PROSPERITY ▼▲ FREEDOM ▼▲ INNOVATION

INTERNATIONAL PROPERTY RIGHTS INDEX 2024

PHARMACEUTICAL PATENTS IN ARGENTINA: A PRACTICAL APPROACH

CASE STUDY

PROF. LUCAS LEHTINEN
Author

UNIVERSIDAD AUSTRAL
DERECHO
Centro de la Propiedad Intelectual

1

INTRODUCTION

Argentina enacted its first patent law in 1864[1], just 11 years after the adoption of its first Constitution in 1853 and several years before the promulgation of its Civil Code in 1871. This law was created with a clear vision of promoting and fostering innovation within Argentine territory, positioning the country as a pioneer in intellectual property protection across the region (Alberdi, 1852). For many years, this framework allowed Argentina to become a model for other Latin American countries, establishing an environment conducive to technological advancement and the creation of new inventions.

However, today, Argentina has shifted onto a different path: patent applications, particularly in high-technology fields, are declining each year, while many residents—whether individuals or public and private entities—are increasingly seeking protection abroad. This trend underscores the current lack of legal security and insufficient incentives within the Argentine intellectual property system, which in turn threatens the country's ability to stimulate development and remain competitive on a global scale.

The implementation of the "Patentability Examination Guidelines" in 2012 marked a pivotal turning point in Argentina's pharmaceutical patent regime. These guidelines, which in practice function as mandatory regulatory restrictions, were introduced by the Ministry of Industry, the Ministry of Health, and the National Institute of Industrial Property (INPI). Initially presented as a measure aimed at balancing intellectual property rights with access to essential medicines, the actual consequences of these guidelines have been far from beneficial. Rather than fostering equity and improving public access to healthcare, these regulations have had profoundly negative effects on innovation and the pharmaceutical market within Argentina.

Since their adoption, there has been a marked decline in investment in research and development (R&D), leading to a significant reduction in patent applications, technology transfer, and the availability of innovative medicines. The system of disincentives created by the joint resolution has adversely affected not only the pharmaceutical industry but also consumers, resulting in higher drug prices and restricted access to cutting-edge treatments.

1. Patent Law 111 – see online: servicios.infoleg.gob.ar/infolegInternet/anexos/280000-284999/281086/norma.htm

Contrary to the initial justification that these regulations would help combat poverty and promote inclusion, empirical data reveals a negative social and economic impact. Instead of enhancing accessibility, the guidelines have erected barriers that hinder the entry of new technologies and therapies, jeopardizing the sustainability of the healthcare system. Furthermore, these guidelines exhibit clear inconsistencies with the principles of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), undermining Argentina's standing in the international intellectual property arena and its ability to attract foreign investment in the sector.

The importance of this study lies in its ability to illustrate—through concrete data from the Argentine system—how disincentives applied across different industrial sectors have a direct impact on quality of life, human development, and the availability of critical technologies necessary for fostering cooperation and development. These findings highlight that restrictive patent policies not only stifle innovation but also limit economic growth and Argentina's capacity to integrate into global value chains, ultimately affecting the well-being of its citizens.

RESEARCH QUESTIONS

1. How do the 2012 "Guidelines" affect the ability of innovators to protect their inventions in Argentina?

2. Is Argentina in compliance with its international obligations under the TRIPS Agreement regarding the patentability of pharmaceutical compounds?

3. What impact have these regulations had on innovation and access to medicines in Argentina?

STRUCTURE OF THE REPORT

The report is organized into sections that address the evolution of the pharmaceutical patent system in Argentina, an analysis of the "Guidelines", international comparisons, specific case studies, and a discussion of the regulatory barriers that affect innovation and access to medicines.

2

RESEARCH METHODOLOGY AND APPROACH UTILIZED IN THE DEVELOPMENT OF THIS STUDY

The methodology employed in the development of this study is grounded in a rigorous selection and analysis of sources, embodying a deep commitment to academic excellence and research integrity. The foundation of this study is built upon the invaluable work previously conducted by distinguished professors from the Intellectual Property Center at Universidad Austral. A comprehensive review of their contributions has enabled the construction of a robust theoretical framework that informs our understanding and critical analysis of intellectual property, emphasizing the evolution of the field and highlighting emerging trends and challenges.

To ensure the objectivity and relevance of the data examined, this research draws extensively on information and statistics from globally recognized and authoritative organizations, including the World Intellectual Property Organization (WIPO), the World Trade Organization (WTO), and the World Health Organization (WHO). These sources not only provide up-to-date and reliable information, but they also enrich the analysis with a global perspective on the multifaceted challenges and opportunities inherent in the protection of intellectual property. By leveraging such data, we are able to contextualize the Argentine intellectual property regime within broader international frameworks, offering a more nuanced understanding of the global dynamics at play.Moreover, a specific inquiry was conducted using the advanced public search module provided by the European Patent Office (EPO). This targeted investigation enabled the collection of comparative statistics, offering insight into the behavior and strategies of various actors in the realm of intellectual property protection.

This comparative approach is particularly valuable for identifying patent filing trends, registration behaviors, and strategies employed by both individual and corporate entities, thus facilitating a more comprehensive understanding of market dynamics at both the European and global levels.

In addition to the international data, this study incorporates sectoral reports developed by independent consulting firms. While these reports are publicly available, they contribute additional value through their specialized focus and ability to identify sector-specific trends. The inclusion of such specialized reports ensures that our analysis captures all relevant dimensions of the topic, addressing both macro-level global trends and more granular industry-specific insights.

It is crucial to emphasize that all sources utilized in this study are thoroughly cited in accordance with academic conventions, ensuring proper acknowledgment of the contributions made by various authors and institutions. This meticulous citation practice not only reflects a commitment to academic integrity but also facilitates transparency, allowing readers and researchers to access primary sources for further exploration and in-depth study.

Finally, this comprehensive research approach underscores the importance of intellectual rigor and integrity in producing a study of high academic and professional standards. By integrating multiple layers of data and insights from diverse, credible sources, the study offers a well-rounded, thoroughly substantiated analysis of the Argentine intellectual property regime and its intersection with global trends in innovation and patent protection.

3

HISTORICAL EVOLUTION OF THE PATENT REGIME IN ARGENTINA: IMPLEMENTATION OF GUIDELINES AND THE TRIPS AGREEMENT

In 2012, the government issued the following resolution: Joint Resolution 118/2012, 546/2012, and 107/2012, enacted by the Ministry of Industry, the Ministry of Health, and the National Institute of Industrial Property (INPI). This resolution established "new guidelines" for the examination of pharmaceutical patent applications, aiming to regulate the patentability criteria in Argentina and aligning the framework with national industrial and healthcare policies.

A patent protects those suitable means that allow for a novel improvement in the state of scientific technology, which is not obvious to a person skilled in the art and can be commercially exploited in the market. Far from being an obstacle to human development, it acts as a "prime mover" in the consecration of other rights (Lehtinen, 2021). It even allows for the combination of known elements, provided that the combination exhibits sufficient inventive step to warrant protection, or alternatively, that competitors can achieve an equally effective result with other elements or a different combination (Mitelman, 2022).

Therefore, it is essential to emphasize that patents do not protect the result itself, nor are they an end in themselves (Breuer, 1957; Zuccherino 2016). As Taubman points out in discussions on intellectual property, it is often assumed that when someone gains a private right, the public loses, or that a policy is only valid if it minimally impacts public access (Taubman, 2015).

This approach conflates three different concepts: enhancing public welfare, maintaining free access to common resources, and increasing the availability of public goods. However, the true purpose of intellectual property law is not to limit the public interest, but to enhance it (Taubman, 2015). The goal is to create an environment that encourages innovation and knowledge, benefiting both creators and the public, without restricting access to culture and education. Yet, there is a natural tendency to view this as a zero-sum game—where "one wins, the other loses"—leading to the erroneous belief that defending intellectual property rights equates to prioritizing private interests over the common good.

In the realm of intellectual property, this perspective often frames intellectual property as an obstacle to other rights, especially when it comes to access to health, value capture, and the recognition of rights over drug development (Taubman, 2015). The principle of granting each individual what is due—suum cuique tribuere—has long represented the notion of responsibility and is one of the most fundamental ideas of justice. When viewed through the lens of equity in today's world, it allows us to address elements that prevent conflicts or mitigate harm (Lehtinen, 2021). However, behind the principle of equity lies the broader concept of justice, which ensures that the rights and positions of all parties are balanced, even if the legal solution is both lawful and just. This debate surfaces whenever access to medicines is discussed and regulated.

The state's intervention in this matter, while ostensibly aimed at achieving this balance, has in reality, as supported by reports from state bodies and other stakeholders, shifted the discussion away from health and access to medicines. Instead, the intellectual property regime has been misused and distorted to disrupt competition, hinder social progress, and ultimately lower the quality of life. This violates the very objective of international human rights instruments, where the enhancement of human dignity is achieved through the improvement of social conditions.

Conversely, undermining intellectual property rights violates the constitutional mandate of progress and diminishes Argentina's innovative and human potential as a sovereign nation. This is done to combat an imagined threat, unsubstantiated by local market data, that claims intellectual property rights harm industry development and negatively impact the economy.

The reality is that weakening the intellectual property system only impedes the construction of scientific, economic, social, cultural, educational, and human value. This leads to stagnation, dragging the country into greater dependency and, as a result, a loss of the essential conditions for social progress.

It is worth recalling the constitutional foundation of intellectual property rights. Our Constitution, in its original form, explicitly establishes in Article 17: "Property is inviolable, and no inhabitant of the Nation can be deprived of it except by virtue of a sentence based on law... Every author or inventor is the exclusive owner of his work, invention, or discovery for the term granted by law."

From this provision, two key conclusions can be drawn: first, deprivation of property requires a law, meaning another branch of the government (the legislative) must be involved. Second, and often overlooked, our Constitution originally stated that the only limitation on intellectual property rights is the term granted by law, signifying that the constitutional solution to balancing public and private goods lies in the temporal limit of exclusivity.

Furthermore, there are indications that the exclusivity system was chosen by the constitutional framers to organize and develop the country, as reflected in the original clause, now embedded in Article 75, Subsection 18: "To provide for the prosperity of the country, the advancement and well-being of all the provinces, and the progress of education by enacting plans of general and university instruction, promoting industry, immigration, the construction of railroads and navigable canals, the colonization of national lands, the introduction and establishment of new industries, the importation of foreign capital, and the exploration of interior rivers through laws protecting these objectives and by granting temporary privileges and incentives."

This spirit and value seem to have shaped the path of progress envisioned by our fundamental law, ensuring the fulfillment of the mandates contained in the preamble as a blueprint for local, federal, and national development.

Thus, the constitutional foundation of intellectual property rights, particularly patents, is deeply rooted and has been reaffirmed by the constituent power in the most recent constitutional reform of 1994. Not only were the relevant articles maintained, but the legislature was also entrusted with specific responsibilities, as outlined in Article 75.

In this context, Article 75, Subsection 19, stipulates: "It is the duty of Congress... To provide for human development, economic progress with social justice, the productivity of the national economy, the generation of employment, the professional training of workers, the defense of the value of the currency, scientific and technological research, its dissemination and application... To enact laws governing education that consolidate national unity while respecting provincial and local particularities; ensuring the State's non-delegable responsibility, the participation of the family and society, the promotion of democratic values, and equality of opportunity and possibilities without any discrimination[2]."

From this, it is clear that there is a need to encourage scientific development, integrate technology, and capture its economic and social value while ensuring that this development is non-discriminatory across sectors. This ensures that the benefits of freedom—in all its forms—are not only secured for us and our posterity but also for all those who wish to invest and develop within Argentina.

This means nothing more than creating the necessary conditions for intellectual property, in all its forms, to be enshrined as a means of human development and, with it, the protection of other rights that safeguard this progress.

With the 1994 constitutional reform, a series of treaties were incorporated into the constitutional framework, placing all rights on the same level and not establishing a normative hierarchy between human rights treaties and those recognized by the National Constitution, thus integrating them into the same constitutional framework.

The only hierarchical distinction superior to laws is granted to treaties mentioned in Article 75, Subsection 24, which are incorporated into national law as supreme, just below the National Constitution and the new constitutional framework.

Thus, the Constitution, its content, principles, and values, and its legal and political function, remain the focal point of legal and axiological reflection within the legal system.

Therefore, it is crucial to assess whether the regulation proposed by the Argentine State, through Joint Resolution 118/2012, 546/2012, and 107/2012[3], issued by the Ministry of Industry, the Ministry of Health, and the National Institute of Industrial Property, violates this constitutional framework or, on the contrary, harmonizes with it.

In this analysis, it is essential to address the international obligations that Argentina has assumed under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which was incorporated into national law through Law No. 24,425. TRIPS establishes minimum standards for intellectual property protection, including patents, that member states must adopt.

Articles 27 to 34 of TRIPS outline the general and specific conditions for patent protection. Specifically, Article 27 ensures that patents must be granted for any invention, whether product or process, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application. Moreover, patents must be granted without discrimination as to the place of invention, the field of technology, or whether products are imported or produced domestically.

2. See online: infoleg.gob.ar/?page_id=63
3. See online: boletinoficial.gob.ar/detalleAviso/primera/69099/20120508

This non-discrimination principle is fundamental under TRIPS, ensuring that all inventions are eligible for patent protection, provided they meet the three key requirements: novelty, inventive step, and industrial application. Additionally, Article 29 of TRIPS allows member states to impose conditions on patent applicants, such as requiring them to disclose the invention clearly and fully, so that it becomes part of the state of the art after the protection period ends. TRIPS also mandates, in Article 33, that patent protection lasts for 20 years from the filing date, a requirement mirrored in Argentina's national legislation under Law No. 24,481.

However, Argentina's patent "Guidelines" mistakenly assume that WTO member states have broad discretion in defining patentability standards such as "novelty" and "inventive step," which is incorrect. Under international law, the interpretation of treaty terms must follow commonly accepted definitions, not unilateral national interpretations.

Argentina's "Guidelines" have led to inconsistencies with its obligations under TRIPS Articles 27.1 and 29.1. These guidelines have resulted in discriminatory treatment of certain inventions, especially those in the pharmaceutical field, limiting patentability to specific types of compounds and compositions. Such restrictions conflict with the TRIPS mandate of equal treatment across all technological fields.

The interpretation of international treaties, including TRIPS, is governed by the 1969 Vienna Convention on the Law of Treaties, which dictates that treaty terms must be interpreted according to their ordinary meaning, taking into account the intention of the parties.

In the case of patentability under TRIPS, panels of the WTO and its Appellate Body have consistently ruled that treaty terms should not be subject to national legislative interpretations unless specifically defined by the treaty.

In cases like EC – Biotech, the WTO's Panel highlighted that the ordinary meaning of treaty terms can be informed by other international agreements and recognized references. Moreover, the Appellate Body has emphasized that any interpretation must reflect the parties' intent, as expressed in the treaty text and the surrounding context (WTO Panel, 2003).

In conclusion, Argentina's restrictive patent "Guidelines" conflict with the TRIPS standards, particularly with regard to non-discrimination in patent eligibility. Furthermore, Argentina's practices suggest a misapplication of TRIPS flexibilities, which, if stretched too far, undermine the minimum standards for intellectual property protection set by TRIPS. Member states must uphold these international obligations, and any deviation that erodes the protection of intellectual property rights risks being deemed illegitimate. This is further confirmed by the objective numbers and data accompanying this report, which illustrate the tangible impact of these inconsistencies.

4

THE EVOLUTION AND IMPACT OF PHARMACEUTICAL PATENT REGULATIONS IN ARGENTINA: A CRITICAL ANALYSIS OF MARKET DYNAMICS AND LEGAL FRAMEWORKS

The distinction between guidelines and norms lies primarily in their legal force and application. Guidelines are non-binding recommendations that provide guidance on how to act in specific situations, offering flexibility and discretion to those who choose to follow them. They are often used to promote best practices, but they do not carry the weight of law and are not enforceable. In contrast, norms are mandatory rules that set clear obligations and are often codified in laws or regulations. Norms are enforceable, and failure to comply can result in legal consequences. Thus, while guidelines offer a framework for ideal conduct, norms impose strict duties that must be followed under threat of sanction. This distinction is essential to understanding the impact of the "Patent Examination Guidelines" implemented in Argentina in 2012.

The title chosen for the *"Joint Resolution"* is particularly noteworthy, as the use of the term *"guidelines"* suggests a set of recommendations that, in theory, could be interpreted as flexible. However, in practice, these "guidelines" have acquired the force of mandatory norms, imposing a strict formalism that prioritizes procedural demands over substantive evaluation criteria. As a result, even if an invention meets the requirements of novelty, inventive step, and industrial applicability, it must strictly adhere to the examiner's interpretation of these guidelines, limiting the applicants' ability to protect their innovations.

This raises crucial questions about the intent behind these regulations and their real-world impact. Since their introduction in 2012, it has become evident that some of these protectionist measures, applied to key sectors such as pharmaceuticals and biotechnology, have used intellectual property regulations to establish market entry barriers. Among these measures are several joint resolutions that significantly hinder the competitiveness of Argentine companies on the global stage. Furthermore, Argentina's lack of adherence to the Patent Cooperation Treaty (PCT) adds another layer of complexity, limiting local innovators' ability to efficiently obtain international protection and forcing even state entities to seek alternative routes to benefit from international patent systems.

Beyond these procedural and regulatory issues, it is essential to analyze the market dynamics in which this conflict between intellectual property rights and access to medicines unfolds. Over the past 12 years since these guidelines were adopted, it has become increasingly clear that access to basic medicines in Argentina has become more complicated, raising doubts about whether the human right to healthcare is truly being safeguarded under the current regime.

This conflict can be framed as a dispute between two distinct sectors: one focused on intellectual property rights and the other on healthcare access, each representing divergent business models and market structures. At the institutional level, Argentine pharmaceutical companies are grouped into business chambers based on the origin of their capital, affinities, and shared interests (Ministry of Economy, 2022). These include:

a. Cámara Argentina de Especialidades Medicinales (CAEMe): Primarily composed of multinational pharmaceutical companies.

b. Centro Industrial de Laboratorios Farmacéuticos Argentinos (CILFA): Representing medium and large Argentine pharmaceutical companies.

c. Cooperativa de Laboratorios Argentinos (COOPERALA): Consisting of smaller Argentine pharmaceutical firms.

d. Cámara Argentina de Productores de Medicamentos Genéricos y de Uso Hospitalario (CAPGEN): A chamber of small laboratories that manufacture generic medicines locally.

This structure leads to a market where more than 70% is controlled by domestic laboratories, while less than 30% belongs to foreign and innovative companies (National Commission for the Defense of Competition, 2019). As a result, domestic companies wield considerable market power, allowing them to significantly influence the overall regulatory landscape and the allocation of intellectual property rights.

The production profile of these laboratories varies significantly based on the origin of their capital:

- Large Argentine laboratories produce medicines by processing active ingredients, mostly imported, and primarily differentiate their products through branding. They operate on a large scale, with limited investment in R&D, focusing on manufacturing products based on known and off-patent drugs. In some cases, they have faced lawsuits for using patented compounds.

- Smaller Argentine laboratories gained prominence after the enactment of the Generic Drugs Prescription Law, which allowed them to compete with lower-cost medicines under their own brands.

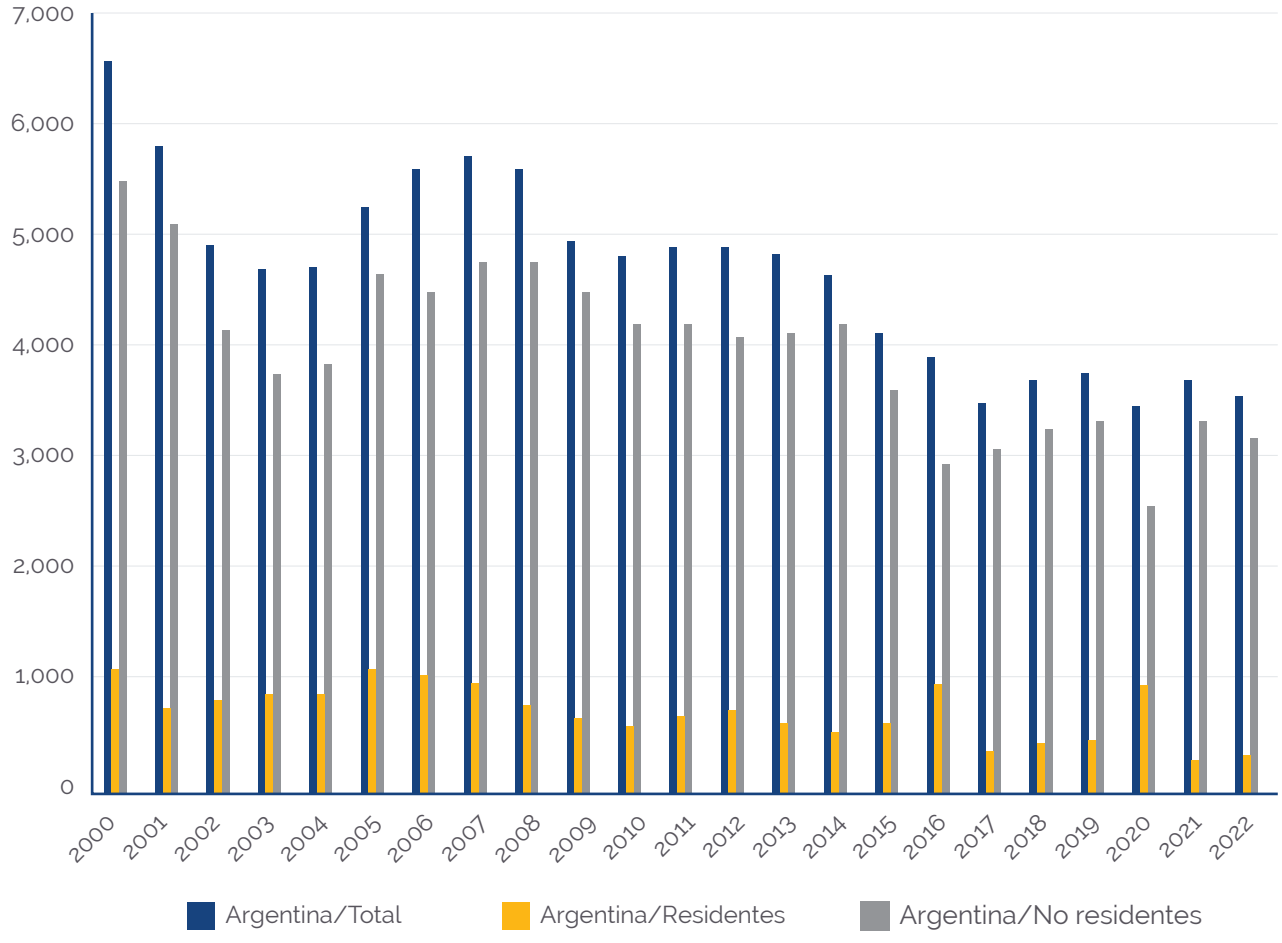
- Multinational laboratories focus primarily on marketing finished products supplied by their parent companies. They heavily invest in R&D, developing innovative products protected by intellectual property rights. Many outsource production or license the manufacturing of certain drugs to domestic laboratories, with over 30 licensing agreements currently in place between foreign and local companies.

Thus, the decision to innovate—or not—is a strategic choice for each actor in the value chain. In the pharmaceutical sector, those who invest in innovation and R&D gain a significant competitive advantage, not only in terms of value capture but also in providing more effective and efficient medical treatments for patients.

In this context, the Argentine government's decision to advance the 2012 regulations can be seen in light of market realities: 82% of circulating medicines have lost patent protection due to the passage of time, with the national sector dominating in terms of revenue. However, these figures also lead to questions about the broader effects of these regulations on Argentina's patent system, particularly in the pharmaceutical sector. To assess this, we turned to statistical data provided by the National Institute of Industrial Property (INPI) and the World Intellectual Property Organization (WIPO), which feeds into the World Bank's development reports (WIPO, 2022; INPI,2023).

A fair analysis of the situation requires a 20-year historical data series, from 2000 to 2022, allowing for a comparison of patent activity before, during, and after the implementation of these regulations. This analysis reveals that Argentina's patent system has steadily lost ground, with annual declines in patent filings ranging from 20.06% to 29.6%, affecting both foreign (non-resident) and domestic (resident) applicants (INPI,2023).

This data-driven approach reveals a troubling trend: Argentina's patent regime, particularly in the pharmaceutical sector, is becoming less attractive, driving innovators—both domestic and foreign—toward alternative strategies for protecting their intellectual property, often outside the country. Graphically, it can be represented as follows:



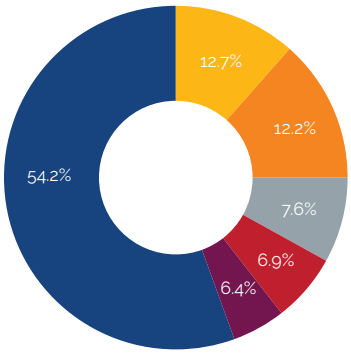
From these numbers[4], several key conclusions can be drawn:Z

- Argentina is primarily a technology-importing country and has not generated significant incentives in recent years to encourage its citizens to protect their innovations. The most pronounced decline in this regard occurred between 2017 and 2019.

- Non-resident (foreign) applicants have consistently outnumbered resident (domestic) applicants in terms of patent filings. The ratio has remained around 78% for non-residents and 22% for residents. The most notable reduction in this gap was observed in 2003.

- Since 2012-2013, the decline in patent filings has become more pronounced, with a steady decrease in the total number of applications filed.

This trend is further evidenced by the composition of technological fields in which patent applications are published each year. The most recent economic report from WIPO (WIPO, 2022), which is compiled biennially, provides the following breakdown of Argentina's technological fields:



Top technical fields; share

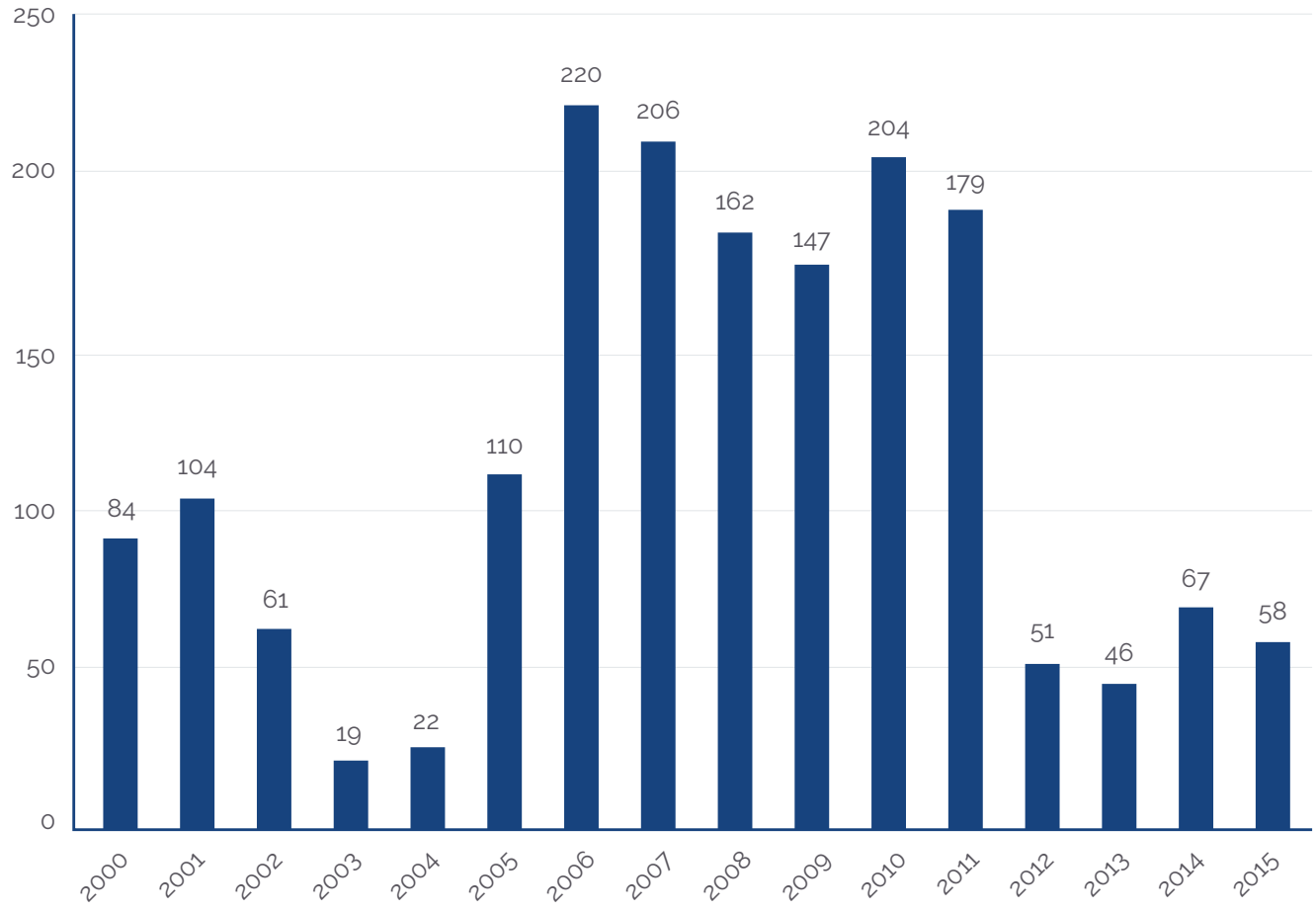
- Other special machines
- Civil engineering
- Furniture, games
- Medical technology
- Biotechnology
- Others

4. See Table 1 in the documentary annex.

Upon reviewing the chart, it is important to clarify that "medical technology" refers to machinery and medical products that do not include pharmaceuticals. Currently, these are grouped with other categories, with only 36 applications under evaluation as of today, most of which belong to a single applicant.

In a pool of over 3,000 patent applications, the fact that only 36 pertain to pharmaceuticals provides a clear indication of the impact of the "Guidelines." The first significant effect of these regulations can be seen in the reduced number of pharmaceutical patents approved by the National Institute of Industrial Property (INPI). Let us now turn to the statistics provided by the institution itself:

Granted pharmaceutical-chemical patents

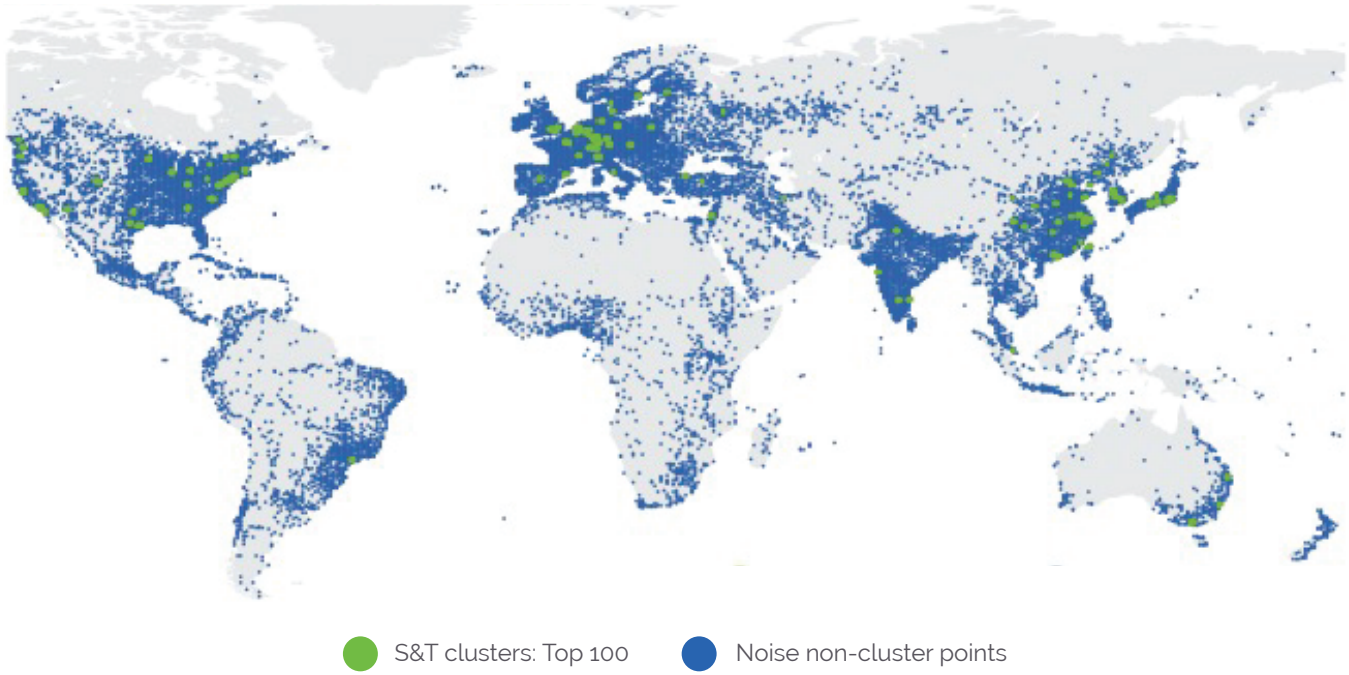


Patents for human use and veterinary use are considered, based on INPI statistics

As evident, the sharp decline in granted patent applications is not merely coincidental. Rather, it is a clear indication that the impact of the "Guidelines" has been decisive in driving up rejection rates at the patent office (INPI,2023).

In fact, Argentina was highlighted in the most recent Global Innovation Index by WIPO (WIPO,2023), where it was noted that the country has only a limited number of innovation clusters:

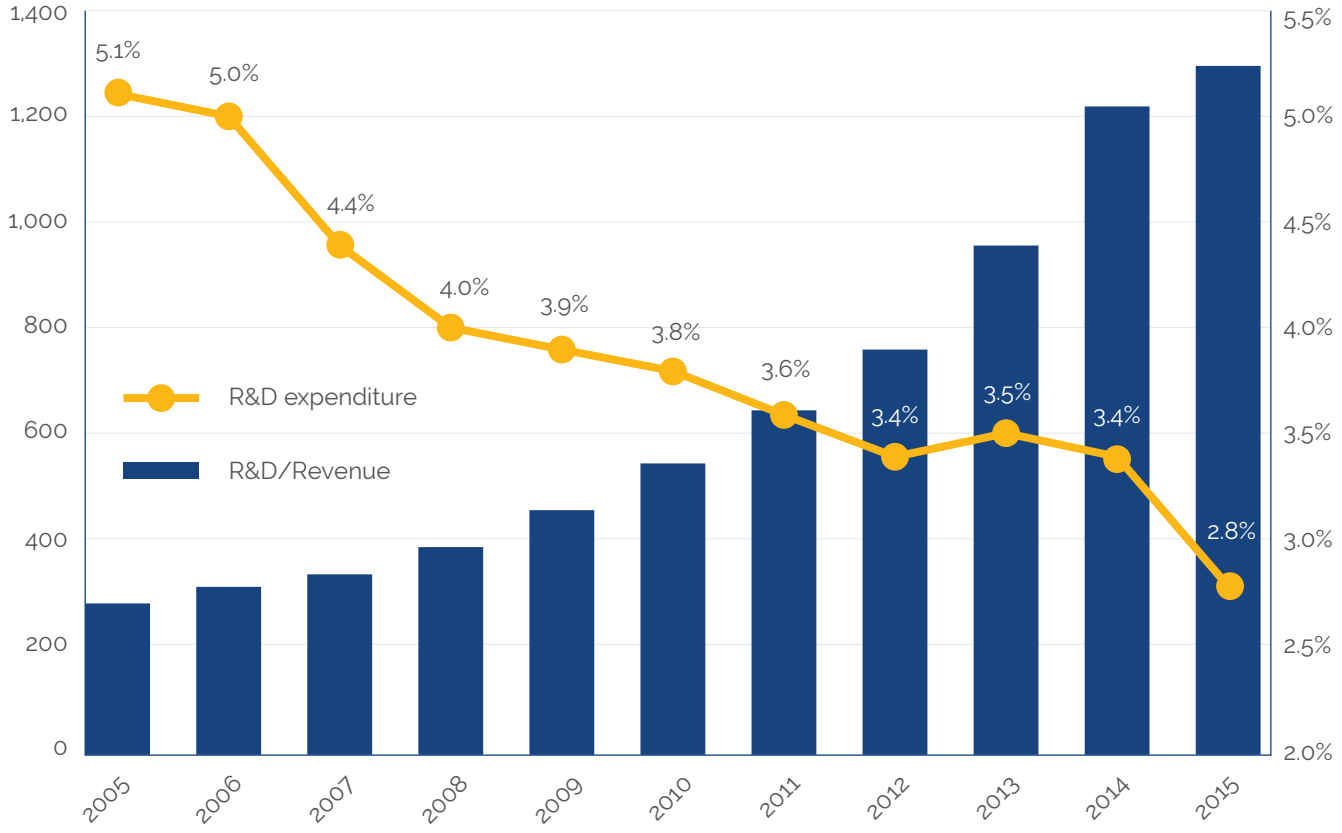
Map 1. Top 100 clusters worldwide, 2023



The justification for increasing formal requirements was allegedly to protect the national industry and prevent a flood of patents that could hinder access to medicines and inflate prices.

However, none of these concerns have materialized in practice. Instead, what is verifiable is that, in the years following the introduction of these "Guidelines," investment in Research and Development has experienced a significant decline:

Evolution of research and development expenditure in the pharmaceutical industry, expressed in millions of $



The chart reveals the stark reality reflected in the government's own statistics. Investment in R&D has consistently declined in the years following the approval of these regulations.

Following the logic that the "Guidelines" would contribute to effective regulation and provide a solution for the industry by applying TRIPS flexibilities, one would expect, based on the available statistical data, unrestricted access to medicines. The problem of scarcity would not exist, and medicines — even those for primary care — should be available at low cost.

Unfortunately, none of these outcomes are reflected in reality. In the absence of a patent protection system that effectively serves all industries, the result has been the opposite of what was intended. Instead of promoting access and reducing costs, the regulations have led to price increases for non-patented products, thereby raising the barriers to access. This has also increased the burden on public health spending, as the government, through its social security system, is the primary purchaser of these medical supplies.

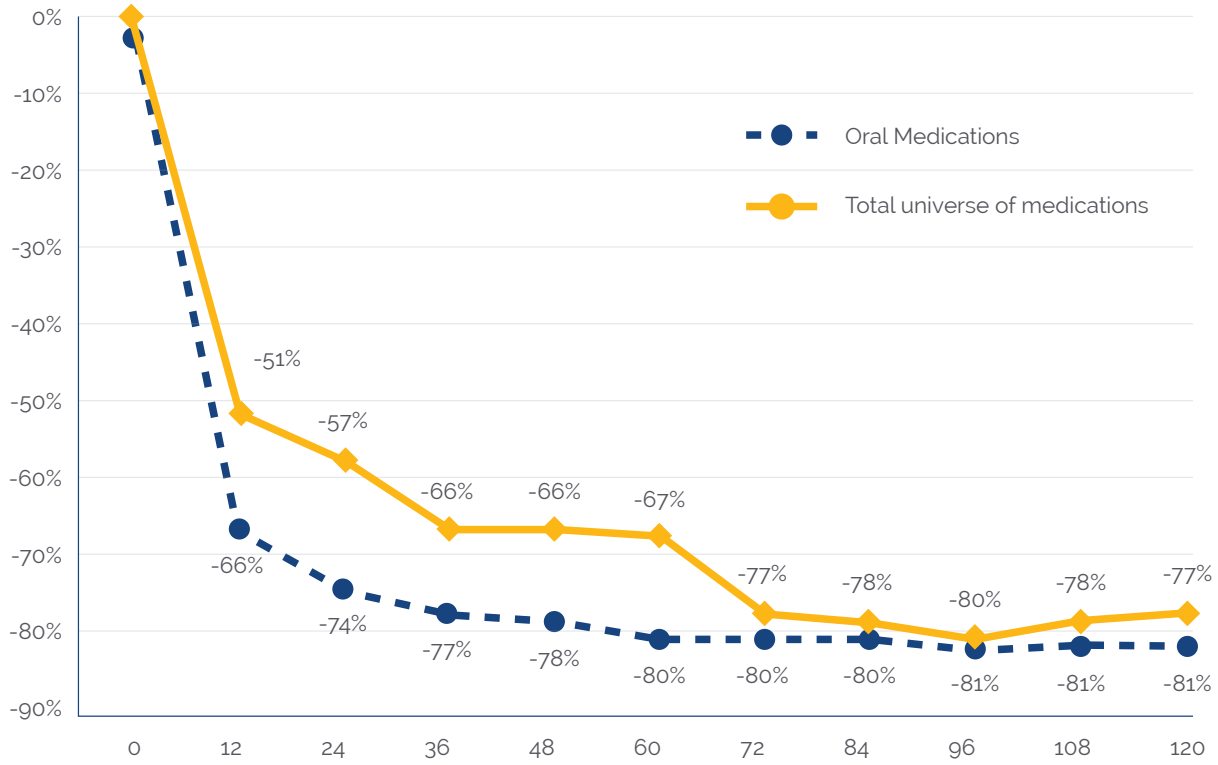
The situation is straightforward: there is no threat of competition, and instead of fostering exclusivity to encourage innovation, a monopoly has been built in favor of the non-innovator. Let us examine some examples of national and foreign medicines, comparing generic copies and original drugs of the same compound, and we will see the price differences, following the historical series of data collected by INDEC[5].

From this simple historical series, it can be concluded that establishing restrictive guidelines on the patentability regime leads to the loss of the price-lowering effect that typically occurs when a patent expires. In other words, the price of the patented product decreases, which in turn increases the presence of competitors in the market, often resulting in a significant share of generic medicines.

This effect of losing exclusive rights is not observed in our country, but let's consider the case of the European community, particularly Spain. A free report by the consulting firm IQVIA titled *"Dynamics of Generics and Brands: What to Expect After Patent Expiration?"* demonstrates how prices fall upon patent expiration, and local competitors gradually increase their market presence. In this way, the phenomenon of building a strong patent system does not distort the market or create a monopoly. Rather, it fosters conditions for a better quality of life and enables greater access to healthcare and medicines at more affordable prices and with improved medical efficacy.

It is crucial to present a graph to clearly illustrate the importance of a robust patent system and its impact on public goods when patent protection expires.

Average price variation of a drug after the loss of exclusivity (every 12 months)



5. See Table 2 in the documentary appendix

Consequently, it can be observed that within 12 months of a drug's patent expiration, prices drop by approximately 77%, demonstrating that the patent system is effective.

Upon the cessation of exclusivity, competitors enter the market, leading to a significant reduction in price. This situation, however, is not reflected in Argentina, where prices of non-patented medicines remain stable, and in some cases, domestic products are priced higher than their foreign counterparts.

5

IMPACT OF PATENTS ON INNOVATION AND ACCESS TO MEDICINES: AN INTERNATIONAL COMPARISON OF PRACTICES AND OUTCOMES IN OTHER COUNTRIES

The Argentine "Guidelines" establish certain criteria that are inconsistent with the country's obligations under Article 27.1 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), specifically regarding non-discrimination in the granting of patents based on the technological field of the invention. These discrepancies are manifested in specific restrictions applied exclusively to pharmaceutical inventions, including but not limited to:

1. **Specific Restrictions on Pharmaceutical Compounds:** The "Guidelines" apply patentability standards that specifically exclude certain chemical forms such as polymorphs, pseudo-polymorphs, and enantiomers when they have pharmaceutical applications, whereas similar compounds in other industrial sectors do not face these restrictions. However, when it comes to veterinary products, the application is the opposite, as seen in: Application No. 20180101458 - VETERINARY VACCINE COMPOSITION COMPRISING AN ANTIGEN COMPONENT AND AN ADJUVANT FORMULATION (INPI, 2023) *Claim 1: A vaccine composition comprising an antigen component and an adjuvant formulation, the adjuvant formulation comprising a triterpenoid saponin, a sterol, a quaternary ammonium compound, and a polyacrylic acid polymer, wherein the antigen component comprises feline leukemia virus. Claim 3: The vaccine composition of claim 1, wherein the saponin is Quil A or a purified fraction thereof, the sterol is cholesterol, and the quaternary ammonium compound is DDA.* Similarly, Application No. 20150104276 - AZOLINE COMPOUNDS SUBSTITUTED WITH A FUSED RING SYSTEM, AGRICULTURAL OR VETERINARY COMPOSITION, AND SAID COMPOUNDS FOR USE IN PROTECTING PROPAGATION MATERIAL OF PLANTS AND/OR PLANTS FROM ATTACK OR INFESTATION BY INVERTEBRATE PESTS (INPI,2023).

2. **Exclusion of Active Metabolites and Prodrugs:** Active metabolites are declared non-patentable *per se* if they have pharmaceutical applications, and additional disclosure requirements are imposed on prodrugs that are not required for chemical compounds with non-pharmaceutical purposes.

3. **Differential Treatment for Pharmaceutical Compositions:** The "Guidelines" state that the disclosure of a genus of pharmaceutical compositions anticipates and excludes the patentability of individual species within that genus, a restriction not applied to chemical compositions outside the pharmaceutical sector. For example, the INPI grants patents for veterinary pharmaceutical compositions, such as: *Application No. 20190102624 - SOFT VETERINARY CHEWABLE COMPOSITION FOR TREATING AND/OR PREVENTING INFECTION OR INFESTATION OF PARASITES IN AN ANIMAL (INPI, 2023).*

4. **Special Disclosure Obligations:** Additional disclosure obligations are imposed for manufacturing methods of active pharmaceutical ingredients that are not required for methods intended to produce non-pharmaceutical chemical compounds.

These differentiated practices, limited solely to pharmaceutical applications, constitute discrimination against innovation in the pharmaceutical field, directly contravening the TRIPS mandates that require equal treatment for inventions across all technological fields. We can summarize all the restrictions in the following table:

REGULATION	DESCRIPTION	IMPACT
POLYMORPHS AND PSEUDO-POLYMORPHS	The "Guidelines" prohibit the patentability of compositions containing polymorphs and pseudo-polymorphs. These crystalline forms, although chemically identical, can have different physical and chemical properties, such as greater stability and better dissolution properties.	The prohibition of patenting these innovations ignores their technical, commercial, and therapeutic value, contradicting Article 27.1 of TRIPS. Before the "Guidelines," INPI recognized the patentability of polymorphs that demonstrated improved properties.
ENANTIOMERS	The "Guidelines" do not consider pure enantiomers derived from previously known racemic mixtures to be novel, even though they can have unique pharmacological properties. Separating and purifying enantiomers is a complex process that can result in safer and more effective drugs.	This simplified interpretation of novelty discourages research and development in the pharmaceutical field. Recognizing the patentability of pure enantiomers would incentivize investment in pharmaceutical research and foster the development of new drugs.
SALTS, ESTERS, AND DERIVATIVES	The "Guidelines" deem salts, esters, and other derivatives of known substances to be non-patentable, which contradicts established scientific principles that state a modified molecule is chemically distinct from its original form.	Denying the patentability of these compounds on the grounds of lack of novelty violates Article 27.1 of TRIPS. This could hinder innovation in the field of pharmaceutical chemistry and limit the development of new therapeutic options.
ACTIVE METABOLITES	The "Guidelines" declare that active metabolites are non-patentable, even though these metabolites can have different safety and efficacy profiles compared to the original compound.	The blanket exclusion of metabolites as patentable contradicts Article 27.1 of TRIPS. Active metabolites can have therapeutic properties that justify their patentability as new compounds.

REGULATION	DESCRIPTION	IMPACT
PRODRUGS	The "Guidelines" impose additional patentability requirements on prodrugs, including proof that the prodrug is inactive until converted in the body and achieves an effective therapeutic level.	Imposing additional patentability requirements on prodrugs exceeds the scope of TRIPS, resulting in an undue burden on innovators that is not permitted under Articles 27.1 and 29.1. These requirements could obstruct the protection of novel pharmaceutical inventions.
FORMULATIONS	The "Guidelines" consider new pharmaceutical formulations and compositions, including controlled-release formulations, to be obvious unless there is evidence of unexpected results or commercial success.	This broad application of the "obviousness" standard limits innovation in pharmaceutical formulations. By pre-emptively excluding new compositions, the "Guidelines" contravene the requirement under TRIPS for individualized assessments of inventive step.

The analysis of the Argentine "Guidelines" highlights their inconsistency with international standards, particularly with the principles established under the TRIPS Agreement. The restrictions placed on pharmaceutical innovations, including specific limitations on patentability and differential treatment compared to other technological sectors, constitute a clear violation of the non-discrimination principle mandated by TRIPS. This selective application of more stringent requirements for pharmaceutical inventions discourages innovation in a critical field, undermining the progress of healthcare and medical advancements.

INTERNATIONAL COMPARATIVE EXPERIENCE

The international patent office's such as the EPO, USPTO, and INPI Brazil adopt more flexible approaches to pharmaceutical innovations claims and other chemical compound patents, encouraging a broader scope of protection for innovations (Martin,2023). Argentina's overly restrictive framework not only places it at odds with global intellectual property standards but also risks stifling innovation in the pharmaceutical industry—a sector that is essential for public health and the development of life-saving treatments. Aligning its "Guidelines" with international best practices would create a more equitable and supportive environment for pharmaceutical research and innovation.

The following table provides a detailed comparison of how different patent offices—specifically in Argentina, the European Union, the United States, and Brazil—approach the evaluation of Markush formulas in patent applications, particularly in the pharmaceutical sector. The table highlights the differences in how these jurisdictions treat the scope of claims, the necessity of examples, and the flexibility afforded to applicants. In Argentina, a notably restrictive approach is applied, limiting the scope of Markush claims to those compounds explicitly exemplified in the specification, as seen in Patent AR 092749 B1(Martin, 2023).

This contrasts with the more flexible approaches adopted by the European Patent Office (EPO), the USPTO in the United States, and the Brazilian INPI, which allow broader protection for chemical compounds through Markush claims. For instance, Patent EP 3523299 B1 in the EPO and its equivalent, Patent BR 112015007422 B1 in Brazil, illustrate how these offices accept broader claims without restricting them to specific examples (Martin, 2023). By comparing these systems, it becomes evident that Argentina's strict policies may hinder innovation, while more flexible systems in other jurisdictions foster a broader scope of protection for pharmaceutical inventions (Martin,2023).

PATENT OFFICE	DESCRIPTION OF APPROACH TO MARKUSH FORMULAS	EXAMPLE	IMPACT
INPI ARGENTINA	In Argentina, patent applications containing Markush formulas in the pharmaceutical sector face a restrictive approach under the "Guidelines" established by Joint Resolution 118/2012, 546/2012, and 107/2012. Examiners often limit the scope of claims only to compounds that are clearly exemplified and characterized in the specification. This restrictive approach is inconsistently applied depending on the technological area.	Patent AR 092749 B1 - Granted in July 2022. The examiner limited the scope strictly to the compounds exemplified in the specification, following multiple reviews.	This strict approach can hinder innovation in the pharmaceutical sector and create disparities in patent evaluations across different fields. It also generates uncertainty for applicants, affecting the effective protection of their inventions.
EUROPEAN PATENT OFFICE (EPO)	The EPO adopts a particular approach to Markush formulas, focusing on the sufficiency of disclosure and inventive step. The EPO's guidelines stipulate that alternatives in a Markush claim must share a common property or function and a significant structural element. Additionally, sufficient examples must be provided in the application.	Patent EP 3523299 B1 - Approved by the EPO. This European patent covers a wide range of compounds in the pharmaceutical sector.	The EPO allows greater flexibility in the scope of claims if adequately justified. This incentivizes applicants to seek protection for a broader range of chemical compounds, as long as the invention is well-supported by examples and specific details, promoting innovation.
USPTO (UNITED STATES)	In the United States, the Manual of Patent Examining Procedure (MPEP) treats Markush formulas as claims listing alternatives that must share structural similarities and a common use. The evaluation of the unity of invention is crucial, and the application must provide a clear description and meet the enablement requirements. The USPTO also introduces the concepts of "genus" and "species" claims.	Patent BR 112015007422 B1 - The Brazilian equivalent to an EPO patent. The Markush claim had a broad scope without being restricted to specific examples.	Markush formulas enjoy strong protection in the United States, allowing applicants greater freedom to include a wide range of compounds within a single claim. The system supports more extensive protection as long as the invention meets the strict enablement and description requirements, encouraging innovation and comprehensive patent protection.

PATENT OFFICE	DESCRIPTION OF APPROACH TO MARKUSH FORMULAS	EXAMPLE	IMPACT
INPI BRAZIL	The Brazilian INPI's Patent Examination Guidelines dedicate a specific chapter to analyzing Markush formulas. These are considered patentable if they meet the criteria of novelty and inventive step. Compounds are considered novel if an expert in the field would not be motivated to modify the structure or if they demonstrate an unexpected technical effect.	Patent WO2020037438A1 - Nanostructured nanoparticles for treating diseases. This Brazilian application used Markush claims to cover multiple active ingredients.	The INPI Brazil is more flexible than Argentina, as it does not require that claims be strictly limited to the provided examples. This allows applicants to protect a wider range of compounds as long as they can demonstrate an unexpected technical effect or justify the novelty of the claimed combinations.

Note: *For this analysis, see the work of Diego Martin (Martin, 2023)*

COMPARATIVE OVERVIEW OF PATENT REGULATIONS IN LATIN AMERICA: KEY DISCREPANCIES AND IMPACT ON INNOVATION

The comparative analysis of patent regulation across various Latin American countries, as seen in Table 3 in the annex (Bensadon et all, 2024), highlights significant discrepancies in the treatment of patentable subject matter, particularly in the pharmaceutical sector. While countries like Brazil, Colombia, and Chile maintain broad acceptance of patent claims on compounds, compositions, combinations, and formulations, Argentina's current legal framework imposes significant restrictions, barring patentability in several categories such as polymorphs, enantiomers, and second medical uses. This shift in the Argentine patent regime since the enactment of the "Pautas" has led to a marked decline in patent applications in critical sectors, thereby diminishing incentives for innovation.

Furthermore, Table 3 reveals that in most of the countries reviewed, including Mexico, Uruguay, and Paraguay, formulations, Markush claims, and even metabolite-related patents are generally accepted without restriction. In contrast, Argentina has applied unique and stringent limitations, denying protection in areas where its regional counterparts are more permissive. This has created an uneven playing field and has generated additional barriers to market entry for pharmaceutical innovators, as the lack of protection for key innovations in Argentina discourages investment and technological development.

In addition to highlighting these disparities, Table 3 also illustrates that Argentina's patent restrictions, justified under the guise of safeguarding public health and ensuring access to medicines, stand out as the most severe compared to neighboring countries. This demonstrates a misalignment with international norms under the TRIPS Agreement, which stipulates non-discriminatory protection across all technological fields. The legal inconsistencies and regulatory hurdles outlined in the annexed table further emphasize the negative impact that Argentina's patent regime is having on both domestic innovation and international competitiveness.

COMPARATIVE SUMMARY OF THE REGULATORY FRAMEWORK

To recap, we can establish that INPI's practice has changed significantly and has become contradictory following the approval of the "Guidelines," as actions that were previously allowed are now prohibited.

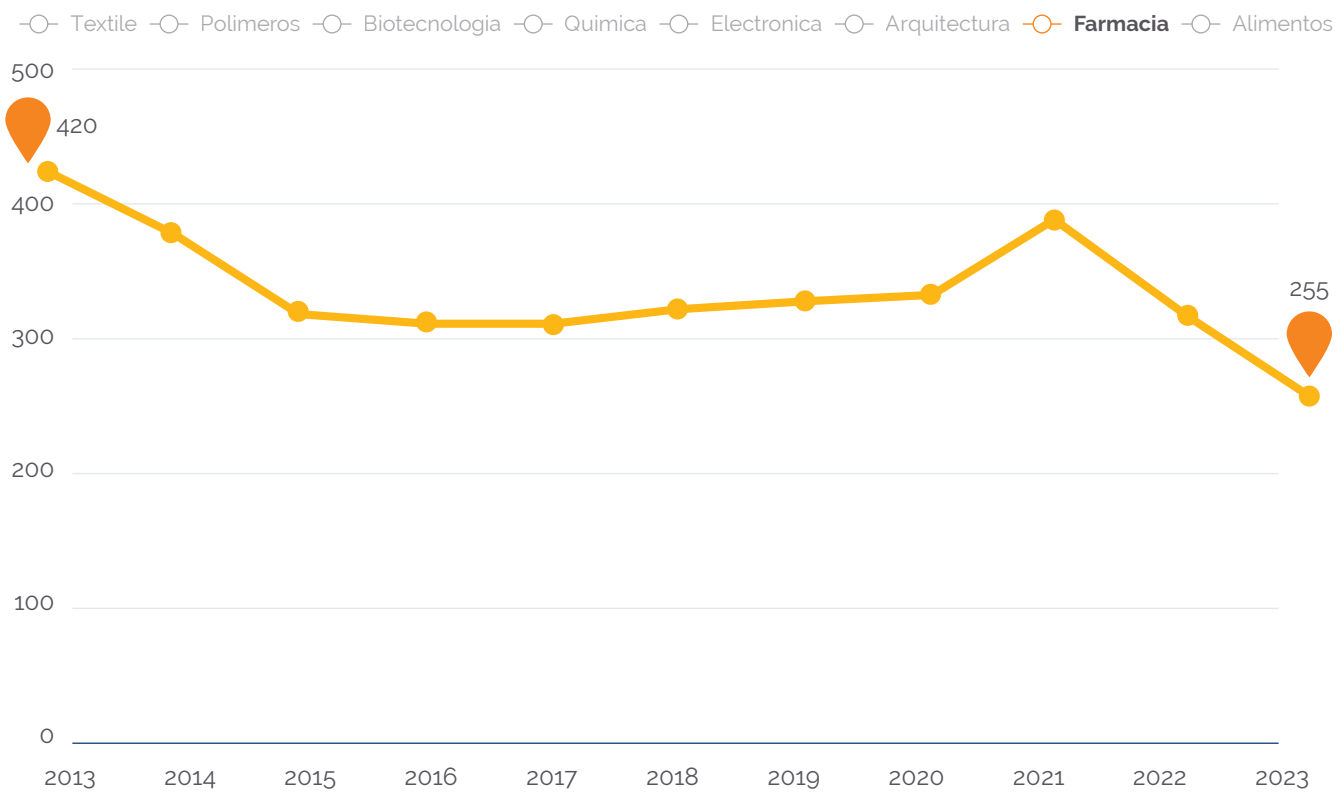
We can observe a comparison between the previous regulatory framework and the current one, as follows:

TECHNOLOGICAL FIELD	BEFORE THE JOINT RESOLUTION	AFTER THE JOINT RESOLUTION
POLYMORPHS – PSEUDO POLYMORPHS	Yes	No
ENANTIOMERS	Yes	No
MARKUSH CLAIMS	Yes	No
SELECTION INVENTIONS	Yes	No
SALTS, ESTERS, AND OTHER DERIVATIVES	Yes	No
FORMULATIONS AND COMPOSITIONS	Yes	No
COMBINATIONS	Yes	No
DOSAGE / DOSING	Yes	No
SECOND MEDICAL USES	Yes	No
ANALOGOUS PROCEDURES	Yes	No

As evidenced, the change in criteria by INPI and the National Government is based on an improper adaptation of the use of "flexibilities," resulting in the distortion of the patent system. Furthermore, the excessive and abusive use of TRIPS Agreement flexibilities by the National Government has had a direct effect, as demonstrated in this study, weakening the intellectual property system, discouraging investment in innovation, and negatively impacting economic development and job creation in high-tech sectors.

It is crucial to understand that preventing the possibility of patenting compromises the sustainability of the healthcare system and future research.

This last point is confirmed by data published by INPI, which shows a 50% decline in patent applications in this technological field (INPI, 2023):



The data extends only until 2013, preventing an assessment of prior situations. However, each year the disincentive grows, further reducing the availability of technology.

It is also worth noting that applications from domestic applicants do not exceed 20% of the total applications filed in Argentina.

6

OVERVIEW OF THE ARGENTINE STATE'S ACTIVITIES AND PUBLIC ADMINISTRATION INVOLVEMENT IN INTELLECTUAL PROPERTY

This report highlights that, while the Argentine State imposes restrictive patent guidelines domestically, it simultaneously develops and manages Markush formulas through its own agencies in foreign patent systems. Despite the stated goal of protecting public goods like access to healthcare and the restrictive interpretation of TRIPS rights, Argentina implements different practices abroad. This divergence suggests that the true objective of the "Guidelines" may be to create indirect market entry barriers to protect specific national industries rather than uphold the principles of free competition.

For example, patent applications filed in the European Patent Office (EPO) on behalf of Argentine entities such as CONICET (National Scientific and Technical Research Council) demonstrate how Argentina actively seeks patent protection for complex chemical compounds, including Markush formulas, in other jurisdictions. This duality points to a broader strategy aimed at protecting national industries domestically while pursuing intellectual property rights abroad.

EXAMPLE 1: PHARMACEUTICAL COMPOSITION FOR TOPICAL WOUND TREATMENT

- PCT Application: WO2021046290A1
- Description: A pharmaceutical composition for treating wounds, including nitrogenous heterocyclic compounds, enzymes, and carboxylic acids. The application, with over 20 examples of use, has passed patentability reviews across multiple jurisdictions without challenges regarding novelty or inventive step.
- Jurisdictions: Argentina, Australia, Brazil, Canada, Europe, Japan, and others.
- Comments: The wide scope of claims, such as "5 or 6 atoms" and "one or more compounds," indicates that Argentina, despite domestic restrictions, supports broad claims in foreign patent offices.

EXAMPLE 2: ANTIMICROBIAL PEPTIDES AND THEIR USES

- PCT Application: MX360559B
- Description: Antimicrobial peptides with activity against both gram-positive and gram-negative bacteria. The broad claims were accepted in multiple jurisdictions, reflecting Argentina's commitment to securing intellectual property rights abroad.
- Comments: The approval of this application across various jurisdictions reinforces the notion that Argentina recognizes the importance of patent protection on a global scale.

EXAMPLE 3: PHARMACEUTICAL COMPOSITION IN POWDER FOR ALZHEIMER'S TREATMENT

- PCT Application: WO2020208398A1
- Description: A pharmaceutical composition for cognitive deterioration associated with Alzheimer's disease, including memantine and donepezil in extended-release microgranules.
- Markush Claims: Yes
- Comments: The use of broad Markush claims demonstrates how Argentine laboratories, like Bagó, actively protect their innovations abroad, despite domestic restrictions.

These examples reveal that Argentina actively protects intellectual property internationally, while the "Guidelines" serve as a domestic barrier to market entry, favoring specific sectors of the national economy. Reports from the National Competition Defense Commission and the Ministry of Economy confirm that the pharmaceutical sector, dominated by non-innovative companies producing off-patent drugs, benefits from this protectionist stance.

7

CONCLUSION & KEY POLICY SUGGESTIONS

The analysis presented in this report highlights critical issues in the current patent system in Argentina, particularly following the implementation of the "Guidelines." These regulations, while intended to align with international frameworks like the TRIPS Agreement, have had the unintended consequence of weakening the intellectual property regime, discouraging innovation, and limiting technological advancement. Based on these findings, several key policy suggestions emerge:

1. **Rescind the "Guidelines" to Align with International Standards:** Argentina should reassess its restrictive patent guidelines, particularly those targeting the pharmaceutical sector, to align with international practices. This would ensure compliance with the TRIPS Agreement, especially regarding non-discrimination across technological fields.

2. **Foster Innovation by Reducing Bureaucratic Barriers:** The overly restrictive interpretation of patentability criteria, such as for polymorphs, enantiomers, and Markush claims, should be reconsidered. Simplifying these processes and allowing broader claims, as seen in other jurisdictions like the EPO and USPTO, would encourage innovation and investment in high-tech sectors.

3. **Promote Transparent and Consistent Application of Patent Laws:** Addressing the inconsistency in the evaluation of patent applications across different technological areas is critical. Clear and uniform guidelines should be established to ensure fairness and transparency in the examination process, which will build trust among inventors and investors.

4. **Encourage Investment in Research and Development:** Policies should be introduced to incentivize domestic innovation, particularly in the pharmaceutical and biotechnology sectors. This includes offering tax incentives, grants, or other financial support to encourage companies to file patents and invest in R&D activities.

5. **Strengthen Collaboration with International Patent Systems:** Argentina should foster stronger relationships with international patent systems and leverage the PCT mechanism to ensure that domestic innovators have access to international protection. This would not only improve the competitiveness of Argentine companies but also enhance the country's integration into global innovation networks.

6. **Enhance Public Awareness and Support for Intellectual Property:** Educating both the public and policymakers about the importance of intellectual property rights for economic growth, healthcare sustainability, and technological development is essential. A broader understanding of the benefits of a robust patent system will help garner support for reforms that promote innovation.

By implementing these key policy suggestions, Argentina can create a more balanced and effective patent system that fosters innovation, aligns with international best practices, and drives economic growth in critical sectors like pharmaceuticals and technology.

8

REFERENCES

- Alberdi, J. B. (1873). *Bases y puntos de partida para la organización política de la República Argentina*. Asociación de Abogados y Abogadas de Buenos Aires.
- Bensadon, M et. all (2024), *Derecho de Patentes*. Abeledo Perrot, Buenos Aires, Argentina
- Breuer Moreno, Pedro C. (1957). *Tratado de patentes de invención*, Abeledo-Perrot, Buenos Aires.
- IMS HEALTH (2015), *GLOBAL INDEX*.
- IQVIA (2022) *"Dynamics of Generics and Brands: What to Expect After Patent Expiration?"*.
- Lehtinen, L.M. (2021). Intellectual Property: Reforming its Concept as the Realization of a Social Good – From Ius Excludendi to Ius Innovationis, Working Paper CPI, Austral University.
- Martin, D. F. (2023). *Solicitudes De Patente Relacionadas Con Compuestos Químicos - Análisis y propuesta de criterios en el estudio de fórmulas Markush*. Universidad Austral Ediciones.
- Ministry of Economy, available online: argentina.gob.ar/sites/default/files/industria_farmaceutica_-_version_web_febrero_2022.pdf and Opinion No. IF-2019-111971583-APN-CNDC#MPYT – National Commission for the Defense of Competition.
- Mitelman, C.O. (2022), *Tratado de la Propiedad Industrial* – Tomo 3° - Invenciones y Otras Innovaciones, Editorial ElDial.com.
- National Institute of Intellectual Property (2023), online data base for patents, available online: datos.inpi.gob.ar/Home/PatentesAreaTecnica.
- Rapela, M. A., & Lehtinen, L. M. (2021). COVID-19, Patentes y Vacunas: ¿Acceso o Transferencia de Tecnología?. El Dial.com.
- Seymore, S. B. (2008). Heightened Enablement in the Unpredictable Arts. UCLA Law Review, 56(127-168).
- Schötz, G. J., Iannello, P., Migliore, J., & Núñez, J. F. (2013). Patentes y medicinas esenciales: La armonización entre el derecho a la salud y la propiedad intelectual. Editorial Heliasta.
- Taubman A. (2015) - *TRIPS Jurisprudence in the Balance: Between the Realist Defense of Policy Space and a Shared Utilitarian Ethic* - Social Science Research Network Legal Scholarship Network ANU College of Law Research Paper No. 08-10 – online: *ssrn.com/AbstractID=1130683*
- WIPO (2022). *Global Innovation Index.*
- WIPO (2023). *Global Innovation Index.*
- WTO (2003). *EC Biotech - Panel*
- Zuccherino, D., & Mitelman, C. (1994). Derecho de Patentes: Aislamiento o Armonización. Editorial Ad-Hoc.

- Zuccherino, D., & Mitelman, C. (1995). El Derecho de Propiedad del Inventor. Editorial Ad-Hoc.
- Zuccherino, D., & Mitelman, C. (1997). Marcas y Patentes en el GATT: Régimen Legal. Editorial Abeledo-Perrot.
- Zuccherino, D., & Mitelman, C. (1998). Patentes de Invención: Introducción al estudio de su régimen legal. Editorial Ad-Hoc.
- Zuccherino, D., & Mitelman, C. (2000). Derecho Económico Empresarial. Editorial Errepar.
- Zuccherino, D., & Mitelman, C. (2006). Código de Comercio Comentado (Tomo 6: Propiedad Industrial). Ed. Hammurabi.
- Zuccherino, D., & Mitelman, C. (2016). Patents Throughout the World. Thomson Reuters.

8

APPENDIX

Table 1

		2000	2001	2002	2003	2004	2005
ARGENTINA	RESIDENTS	1 062	691	718	792	786	1 054
ARGENTINA	NO RESIDENTS	5 574	5 088	4 143	3 765	3 816	4 215
ARGENTINA	TOTAL	6 636	5 779	4 861	4 557	4 602	5 269

		2005	2006	2007	2008	2009	2010
ARGENTINA	RESIDENTS	1 054	1 020	937	801	640	552
ARGENTINA	NO RESIDENTS	4 215	4 597	4 806	4 781	4 336	4 165
ARGENTINA	TOTAL	5 269	5 617	5 743	5 582	4 976	4 717

		2011	2012	2013	2014	2015	2016
ARGENTINA	RESIDENTS	688	735	643	509	546	884
ARGENTINA	NO RESIDENTS	4 133	4 078	4 129	4 173	3 579	2 925
ARGENTINA	TOTAL	4 821	4 813	4 772	4 682	4 125	3 809

		2017	2018	2019	2020	2021	2022
ARGENTINA	RESIDENTS	393	425	442	930	406	444
ARGENTINA	NO RESIDENTS	3 050	3 242	3 260	2 562	3 263	3 132
ARGENTINA	TOTAL	3 443	3 667	3 702	3 492	3 669	3 576

Note: *The number of patent applications submitted by residents and non-residents in Argentina is presented based on cross-referenced data from the World Bank and the World Intellectual Property Organization (WIPO). This data provides a comprehensive view of patent filing trends and highlights the differences between domestic and foreign applicants within the Argentine patent system.*

Table 2

ACTIVE INGREDIENT	PRESENTATION	LABORATORY	MEDICATION	TOTAL (IN ARS)
ADALIMUMAB	40mg/0.8ml lap.prell.x 2	Laboratory 1	Medication 1	$ 924,306
		Laboratory 2	Medication 2	$ 506,221
BEVACIZUMAB	100 mg/4 ml a.x 1	Laboratory 1	Medication 1	$ 594,791
		Laboratory 2	Medication 2	$ 533,506
		Laboratory 3	Medication 3	$ 900,612
		Laboratory 4	Medication 4	$ 1,071,141
	400 mg/16 ml a.x 1	Laboratory 1	Medication 1	$ 2,166,504
		Laboratory 2	Medication 2	$ 1,943,274
		Laboratory 3	Medication 3	$ 3,282,250
		Laboratory 4	Medication 4	$ 3,901,586
INFLIXIMAB	100 mg f.a.x 1	Laboratory 1	Medication 1	$ 446,553
		Laboratory 2	Medication 2	$ 477,565
		Laboratory 3	Medication 3	$ 354,407
RITUXIMAB	100 mg vial x 2	Laboratory 1	Medication 1	$ 769,208
		Laboratory 2	Medication 2	$ 625,114
	100 mg/10 ml f.a x 2	Laboratory 1	Medication 1	$ 729,966
		Laboratory 2	Medication 2	$ 1,250,241
	500 mg vial x 1	Laboratory 1	Medication 1	$ 1,923,018
		Laboratory 2	Medication 2	$ 1,559,137
	500 mg/50 ml f.a x 1	Laboratory 1	Medication 1	$ 1,824,913
		Laboratory 2	Medication 2	$ 3,125,601
TRASTUZUMAB	420 mg vial x 1	Laboratory 1	Medication 1	$ 1,639,683
		Laboratory 2	Medication 2	$ 1,760,452

Note: *All amounts are expressed in Argentine pesos (ARS). The value of the medication belonging to an innovative laboratory, which does not rely on a copy-based model, is highlighted in red. This distinction emphasizes the importance of original research and development efforts in the pharmaceutical industry, showcasing the price difference compared to generic or copy-based alternatives.*

Table 3 *(Bensadon et all, 2024)*

COUNTRY	AR	BO	BR	CL	CO	CR	EC	SV	GT	HN	MX	NI	PA	PY	PE	DO	UY	VE
COMPOUNDS	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
COMPOSITIONS	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
COMBINATIONS	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
FORMULATIONS	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
DOSAGES	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
INTERMEDIARIES	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
SALTS	No	Yes	Yes	Yes	Yes	Yes	Yes*	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes*	Yes	Yes	No
ESTERS	No	Yes	Yes	Yes	Yes	Yes	Yes*	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes*	Yes	Yes	No
SOLVATES	No	Yes	Yes	Yes	Yes	Yes	Yes*	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes*	Yes	Yes	No
ENANTIOMERS	No	Yes	Yes	Yes	Yes	Yes	Yes*	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes*	Yes	Yes	No
METABOLITES	No	Yes	Yes	Yes	Yes	Yes	Yes*	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes*	Yes	Yes	No
PRODRUGS	No	Yes	Yes	Yes	Yes	Yes	Yes*	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes*	Yes	Yes	No
POLYMORPHS	No	Yes	Yes*	Yes*	Yes*	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes*	Yes*	Yes	Yes	No
MARKUSH	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes*	Yes	Yes	No
SELECTION	No	Yes	Yes*	Yes*	Yes*	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes*	Yes*	Yes	Yes	No
ANALOGOUS PRODECURES	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No
USES	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	No

Notes:

1. *Yes means the feature is allowed.*
2. *No means the feature is not allowed.*
3. *Yes* refers to certain conditions or exceptions.*

INTERNATIONALPROPERTYRIGHTSINDEX.ORG