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INNOVATION

INTERNATIONAL PROPERTY RIGHTS INDEX 2023

NAVIGATING CHALLENGES IN BRAZIL'S INTELLECTUAL PROPERTY LANDSCAPE

CASE STUDY BY: **MACKENZIE CENTER FOR ECONOMIC FREEDOM**

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INTRODUCTION

In Brazil, the Intellectual Property (IP) system faces significant challenges that undermine both protection and the advancement of innovations. The process of seeking protection is notably protracted, primarily due to operational hindrances within the National Institute of Industrial Property (INPI), including resource and expertise shortages, as well as the persistence of manual processes. INPI, affiliated with the Ministry of Development, Industry, Trade, and Services, is tasked with enhancing and overseeing the granting of intellectual property rights, encompassing areas like trademarks, patents, industrial designs, and computer programs. However, the pursuit of excellence is hindered by the relative sluggishness of the process in comparison to countries such as China, the United States, and Japan. For instance, China

leads in patent applications, with approximately 1,600,000 filed between 2012 and 2021, whereas Brazil registered just over 34,847 between 2013 and 2021. This global discrepancy underscores the urgency of bolstering Brazil's competitiveness within the intellectual property landscape.

The intricate nature of criteria and procedures poses a dual challenge for both applicants and evaluators, resulting in errors, delays, and diminished enthusiasm. Ambiguity in laws and involved entities fosters administrative and judicial conflicts, negatively impacting businesses and creators alike. Small enterprises and individuals with limited resources encounter financial impediments when pursuing protection. Furthermore, the potential for government-mandated compulsory licensing jeopardizes the control

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rights holders maintain over their creations. At present, three bills are under review to reform intellectual property legislation: Bill 303/2003, Bill 2505/2022, and Bill 2056/2022.

Within the context of the 2022 International Property Rights Index (IPRI), Brazil received an IP score signifying moderate protection relative to other countries in the region. The annual decline of -0.592 in the score underscores challenges in this realm, while the 78th global ranking and 9th regional ranking suggest a middling position. The downward trajectory underscores the imperative for sustained endeavors to fortify the safeguarding of intellectual property rights in the nation.

This case study aims to analyze and understand the challenges faced by Brazil's Intellectual Property system, specifically focusing on the impediments to effective protection and innovation advancement. Through an examination

of the complex factors influencing the system, the study aims to provide insights into potential solutions and strategies to enhance intellectual property protection, streamline processes, and foster a more conducive environment for innovation within the country.

This document is structured into three distinct sections. The initial segment delves into Brazil's performance in the 2022 International Property Rights Index, highlighting the domains in which the country experienced setbacks in both position and score. The subsequent section provides an overview of patent applications in Brazil and critically examines the significant backlog within the Brazilian Patent Office. Moving forward, the third section engages in an in-depth exploration of the ongoing intellectual property system reform, delving into the bills currently under congressional discussion and their substantive contents.

PROPERTY RIGHTS IN BRAZIL

The International Property Rights Index (IPRI) is a measure of the strength and effectiveness of a country's protection of intellectual property rights, which includes patents, copyrights, trademarks, and trade secrets. The Index is designed to assess how well a country enforces property rights and encourages innovation and creativity.

The International Property Rights Index (IPRI) ranking for Brazil, as shown in the table, represents Brazil's relative position among countries concerning the strength and effectiveness of intellectual property rights protection. Over the years, Brazil's ranking worsened from 2007 to 2012, indicating regress in intellectual property rights protection. See Figure 1.

There were fluctuations in subsequent years, with rankings in the 40s to 70s range, but Brazil's ranking experienced a decline in recent years, falling to 78th place in 2022. In this context, when the number of the ranking increases, it indicates a drop in Brazil's position, signifying a comparatively weaker performance in protecting intellectual property rights.

Figure 2 presents data on Brazil's International Property Rights Index (IPRI) scores and subindex scores from 2007 to 2022. Over the years, there have been fluctuations in Brazil's scores, showing periods of improvement and slight decline. Brazil's Intellectual Property Rights score for 2022 reflects a scenario of moderate intellectual property protection within the region, albeit with a concerning annual decline of -0.592. This decline underscores the ongoing challenges

and areas of improvement needed in safeguarding intellectual property rights in the country.

The subindex scores, including Legal and Political (LP), Physical Property Rights (PPR), and Intellectual Property Rights (IPR), offer insights into specific aspects of property rights protection. These scores indicate the perceived strength of intellectual property rights protection in Brazil over these years. Higher scores generally suggest stronger protection and enforcement of intellectual property rights, which can encourage innovation and attract foreign investment.

Looking at the trend, it appears that Brazil's IPRI score improved from 2007 to 2011, indicating progress in property rights protection. However, the score has been somewhat fluctuating in the subsequent years. The drop in 2022 to 4.6220 suggests a potential decline in the perceived effectiveness of property rights protection in Brazil in that specific year.

Legal and Political Subindex scores range from approximately 3.616 in 2007 to 4.219 in 2022. Physical Property Rights Subindex scores range from approximately 4.831 in 2007 to 4.182 in 2022. Intellectual Property Rights Subindex Scores range from approximately 4.913 in 2007 to 5.465 in 2022.

According to Figure 3, Brazil's property rights protection in 2022 is characterized by moderate overall performance, areas of concern in the legal and political environment, and a relatively stronger framework for safeguarding intellec-

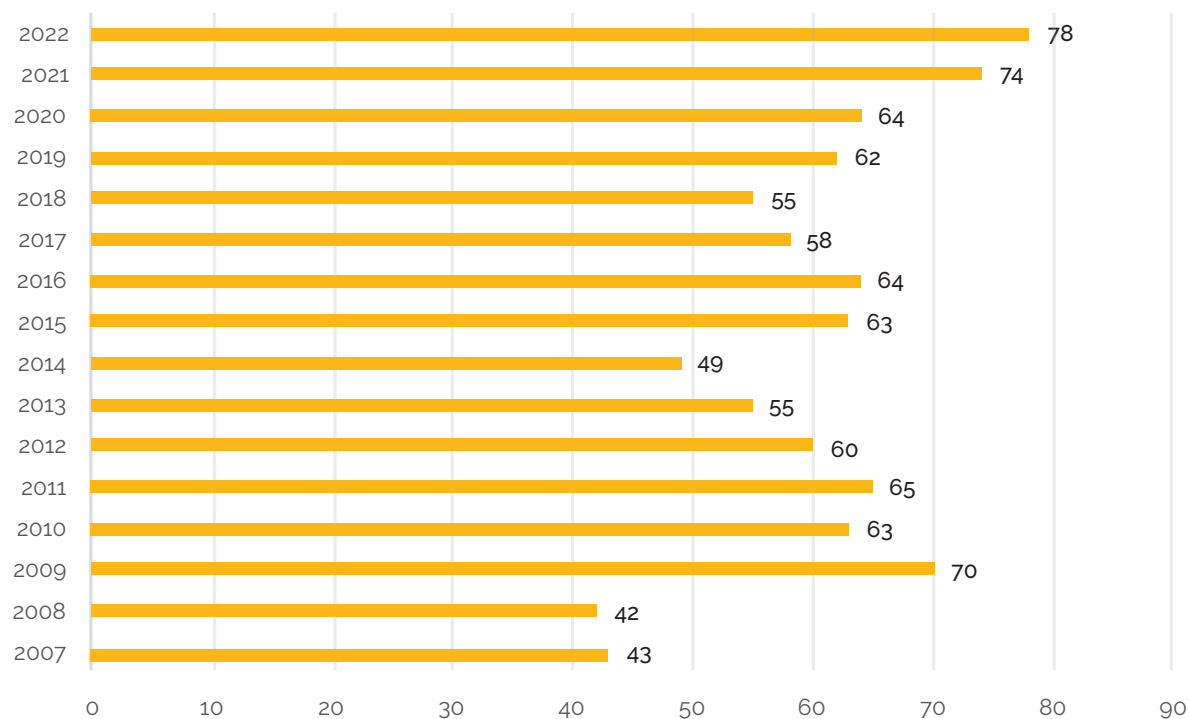


Figure 1 - Brazil: Ranking IPRI

Source: Montanari, Thompson & Levy-Carciente (2023)

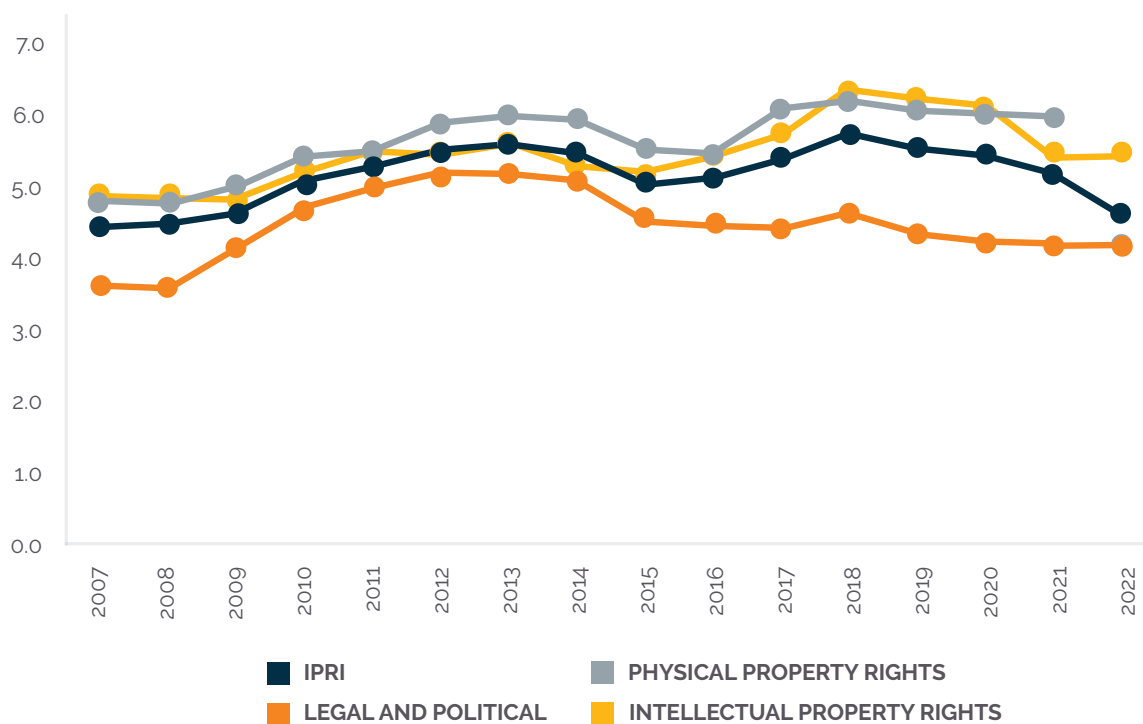


Figure 2 - Brazil: IPRI Evolution (2007-2022)

Source: Montanari, Thompson & Levy-Carciente (2023)

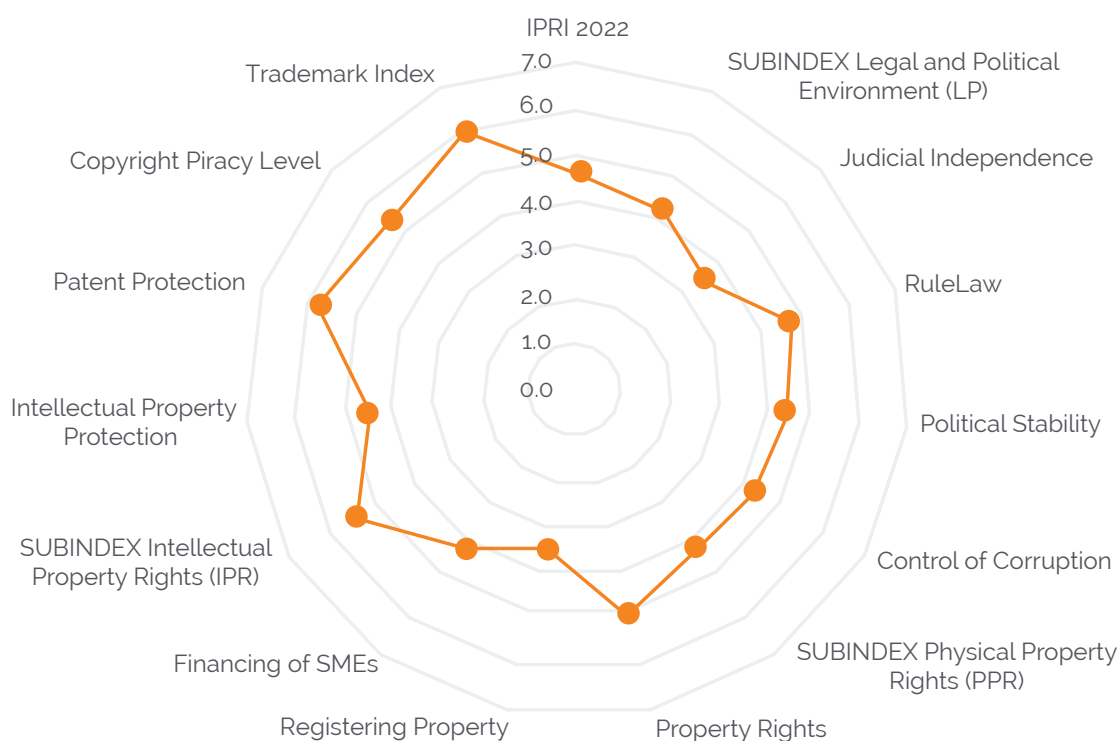


Figure 3 – Brazil: 2022 IPRI and its Components

Source: Montanari, Thompson & Levy-Carciente (2023)

tual property rights. Addressing weaknesses in legal institutions and governance can contribute to a more favorable property rights environment, supporting innovation and economic development.

Brazil's IPRI score for 2022 is 4.6. This score suggests a moderate level of property rights protection but leaves room for improvement. While not extremely low, Brazil's IPRI score indicates that there are challenges in the overall framework for protecting various forms of property rights, including intellectual property, physical property, and legal and political aspects.

Brazil's LP subindex score is 4.2 in 2022, indicating that there are some concerns in the legal and political factors affecting property rights

protection. The relatively low scores in components such as "Judicial Independence" and "Rule of Law" suggest potential weaknesses in the country's legal system and governance.

Brazil's PPR subindex score is also 4.2 in 2022, which suggests areas that may require attention in terms of protecting physical property rights. The lower score in "Registering Property" implies potential difficulties in property registration, which can affect land and real estate ownership.

Brazil's IPR subindex score is average at 5.5 in 2022, indicating a relatively stronger framework for protecting intellectual property rights compared to other aspects. The higher scores in components such as "Copyright Piracy Level"

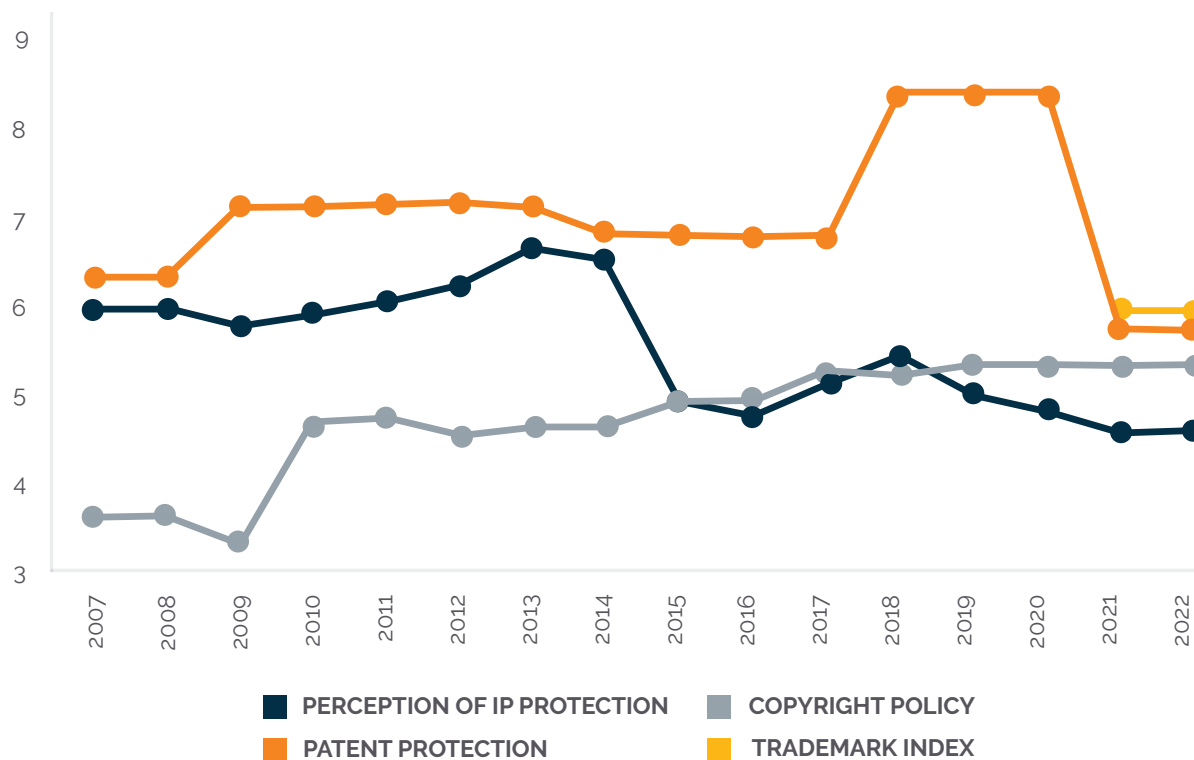


Figure 4 – Brazil: Intellectual Property Rights

Source: Montanari, Thompson & Levy-Carciente (2023)

and "Trademark Index" suggest that Brazil has made efforts to protect copyrights and trademarks effectively concerning intellectual property protection.

Figure 4 shows that Brazil's performance in the Intellectual Property Rights Subindex is mixed. The country has generally maintained a positive perception of patent protection, while there has been a substantial improvement in the perception of copyright policy. Additionally, the favorable trademark index scores for 2021 and 2022 indicate a positive perception of trademark protection.

The "Patent Protection" perception score has shown variations over the years but generally remained at a relatively high level. It started at

6.381 in 2007 and decreased to 5.805 in 2022, suggesting that while there have been some fluctuations, the perception of patent protection has remained relatively positive.

The perception of Brazil's "Copyright Policy" experienced a notable increase from 3.691 in 2007 to 5.4 from 2017 to 2022. This significant improvement indicates a more positive perception of Brazil's policies for protecting literary, artistic, and creative works.

However, the overall perception of IP protection has declined over the years, indicating a need for continued efforts to enhance the IP framework and ensure that it aligns with international standards, thereby fostering innovation, investment, and economic development.

The recent Latin American Subnational Innovation Competitiveness Index shows that the innovation capacity component of the Index, highlights a multifaceted landscape of challenges and opportunities across different states within the country. It underscores the potential for Brazil to strengthen its subnational innovation capacity, thereby creating an environment conducive to sustainable economic growth, technological advancement, and inclusive development. Three of the aspects to realize this potential are: Fortified IP Protection Legislation (strengthening IP protection legislation is vital to incentivize creativity and innovation), Robust IP laws (that can provide the necessary framework for inventors, creators, and businesses to

protect their intellectual assets effectively), and IP Culture Promotion (promoting a culture of IP awareness and respect is equally important — educational programs and campaigns can inform the public, entrepreneurs, and researchers about the significance of IP rights and their role in driving innovation). (Lazar et al., 2023)

While the National Strategy of Intellectual Property has addressed these aspects to some extent, recent advancements still fall short of the country's pressing needs. To fully unlock Brazil's innovation potential, a more proactive and comprehensive approach to IP protection and promotion is essential.



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PATENT APPLICATION AND BACKLOG

Intellectual Property in Brazil and its protection system are administered by the National Institute of Industrial Property (INPI) of the Brazilian Patents and Trademarks Office (PTO). INPI, a federal agency linked to the Ministry of Development, Industry, Trade, and Services, is responsible for enhancing, disseminating, and managing the Brazilian system for granting and guaranteeing intellectual property rights for the industry. (Brasil, 2020)

INPI's role is to stimulate innovation and competitiveness through technological development. Therefore, it oversees the registration of trademarks, industrial designs, geographical indications, computer programs, and integrated circuit topographies. Additionally, INPI handles patent grants, records franchise agreements, and various forms of technology transfers.

When we compare Brazil to countries such as the United States, China, and Japan in terms of

the number of patent applications registered by the World Intellectual Property Indicators (WIPI), a striking disparity becomes evident. International data spanning from 2012 to 2021 reveal that China has amassed approximately 1,600,000 patent applications during this period, whereas Brazil, as reported by the INPI, has registered just a fraction of that number compared to the rest of the world. To truly appreciate the magnitude of this discrepancy, one need only examine the volume of patent applications filed at the world's foremost registration offices.

According to international statistics, China emerged as the leader in patent applications in 2017, boasting a staggering 1,381,594 requests, followed by the United States with an average of 600,000 and Japan with approximately 300,000. In stark contrast, Brazil's INPI recorded a meager 34,847 applications between 2013 and 2021, as depicted in the figure below.

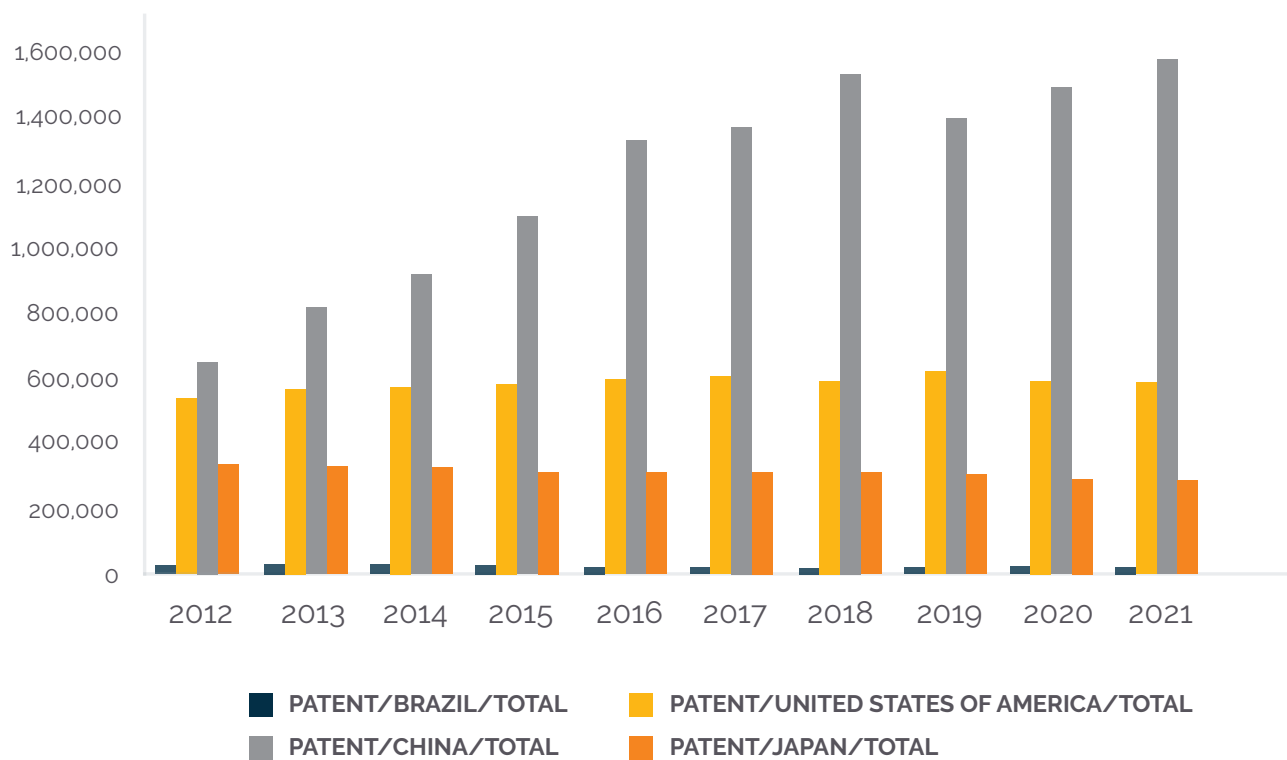


Figure 5 - Patent Applications (2012 to 2021)

Source: WIPO Statistics Database, August 2021

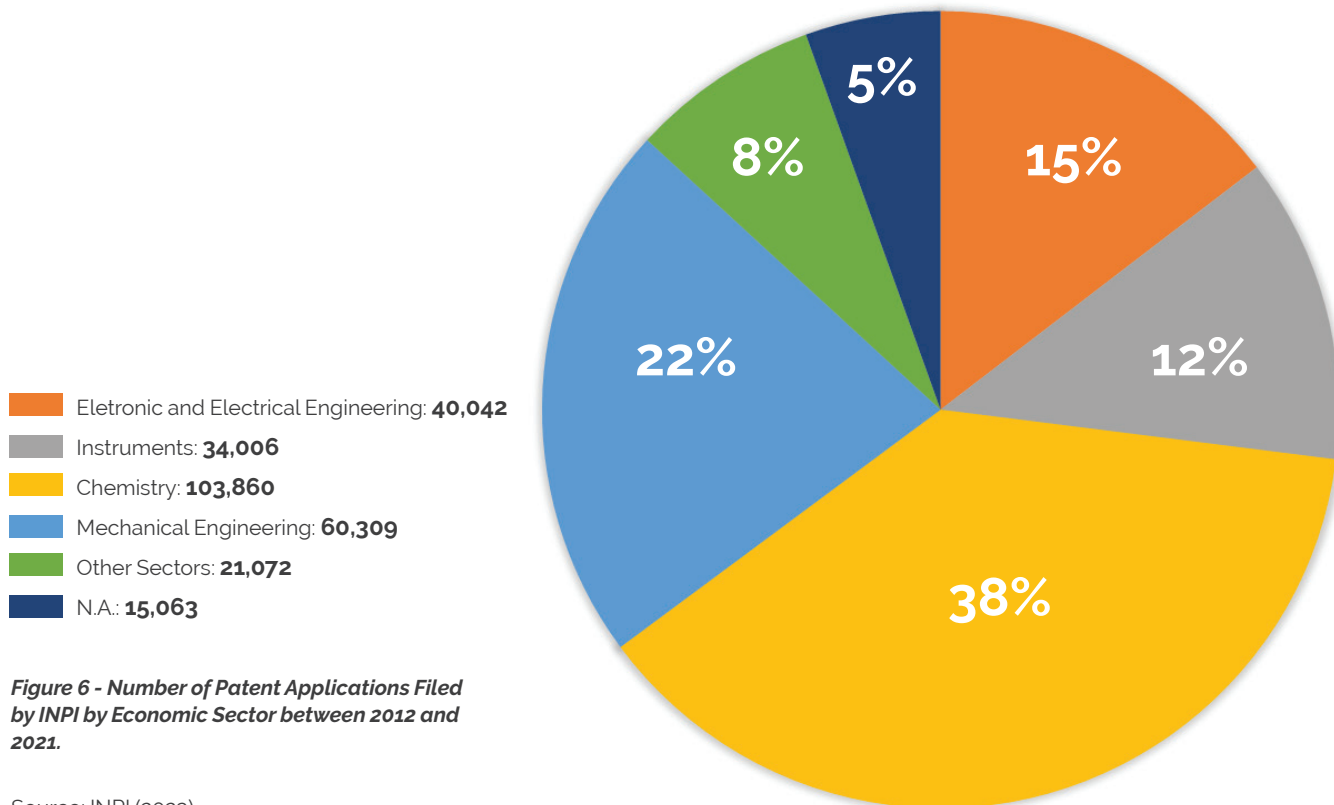


Figure 6 - Number of Patent Applications Filed by INPI by Economic Sector between 2012 and 2021.

Source: INPI (2023)

In the Brazilian context, it is noteworthy that the Chemistry sector leads the way with 38% of patent applications during the period spanning from 2012 to 2021, whether submitted by residents or non-residents. Following closely is Mechanical Engineering, accounting for 22% of patent applications within the same timeframe. Over the years from 2012 to 2021, this sector consistently represented 22% of the total patent applications. Additionally, we observe Electrical and Electronic Engineering at 15%, and the Instruments sector at 12%, as illustrated in the figure below.

Within the economic sectors, when we delve into technological subcategories, we observe the following rankings: Fine Organic Chemistry and Pharmaceuticals lead the pack with 6.7%, closely followed by Medical Technology at 6.5%. In contrast, Semiconductors and Basic Communication Processes lag with 0.4% and 0.2%, respectively. The higher number of applications in the Chemistry sector can be attributed to the pandemic period and the increased demand for items such as vaccines. Conversely, the Semiconductor sector, essential for electronic equipment manufacturing, records a lower number of applications in Brazil due to the predominant

production of these components in China. Below is the table displaying the rankings for the stand-out technological areas.

Despite a relatively low number of patent registration requests in Brazil, the organization faces a significant backlog in processing these applications. In response to this challenge, the Brazilian Federal Government introduced a Patent Backlog Reduction Plan with the goal of reducing the time it takes to process and grant patents from an average waiting period of 11 years to just two years.

According to the INPI, the implemented backlog reduction plan aimed to address approximately 80% of the 149,000 patent applications through Resolution No. 241/19, which mandated the reduction of processing time to two years. As of August 2021, INPI had successfully examined or definitively archived 100,193 patent applications because of this initiative.

In the table below, you can see a decline in the number of pending patent applications following the implementation of the backlog reduction plan. In 2019, there were 147,217 applications awaiting processing, and three years later, this

RANKING	RANKING TECHNOLOGICAL AREA	TOTAL	%
1ST	Fine Organic Chemistry	18.425	6,7%
2ND	Pharmaceutical Products	18.394	6,7%
3RD	Medical Technology	17.932	6,5%
34TH	Semiconductors	1.046	0,4%
35TH	Basic Communication Processes	605	0,2%

Table 1 - Patent Applications by Technological Area

Source: Patent applications filed with the National Institute of Industrial Property (INPI), 2000-2021 (Compiled by the authors).

YEAR	BACKLOG	%
2019	147.217	51%
2020	93.706	33%
2021	46.806	16%

Table 2 - Patent Application Decision or Archiving Backlog

Source: Evolution of the INPI's Patent Backlog Reduction Plan. 2023 (Compiled by the authors).

number had decreased to 46,806 pending applications..

This 32% reduction in the backlog illustrates that the action has had a positive impact, not only on the data but, more importantly, on the reduction in the time it takes to handle and analyze patent applications submitted to INPI.

While Brazil still lags behind countries like China or the United States in terms of patent registrations, particularly in the field of technology, there are notable achievements in the data recorded from 2012 to 2021, especially in the

areas of pharmacy, fine organic chemistry, and the medical industry.

The decision to streamline the approval and archiving processes reflects a commitment made in 2019 to enhance service delivery, attract investment, and promote technology adoption across various sectors of the Brazilian economy. The changes introduced by Resolution No. 241/19 to the INPI system not only reduced the time required for analysis but also injected a measure of efficiency into the process, better serving its users.

INTELLECTUAL PROPERTY LEGISLATION IN BRAZIL

The concept of Intellectual Property (IP) encompasses the legal protection and recognition of authorship for creations that result from intellectual endeavors. This includes innovations, patents, trademarks, industrial designs, geographical indications, and artistic expressions. This concept grants creators the right to exclusively exploit their creative work for a specified period.

The origins of the Intellectual Property concept can be traced back to the 15th century within the context of the Republic of Venice. Local authorities enacted regulations aimed at safeguarding inventors in the realms of arts and sciences.

HISTORICAL BACKGROUND AND LEGAL FRAMEWORK

Artifacts with an industrial focus, such as trademarks, patents, and other distinctive indicators, fall under the umbrella of Intellectual Property (IP). Meanwhile, literary and artistic expressions are safeguarded by copyright laws.

The sphere of IP provides creators with the exclusive prerogative to exploit their protected creations. It serves to reward innovative efforts, including laborious work, financial investments in research and development, and more.

In simpler terms, this exclusive prerogative empowers IP rights holders to prevent third parties from economically exploiting their protected creations. For example, a patent holder can prevent a competitor from selling a product identical to theirs that uses the same technology.

Likewise, a trademark holder can block a competitor from introducing a product into the market that carries an identical or similar trademark. Intellectual Property, therefore, plays a pivotal role in fostering innovation by creating an environment conducive to the development of new products and technologies.

Consequently, it is crucial to gain a deep understanding of how this framework operates and

how the legal framework governing IP can ensure the protection of one's creations or the assets of institutions. In the Brazilian context, these regulations are outlined in Law 9,279/96.

On the global stage, the World Intellectual Property Organization (WIPO) was established in 1967 to promote international collaboration in creating, disseminating, using, and safeguarding works originating from human intellect. This contributes to economic, cultural, and social progress.

At the national level, Brazil established the INPI within its Patents and Trademarks Office in 1970, which is responsible for granting intellectual property rights.

CHALLENGES IN SAFEGUARDING INTELLECTUAL PROPERTY IN BRAZIL

In Brazil, it is widely recognized that individuals seeking protection through the Intellectual Property (IP) system can encounter a myriad of challenges and issues that directly impact their applications. These difficulties not only impede innovation within the country but also hinder public access to new technologies.

It is a common occurrence for the process of applying for IP protection in its various forms to be notably time-consuming in Brazil. A portion of this delay can be attributed to operational hurdles faced by INPI. Among the primary reasons cited by INPI personnel are insufficient resources, a shortage of experts, and the persistent reliance on manual processes in certain instances.

In this context, the extensive documentation requirements and intricate procedures can

prove perplexing both for applicants seeking protection and for those responsible for evaluating the applications. In some cases, this complexity can lead to errors that imperil the validity of the requests, causing delays and discouraging prospective applicants.

Moreover, the lack of clarity in certain provisions of the laws governing intellectual property and the entities involved in the process, coupled with delays in granting rights, creates fertile ground for administrative and legal disputes. This situation is particularly detrimental not only to businesses and creators relying on the protection of their creations but also to ordinary individuals who often depend heavily on products, technologies, and services developed by these applicants.

While the application process is unduly protracted, uncertain, and often lacking transparency for major innovators, it poses a significant financial barrier for small businesses, startups, and individuals with limited resources. Therefore, although quantifying the number of innovations that go unrealized each year due to the absence of proper incentives is challenging, especially concerning the protection of intellectual property rights, it is of paramount importance to acknowledge this reality when addressing the issue holistically.

Additionally, alongside these well-documented challenges, it is noteworthy to mention the looming threat of compulsory licensing as soon as the government deems a significant public interest in the process. This implies that, in specific situations, the government can grant third parties the right to produce or use a creation protected as intellectual property without the consent of the rights holder. While granting public access to

technology may seem justified in the short term, it is essential to bear in mind that potential new applicants may reconsider the development and registration of novel technologies, given the possibility of inadequate compensation for their research and development efforts. Thus, contrary to the expectations of compulsory licensing advocates, this practice can erode the ability of creators and companies to control the commercial exploitation of their own creations, jeopardizing their competitive edge.

LEGISLATIVE PROPOSALS ADDRESSING INTELLECTUAL PROPERTY IN BRAZIL

With each new legislative session, a slew of proposals emerges with the aim of reforming Law 9,279/96 and other related legal frameworks. Presently, there are at least three well-developed proposals in various stages of legislative consideration:

- i. Bill 303/2003, initiated by the late Deputy José Aristodemo Pinotti (PMDB).
- ii. Bill 2505/2022, introduced by Senator Paulo Paim (PT).
- iii. Bill 2056/2022, authored by Deputy Alexis Fonteyne (NOVO).

Bill 303/2003

Between November 1999 and June 2000, the Parliamentary Inquiry Committee (CPI) on Medicines in the Chamber of Deputies conducted an inquiry into various issues within the Brazilian pharmaceutical landscape. The CPI examined issues such as the dwindling domestic production of pharmaceuticals by multinational corporations, a trend that, according to

the CPI, resulted in the increasing importation of products from their parent companies. Other concerns included the alleged concentration of technological knowledge within multinational corporations, largely driven by patent protection, and the persistent and expanding deficit in the pharmaceutical sector, leading to substantial imports.

The CPI underscored Brazil's significant reliance on imports for pharmaceutical inputs and the lack of innovative developments, despite the country's abundant natural and cultural resources. In response to the CPI's findings, then-Deputy and physician José Aristodemo Pinotti introduced Bill 303/2003. This bill sought to eliminate the possibility of manufacturing patented products abroad, based on the notion that local production was economically unviable.

Within this context, the initiative aimed to reduce technological dependence while fostering domestic research, development, and manufacturing. It also aimed to create a more balanced environment within the pharmaceutical sector. Unlike advocating compulsory licensing solely to address a supposed public interest, the proposal aimed to incentivize the national industry and transform Brazil into a producer rather than a mere importer of pharmaceuticals.

During the bill's legislative process, 17 appendices were added to it. Many of these appendices sought to regulate compulsory licensing, and some even aimed to completely repeal Article 40 of Law 9,279/96 (Bill 3,944/2012). The Box below provides a list of the bills appended to Bill 303/2003, along with their objectives, legal instruments, and proponents.

BILL NUMBER	PURPOSE	LEGAL INSTRUMENT	AUTHOR, PARTY, AND STATE
BILL 2511/2007	Prevent the patenting of pharmaceutical products and processes.	Addition of Section IV to Article 18 of Law 9,279/1996	Fernando Coruja - PPS/SC
BILL 3995/2008	Restrict the patentability of the second use and new forms of substances, also known as polymorphs.	Addition of subsections to Article 10 of Law No. 9,279/1996	Paulo Teixeira - PT/SP
BILL 3709/2008	Establish that the granting of patents for products and processes in pharmaceuticals will depend on prior approval from the National Health Surveillance Agency – a.k.a. 'ANVISA'.	Amendment of Article 229-C of Law No. 9,279/1996	Rafael Guerra - PSDB/MG
BILL 7965/2010	Establish that the granting of patents for products and processes in pharmaceuticals will depend on prior approval from ANVISA.	Amendment of Article 229-C of Law No. 9,279/1996	Moreira Mendes - PPS/RO
BILL 3943/2012	Establish that the granting of patents for products and processes in pharmaceuticals will depend on prior approval from ANVISA, based on chemical, biochemical, and pharmacological technical and scientific knowledge, clinical experience, and public health usage consensus between INPI and ANVISA.	Amendment of Article 229-C and addition of paragraphs in Law No. 9,279/1996	Jandira Feghali - PCdoB/RJ
BILL 5176/2009	Ensure compulsory non-exclusive licensing for an indefinite period whenever competent authorities ascertain a shortage of continuous-use medicines in the market.	Addition of Article 71-A to Law 9,279/96	Rodrigo Rollemberg - PSB/DF
BILL 2846/2011	(I) Establish compulsory licensing in cases of non-manufacturing or incomplete manufacturing of the product in Brazil, even if it is patent protected. (II) Allow third-party importation of products manufactured according to patented processes or products, provided they have been placed on the market directly by the owner or with their consent. (III) Require licensees to commence the exploitation of the patented object within 2 (two) years of license grant. (IV) Eliminate cases of non-compulsory license grant due to the protected party's request.	Amendment of Articles 1, 68, and 74 of Law 9,279/96. Full repeal of Article 69 of the same law.	Carlos Manato - PDT/ES
BILL 3944/2012	Repeal the provision that stipulates the duration of invention and utility model patents to stimulate research and facilitate access to medicines.	Full repeal of Article 40 of Law 9,279/96.	Jandira Feghali - PCdoB/RJ
BILL 6968/2017	Alter the duration of invention and utility model patents. A term of 20 (twenty) years for invention patents and 15 (fifteen) years for utility model patents from the date of filing, extendable for 3 (three) successive periods of 5 (five) years each.	Amendment of Article 40 of Law 9,279/96.	Gorete Pereira - PR/CE
BILL 4921/2019	Determine a minimum term of no less than 10 (ten) years for invention patents and 7 (seven) years for utility model patents, starting from the grant date.	Repeal of the sole paragraph of Article 40 of Law No. 9,279/96	Elias Vaz - PSB/GO
BILL 1471/2023	Determine that patent extension will be determined based on the requirements: a) a maximum of 5 (five) additional years of patent protection, b) a minimum of 10 (ten) years between the application date and patent grant, and c) granting of only 1 (one) extension per product.	Amendment of Article 41 of Law No. 9,279/96.	Kim Katagui - UNIÃO/SP

BILL NUMBER	PURPOSE	LEGAL INSTRUMENT	AUTHOR, PARTY, AND STATE
BILL 3945/2012	Establish the non-patentability of medicines used in the diagnosis and treatment of neglected diseases and promote the production of these medicines without payment of compensation due to compulsory licenses.	Amendment of Articles 18 and 68 of Law 9,279/96.	Jandira Feghali - PCdoB/RJ
BILL 5402/2013	Revise patent law to limit the duration of patents, add objects not considered inventions, change patentability criteria, create a mechanism for opposing patent applications, modify the provision on prior approval from ANVISA, address the protection of pharmaceutical test data as unfair competition, and introduce the non-exclusive use mechanism.	Full repeal of its Article 40 and amendment of Articles 10, 13, 14, 31, 195, and 229-C, and addition of Articles 31-A and 43-B to Law 9,279/96. Amendment of Law 9,782/1999, to amend its Article 7	Newton Lima - PT/SP
BILL 8090/2014	Provide for compulsory licensing of patented products for the purpose of production and exportation under exceptional circumstances to countries that do not have the capacity or have insufficient capacity for production.	Amendment of Article 68 of Law No. 9,279/96	Committee on Social Security and Family
BILL 8091/2014	Replace the internal exhaustion of intellectual property rights with international exhaustion. This means that the rights of the patent holder are exhausted when the product is placed on the market in any country worldwide.	Amendment of Articles 43 and 184 of Law No. 9,279/96	Committee on Social Security and Family
BILL 9408/2017	Ensure the right of patent holders to restoration in the event of patent extinction due to non-payment of annual fees within six months.	Amendment of Article 87 of Law No. 9,279/96.	Carlos Bezerra - PMDB/MT
BILL 2123/2021	Provide for compulsory licensing of medicines exclusively to meet the needs of the Unified Health System in the event of non-exploitation of the patent object in Brazilian territory due to lack of manufacturing or incomplete manufacturing of the product, or lack of full use of the patented process.	Amendment of Article 68 of Law No. 9,279/96	Domingos Sávio - PSDB/MG

Box 1 – Bills Appended to Bill 303/2003

Source: Brazilian House of Representatives

The bill is subject to plenary review and holds a priority position in its processing (Article 151, II, Standing Rules of the House of Representatives). There is a deliberative session scheduled for 12/22/2023 at 2:00 PM. Given the current government's shifting alignment and the previously known case of compulsory licensing of Efavirenz during the Lula administration, there is a possibility that the bill will be approved, potentially further impacting the patent protection framework in Brazil.

BILL 2505/2022

Bill 2505/2022, which proposes a focus on access to manufacturing information and know-how, emerges as an attempt to address a recognized gap in the current legal framework.

The proposal ostensibly aligns with international standards that regulate intellectual property. The discussion underscores that the compulsory sharing of industrial secrets does not contradict the Agreement on Trade-Related Aspects of

Intellectual Property Rights (TRIPS), given the rejection of attempts to prohibit such sharing during negotiations related to this agreement.

The proponent argues that the proposal aligns with Article 39 of TRIPS, which contemplates exceptions to the protection of confidential information, prioritizing the consideration of the public interest. The discussion emphasizes that in health crises, where access to essential technologies such as medicines and vaccines plays a critical role in preventing loss of life, disease spread, and suffering, the argument for exceptions gains weight throughout the text.

The project aims to update the national legal framework, especially concerning compulsory licensing, to facilitate access to and replication of innovations relevant to addressing public health emergencies or circumstances of public/collective interest.

The crisis triggered by COVID-19 has revived discussions on provisions provided by TRIPS, especially the central role of sharing industrial secrets in expanding access to vaccines and reducing global disparities.

In this sense, the proposal seeks to reinforce a short-term political understanding of the public interest and reduce the control exerted by pharmaceutical companies over patented technologies, promoting sharing in critical health contexts. The final argument highlights the search for a balance between private interests and the public good, as outlined in the intellectual property system, but does not make clear how this would be achieved.

There is a proposed change to Article 68 of Law 9,279/1996, allowing, in the context of

compulsory licensing, the non-availability to the public on reasonable terms and through the Unified Health System of patented products or processes developed using government funds, or with the participation of the Brazilian population in clinical research.

There is also a provision to amend Article 71, requiring the patent holder to share not only information but also biological material in cases of need. In case of refusal to release this information and materials, the proponent establishes the fine provided in Article 24 and in Chapter VI of Title I of Law 9,279/1996.

The emergency caused by COVID-19 has accelerated a process of erosion of patent rights that has been ongoing since at least 2003. Political actors who have long advocated for flexibility based on a short-term view of access to medicines and other innovations have seized the moment of vulnerability and are currently supported by the federal executive.

The project is awaiting a rapporteur but has already passed through the Committee on Economic Affairs of the Brazilian Federal Senate.

BILL 2056/2022

Among the bills addressing intellectual property matters in Brazil, this is the only one aimed at improving the system without addressing compulsory licensing.

In broad terms, the bill seeks to include a series of obligations with the goal of having the INPI adopt measures and present periodic strategic plans to enhance public governance and optimize the agency's management. The idea is also to promote greater efficiency in INPI's oper-

AMENDMENT	OBJECTIVE
INCLUSION OF ARTICLE 6 IN LAW 5.648/1970	To mandate that INPI presents periodic strategic plans for enhancing governance and management of the agency.
AMENDMENT TO § 3 OF ARTICLE 6 AND §1 OF ARTICLE 16 OF LAW 9.279/96	To incorporate the option for one or multiple holders to claim the right of priority.
CAPUT OF ARTICLE 26 OF LAW 9.279/96	To remove the term "end of examination" as a deadline for submitting divided applications.
INCLUSION OF THREE PARAGRAPHS IN ARTICLE 26 OF LAW 9.279/96	To establish the decision of Article 37, which pertains to patent granting, as the deadline for filing divided applications.
INCLUSION OF §2 IN ARTICLE 31 OF LAW 9.279/96	To define the end of examination as the point when the administrative route for the applicant is exhausted.
AMENDMENT TO ARTICLE 32 OF LAW 9.279/96	To allow amendments until the end of examination, limited to the subject matter of the initial application, upon payment of the relevant fees.
INCLUSION OF ARTICLE 40-A IN LAW 9.279/96	To set a 5-year statute of limitations for requesting patent term compensation through administrative or judicial means.
INCLUSION OF TWO PARAGRAPHS IN ARTICLE 42 OF LAW 9.279/96	To ensure interim relief for patent holders, including customs clearance, and to specify that foreign jurisdiction laws or judicial decisions will not limit the property rights granted in Brazil.
AMENDMENTS TO ARTICLES 183, 184, 185, 187, 188, 189, 190, 191, 193, 194, 195, 200, AND 2001 OF LAW 9.279/96	To introduce punitive amendments aimed at imposing more suitable penalties to prevent illicit conduct affecting patent holders' assets. Notably, this includes allowing criminal proceedings only upon a formal complaint, without the requirement for involvement from a police officer or judge.
INCLUSION OF ARTICLE 216-A IN LAW 9.279/76	To mandate the presence of legal representation in contentious administrative proceedings at INPI.
AMENDMENT TO ARTICLE 225, HEADING, AND ADDITION OF ARTICLES 225-A AND 225-B TO LAW 9.279/96	To extend the statute of limitations to 10 years for actions seeking damages related to industrial property rights when involving two private parties. This proposal also outlines a 5-year statute of limitations for actions against the INPI and for adjusting the validity term, counting from the expiration of the original term.
AMENDMENT TO ARTICLE 228 OF LAW 9.279/96	To allocate funds collected as fees exclusively for remunerating the provision of public services within the INPI's jurisdiction related to the management of the Brazilian patent system.

Box 2 – Proposed Changes to Bill No. 2056/2022

Source: Brazilian House of Representatives

ations, in line with international best practices, with the intention of encouraging development, research, and innovation in the national context. One of the central focuses of public governance is administrative simplification, modernization of public management, and the integration of public services, especially through electronic platforms.

The implementation of these measures reflects the pursuit of adopting the best management and governance practices within the scope of Public Administration. This approach is in line with ongoing efforts, initiated in 2017, by the Brazilian state to enhance governance quality and align with international guidelines. This proposal aims to improve both the deci-

sion-making process of entities and bodies whose activities impact the economy and promote national economic development, as is the case with INPI, and Brazil's aspirations for accession to the Organization for Economic Cooperation and Development (OECD).

In the box on the right, it is possible to check the changes and additions introduced by the project.

Currently, the project is awaiting the appointment of a rapporteur in the Committee on Administration and Public Service, from where it should proceed to the Committee on Economic Development, and subsequently to the Commit-

tee on Constitution and Justice. Only after discussions and amendments will it be voted on in the House of Representatives.

Considering that most of the projects related to this matter seek to delve deeper into the compulsory licensing institute in Brazil and occasionally expand it, the likelihood of the proposed changes succeeding in parliamentary approval is rather low. There are still debates to be held in both the special committees of the House and the Senate, so the chances of substantial modifications to the proposal remain considerable.



5

FINAL REMARKS

The landscape of Intellectual Property Rights (IPR) in Brazil is facing a critical juncture, necessitating substantial reforms and improvements. Brazil, home to the National Institute of Industrial Property (INPI), is entrusted with overseeing intellectual property rights, covering trademarks, patents, industrial designs, and computer programs. However, in comparison to global peers like China, the United States, and Japan, Brazil currently lags behind significantly.

China's astounding 1,600,000 patent applications filed between 2012 and 2021 stand in stark contrast to Brazil's meager 34,847 during the same period. This glaring disparity underscores the pressing need for Brazil to enhance its competitiveness in the realm of intellectual property. Complex criteria and procedures within Brazil's intellectual property framework pose significant challenges for both applicants and evaluators, often resulting in errors, delays, and a diminishing sense of motivation.

The presence of legal ambiguity and organizational opacity further compounds the issue, leading to administrative and judicial conflicts that directly impact businesses and creators alike. Brazil's International Property Rights Index (IPRI) score for 2022 paints a picture of moderate

regional protection, with a concerning annual decline of -0.592, indicative of the prevailing challenges.

With Brazil holding the 78th global rank and the 9th regional rank in intellectual property rights protections, it is evident that concerted and sustained efforts are urgently required to fortify this vital aspect of the nation's legal framework. The disparities in patent applications and international rankings underscore the importance of reforming and streamlining Brazil's intellectual property ecosystem to foster innovation, stimulate economic growth, and ensure a fair playing field on the global stage.

Another significant aspect is the drive towards enhancing governance and efficiency within Brazil's intellectual property institutions, notably INPI. Proposed bills like PL 2056/2022 aim to modernize administrative processes, align with international best practices, and stimulate research and development. INPI, linked to the Ministry of Development, Industry, Trade, and Services, plays a pivotal role in this transformation. Its modernization is not merely a policy choice but an imperative for progress and competitiveness in the 21st century. The institution must actively address the challenges

it faces, including a backlog of patent applications and inefficiencies in the evaluation process. Modernizing Brazil's intellectual property infrastructure and establishing a clear and efficient system are essential steps to encourage innovation and safeguard the rights of creators and inventors.

In general, to strengthen property rights in Brazil, policymakers should focus on enhancing the legal and political environment by ensuring judicial independence, improving the rule of law, and promoting political stability and transparency. Streamlining property registration processes for physical assets, particularly land and real estate, and facilitating financing for SMEs (small and medium-sized enterprises) can encourage investment and economic growth. Robust intellectual property protection, covering patents, copyrights, trademarks, and trade secrets, should be a priority, along with efforts to deter IP violations and piracy. Building on the positive perception of copyright policy and trademark protection, Brazil should collaborate with stakeholders in creative industries and promote public awareness of IP rights. International cooperation to align with global standards plus continuous monitoring and evaluation of policy effectiveness are essential to create a conducive environment for property rights, fostering innovation and economic development.

One of the central themes in this case study has been the proposed expansion of compulsory licensing mechanisms. These proposals aim to facilitate access to essential medications and technologies, particularly during health crises like the COVID-19 pandemic. While the intent is to prioritize public interest, these changes have sparked debates on how they might impact innovation, investments, and international trade agreements. The discussions reveal the delicate

equilibrium that Brazil seeks to strike between public welfare and economic interests. At the end of the day, maybe Brazil will not have any if it hurts intellectual property rights.

Throughout this study, we have seen that the legislative process is intricate and multifaceted. Bills pass through multiple commissions and chambers, and they often undergo substantial modifications as they progress. The fate of these proposed changes remains uncertain, as they must navigate the complex landscape of Brazilian politics and the global intellectual property arena.

Brazil's journey in reforming its intellectual property framework reflects the nation's trade-offs to balancing economic interests with public health and innovation. As the debates continue, Brazil will need to tread carefully to ensure that any changes made strike a harmonious chord between fostering innovation and safeguarding public welfare. The coming years will be pivotal in shaping the future of intellectual property rights in Brazil, and the global community will be watching closely as these discussions unfold.

The path forward requires strategic planning, robust legislative measures, and a commitment to transparency, making Brazil a more attractive destination for intellectual property investments and innovation-driven growth. In conclusion, Brazil's quest to bolster its intellectual property rights protections is not just a matter of regulatory reform; it's an imperative for progress and competitiveness in the global arena. The nation must rise to the occasion, aligning its intellectual property framework with global standards, fostering innovation, and ensuring that creators and innovators are empowered to thrive in the dynamic landscape of intellectual property.

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