowledge to be transformed into innovations and high value-added products and services must be strengthened. While the country ranks well in most indicators generally used to measure innovation—for example, the number of patents filed per inhabitant per year—more than three-quarters of R&D is conducted by the public sector. Thus, there is still plenty of room for private innovation to grow. This is where the IPR system and its effective enforcement plays a fundamental role.

The areas of the IPR system concerning patents that need to be strengthened have been identified for decades. For Argentina to develop its potential in biotechnology, concrete progress needs to be made to address the following areas:

- **Restrictive patentability criteria**: Through Resolutions 118/12, 546/12 and 107/17, the Ministries of Health, Production, and INPI defined a series of evaluation and patentability criteria for chemical and pharmaceutical inventions. These administrative rules and guidelines exclude from patent protection most products that constitute a new entity, limiting the patentability of inventions in the pharmaceutical industry far beyond the standards of most patent offices in the world.[9] These regulations have created significant space for domestic pharmaceutical companies to develop alternatives to innovative products based on original research from others, thereby considerably discouraging innovation by restricting patentability across various groundbreaking areas.

  Argentina should therefore repeal its restrictive patentability criteria and extend the protection it affords to IPRs to all types of chemical and pharmaceutical innovations, thereby bringing these protections up to the level of international practices. This reform would be a major signal for foreign investors that Argentina is committed to protecting IPRs and could put the country on track to becoming a regional hub for pharmaceutical and medical innovation.

- **Live matter patentability:** INPI Resolution 283/15 introduced a more restrictive interpretation of Article 6 of the Patent Act that restricts live matter or gene patentability. As a result, the patentability of nucleotides or amino acids is limited compared to other countries such as the U.S. Like the patentability guidelines for synthetic pharmaceutical products, this regulation limits the return on investment in R&D in genetic engineering. Argentina's considerable potential in genetic engineering was drastically reduced by this measure, as innovation in key areas like seeds (similar to the transgenic HB4 wheat developed domestically), animals, and even functional foods or biofactories lags behinds other markets due to the absence of patentability requirements. This is compounded by the fact that Argentina maintains the UPOV 1978 standard, whereby seed patents and breeders' rights cannot coexist.

  Recognizing the patentability of live matter would allow Argentina to develop groundbreaking inventions in an area in which it has shown considerable comparative advantages already with the development of HB4 wheat. This could be combined with the adoption of UPOV 91 standards to ensure the protection of plant varieties to encourage innovation in an area where Argentina could become a global leader.

- **Low standards for test data protection and exclusivity:** Another ongoing challenge to the innovative agricultural chemical and pharmaceutical sectors is inadequate protection against the unfair commercial use, as well as the unauthorized disclosure of undisclosed test or other data generated to obtain marketing approval for products in those sectors. The Argentine IP system permits regulatory approval based on bioequivalence and bioavailability standards, which allows domestic companies to take advantage of—practically at no cost—clinical trial data published by foreign pharmaceutical companies disclosed before the regulatory authorities of other countries. This allows domestic companies to act as free riders and benefit from R&D efforts made by competitors. Compounded with strict patentability standards, the low level of protection of test data considerably discourages investment in clinical trials by foreign pharmaceutical companies in Argentina.

  Argentina should consider extending protection to test data and recognizing its exclusivity, a necessary requirement for innovation in applied chemistry and pharmaceuticals in today's world. This would bring Argentina in line with most other countries in the world that have recognized this increased protection of intellectual property rights. Granting protection and exclusivity to test data would provide a major and immediate signal of Argentina's commitment to IPR protection, especially for clinical trials where Argentina has shown a high potential for further development owing to its clear competitive advantages.

- **Patent extensions**: The protection afforded by a patent lasts for 20 years, but this term is counted from the filing date and not from the moment the patented product receives regulatory approval or is put on the market. The period between the filing date and the moment the patent is approved or rejected usually lasts from 5 to 7 years. And even if the patent receives approval, the product must receive regulatory authorization by a regulatory authority (ANMAT in Argentina's case) to be marketed. This additional period reduces the effective protection of a patent in most countries from 20 years to 7 to 10 years. In most countries, this is resolved by granting patent holders an additional period after expiration to compensate the delay caused by the approval of the regulatory authority. This is not the case in Argentina where no extensions are given despite the long periods before a patent is approved.

  Extending the term of patents in a context of considerable delays for patent review would ensure that the intended level of protection granted by patents is effective in practice. Argentina should follow established international practice and consider extending patent terms by up to 5 years where applicable to foster an innovative environment that takes into consideration a delay that is not attributable to innovators.

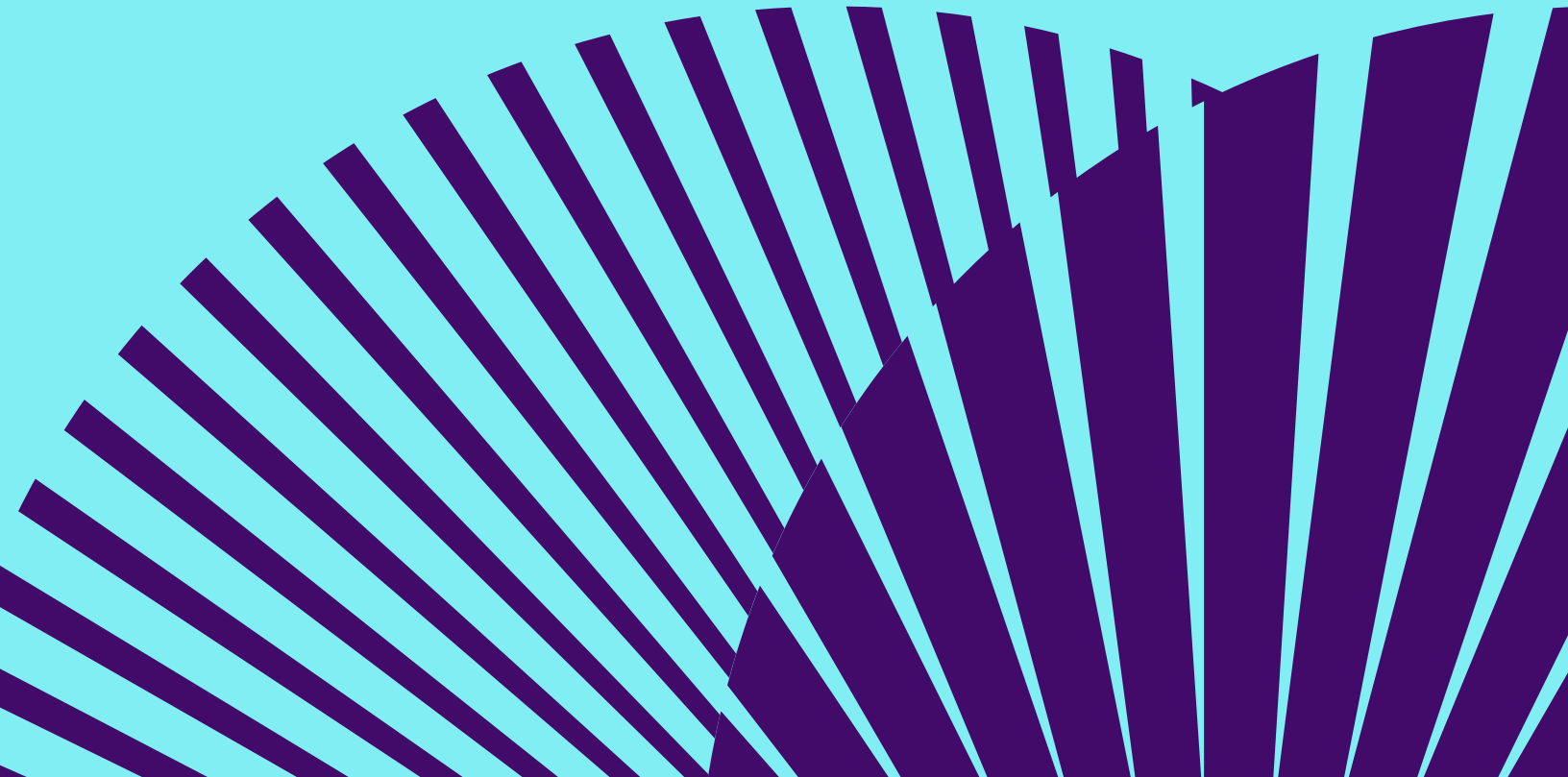
- **Delays and backlog for patent examination**: Delays in patent review create uncertainty and increase the risk that the invention is copied and reduce the effective protection granted by the 20-year term of a patent. Even if Argentina made progress in recent years, like Resolution 56/2016 and the State Simplification and Debureaucratization process implemented in 2018, there still are major delays—around 6.5 years on average—to receive approval of pharmaceutical and biotechnology patents without any mechanisms to compensate for that delay. Argentina, according to the WIPO World Intellectual Property Indicators 2021, has the longest period for first patent office action (60 months) and final decision (72 months) of all countries reviewed (the pandemic in 2020 might have had an effect on this). Since 2018, Congress has not made progress in pursuing strategies that Argentina could adopt to streamline the granting of patents to reduce the backlog, such as becoming a party of the Patent Cooperation Treaty (PCT) or any concrete measure for patent streamlining.

  As delays in patent examination cripple innovation, Argentina should continue its efforts to reduce delays with other proactive measures. It could draw inspiration from the Backlog Combat Plan adopted by Brazil's INPI in 2019, which allowed the country to considerably reduce its patent backlog from around 147,000 pending examinations to only 16,764 in three years, according to official data. Streamlining patent procedures could be a first step for Argentina to reduce its lengthy examination timeline.

- **IP enforcement**: A key tool to mitigate the impact of IP infringement is the possibility to obtain a judicial order to stop the sale of the infringing product while the dispute is resolved. However, this type of enforcement has been typically low in Argentina, as pharmaceutical companies report that the process to obtain a judicial order is slow and bureaucratic, which in practice severely limits the relief that preliminary measures should provide.

  Among other policy options or initiatives, Argentina should consider the possibility of a capacity-building program for its judiciary to address the importance of enforcement of intellectual property rights as part of Argentina's international obligations under TRIPS. This could be complemented with explanations on the economic impact and rationale of intellectual property protection that are suitable for legal operators. The program could be organized in coordination with the U.S. Patent and Trademark Office or WIPO's already existing international IP enforcement initiatives.

Reforming each of these areas of the patent protection system to modernize them and provide greater protection would entail a major step toward encouraging innovation in Argentina. This would allow Argentina to leverage its excellent baseline conditions for innovation in biotechnology, medicines, and seeds, a potential that is currently hindered by a lack of an effective framework to invest in R&D. As long as this situation persists, Argentina will remain below its potential as a regional—or even global—leader for high value-added activities like clinical trials or genetic engineering of seeds.



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4. Matthias Bauer. (2021). On the Importance of Intellectual Property Rights for the Production of High-value Medicines in the EU. Brussels: European Centre for International Political Economy.

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6. Among the almost 90 R&D institutions and centers dedicated to biotechnology, the main highlights are Instituto Leloir, Instituto Lanari, Instituto Milstein, INTA, INTI, Hospital Italiano de Buenos Aires, Fundación Favaloro, Centro de Educación Médica e Investigaciones Clínicas "Norberto Quirno" (CEMIC), as well as an entire network of research centers associated to CONICET, Argentina's university research agency.

7. Daniel Blinder; Lautaro Zubeldía & Sofya Surtayeva. (2021). Pandemia, negocios y geopolítica: producción de vacunas en Argentina, in Desarrollo y Políticas de Ciencia, Tecnología e Innovación en un mundo en transformación: Reflexiones sobre la Argentina contemporánea. Tandil: Universidad Nacional del Centro de la Provincia de Buenos Aires, pp. 15–47.

8. Ibid.

9. These resolutions have led INPI to stop considering polymorphs and pseudopolymorphs, enantiomers, Markush-type claims, inventions of selection, salts and esters, formulations and compositions, combinations, dosages and doses, and second medical uses as patentable inventions.