

INTELLECTUAL PROPERTY PROTECTION AND DRUG PATENTS IN BRAZIL

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Abstract

The article aims to reconstitute the central events of the Intellectual Property (IP) protection system in Brazil, highlighting the exception of medicines patent granting. In a second moment, we discuss the influences of corporations and of Special 301 Reports in the Intellectual Property Law (1996), which marks the recognition of drug patents granting in the country. Subsequently, we present an analysis of the growth of patents in the largest offices, highlighting Brazil's peripheral participation in innovation. Finally, the article seeks to demonstrate the current relationship between patents and public health by considering the patent invalidation in Brazil and the international cooperation between States and corporations in developing vaccines during the COVID-19 pandemic.

Keywords: Intellectual Property (IP); Patents; Medicines; COVID-19.

Resumo / Resumen

PROTEÇÃO À PROPRIEDADE INTELECTUAL E PATENTES DE MEDICAMENTOS NO BRASIL

O artigo reconstitui o sistema normativo de proteção à Propriedade Intelectual no Brasil, destacando a exceção ao patenteamento de medicamentos. Em um segundo momento, discutem-se as influências dos agentes corporativos e dos Special 301 Reports na Lei de Propriedade Intelectual (1996), que marca o reconhecimento das patentes de medicamentos no país. Posteriormente, apresenta-se uma análise do crescimento das patentes no mundo, destacando a participação periférica do Brasil na inovação. Finalmente, as relações atuais entre patentes e saúde pública são abordadas a partir da anulação de patentes pelo Brasil e das cooperações internacionais entre Estados e corporações visando o desenvolvimento de vacinas durante a pandemia de COVID-19.

Palavras-chave: Propriedade Intelectual (PI); Patentes; Medicamentos; COVID-19.

PROTECCIÓN DE LA PROPIEDAD INTELECTUAL Y PATENTES DE MEDICAMENTOS EN BRASIL

El artículo reconstituye el sistema normativo para la protección de la Propiedad Intelectual en Brasil, destacando la excepción de patentar medicamentos. En un segundo paso, se discuten las influencias de los agentes corporativos y los Special 301 Reports sobre la Ley de Propiedad Intelectual (1996), que marca el reconocimiento de las patentes de medicamentos en el país. Posteriormente, se presenta un análisis del crecimiento de las patentes en el mundo, destacando la participación periférica de Brasil en la innovación. Finalmente, se aborda la relación actual entre patentes y salud pública desde la anulación de patentes en Brasil y la cooperación internacional entre Estados y empresas en el desarrollo de vacunas durante la pandemia de COVID-19.

Palabras-clave: Propiedad Intelectual (PI); Patentes; Medicamentos; COVID-19.

INTRODUCCION

Territory and market are conjoined concepts, as defined by Santos (1996, p. 184), that is, two entities so interwoven that it would be impossible for them to exist independently. This assertion is the starting point for the debate on changes in the legal frameworks related to Intellectual Property (IP¹) in the Brazilian territory since the State and the market alternate between periods of cooperation and conflict. In this context, this study focuses on the changes in the protection of medicines and their production processes.

The relationship between the national territory and its borders as an envelope of norms (Law, legalities, and illegalities) is a rich chapter in Political Geography, which demarcates the relationship of mutual conditioning between legal norms and geographic forms. In peripheral capitalist socio-spatial formations, such as Brazil, state institutions have taken on the function of securing the private monopoly of innovation via patents. However, in various situations, this has not prevented the State from suspending patents, when not taking on the production of those medical supplies considered essential.

In particular, a reconstitution of the legislative events of the Brazilian state policy for the protection of medicines shows how the treatment of this issue has changed, based on the Intellectual Property Law (Law No. 9,279 / 1996). In this sense, it is clear that the former internationalization of the territory was associated with efforts aimed to develop the national industry and safeguard drugs, as well as food, from patenting.

The sphere of innovation-based knowledge was consolidated worldwide in the post-World War II period, marking a new era in the capitalist mode of production. Even if this domain is not truly production, it is evident that the efficiency, productivity, optimization, quality, and operation of products require the insertion of knowledge as a productive factor, upstream and downstream, in the most varied productive sectors. Therefore, the singularity of the planetary technique (SANTOS, 2000), the technical basis that would define globalization processes, also involves the standardization of its creation and development. Thus, capitalism's current paradigm requires the mastery of information and computerization (HARDT and NEGRI, 2000), creating a "knowledge economy" (VELTZ, 2010).

However, as highlighted by Lash (2002), knowledge and information are not amorphous, information has living and dead zones. Thus, patents act like codes that ensure their exclusive property and geographically selective circulation. In this informational inequality, norms perform as relays to regulate the production, reproduction, and circulation of knowledge transformed into products and services. Consequently, the disparity in the production and circulation of information and the selective role of norms lead to the geopolitics of innovation (IBAÑEZ, 2011; TOZI, 2012, 2020; TUNES, 2015). This is understood as the articulation between state and private agents from their territorial bases of action, which activate national borders, laws, resources, and institutions to support their insertion in the international division of labor.

This study's methodology is based on a systematic review of databases, documents, and reports, and a bibliographic review on Intellectual Property, the patent system, and the historical changes in national and international norms. Given the rise in the importance of the medicine and pharmaceutical sector since the 1990s, which reveals the historical convergence between innovation, patents, state policies, and corporate actions, it receives analytical prominence throughout the text.

FROM THE TRANSPOSITION OF COLONIAL STANDARDS TO TERRITORIAL SOVEREIGNTY: THE FIRST LAWS TO PROTECT INNOVATION AND THE EXCEPTION OF MEDICINES IN BRAZIL

The reconstitution of central events in the history of norms in Brazilian territory reveals ruptures, but, especially, continuities, even in the face of major changes in the political system, such as the transition from the Colony to the Empire and then the Republic. As the *modus operandi* between the colonized territories, the first norms related to Brazil were transposed from Portugal, creating the alienated territory's legal base, as defined by Cataia (2003).

According to Raffestin (1993 [1980]), all Geography of Power is based on the control of two territorial resources: energy and information. As a result, controlling the circulation of information was a strategy for the exercise of colonial power. At that time, books and other printed materials embodied the most advanced knowledge. The Philippine Code (1985 [1603]) imposed on Brazil and other Portuguese colonies, did not abstain from censoring and imposing sanctions on the forgery of goods and books (Book V, Title CII, p. 1249). The Code was only replaced in 1916, with the promulgation of the first Civil Code of the States and Municipalities of Brazil (Law 3.071, of 01/01/1916). Hence, the Code applied in the Brazilian territory long after it was revoked in Portugal and almost one hundred years after independence. The Civil Code (Book II, Title II, Chapter VI) adopted the Roman-Germanic principle of *Droit d'auteur*, which was regarded as a moral, exclusive, and hereditary right, distinct from the Anglo-Saxon copyright (©) ².

The first Brazilian regulation dedicated to Industrial Property (Alvará of April 28, 1809, signed by D. João VI) promoted industrialization by granting fourteen years of rights to the inventors and introducers of new machines in Brazil. After that period, priority was given to the public interest and the Invention Plan should be published "...so that at the end of that term, the whole nation will enjoy the fruit of this Invention". The 1824 Political Constitution of the Empire of Brazil (Art. 179, XXVI) maintained these principles while the Law of August 28, 1830, signed by D. Pedro I, granted patents to useful discoveries. Inventions patented in a foreign country lost their validity in Brazil, although their introducer's privileges in the country were guaranteed. The monopoly would be forfeit if the patent were not used within two years, imposing a faster time for the spread of inventions, which should go from abstraction to concreteness.

However, a further internationalization of the territory was already in force and indicated Brazil's participation in the international division of technical and scientific work, that differentiated between creative and consuming countries. Patents were granted to foreigners such as Thomas Edison's "[...] machine called the phonograph", in 1878. The following years brought key events for the internationalization of innovation protection norms: the first International Patent Convention (1879) was the basis of the International Union Convention for the Protection of Industrial Property, which in turn idealized the Union for the Protection of Industrial Property (Paris Convention for the Protection of Industrial Property, 1883). The United States of Brazil was among the first signatories of the Paris Convention. Subsequently, the Berne Convention (1886) systematized copyright protection.

Nevertheless, political action is not limited to norms. Piracy and the practice of copying inventions and expropriating patents underpinned national industrial policies, as noted by Chang (2004 [2002]). According to Gille (1993 [1948], p. 1341), few countries ratified the text resulting from these Conventions and, as patents are granted by national States, there were conflicts between norms. Despite this, cosmopolitanism overcame isolationist tendencies, especially after the Second World War (BADIE, 2016; GOTTMANN, 1975), that is, the world's tempo starts to impose itself more strongly on the tempos of national territories.

As a result, new efforts were orchestrated to create an international Intellectual and Industrial Property Law. In 1947, the GATT (General Agreement on Tariffs and Trade) was adopted, while the 1952 Geneva Convention regulated the adoption of the copyright principle by the Bern signatories. In 1967, the World Intellectual Property Organization (WIPO) was established, leading to the approval of the Patent Cooperation Treaty (PCT) in 1970. This normative basis created the legal guarantee which enabled the subsequent expansion of global companies.

Brazilian specificities persisted: the spirit of exception to the rules of 1809, 1824 and 1830 was maintained in the Industrial Property Code (Decree-Law No. 7.903, of 1945). This Code guaranteed patenting rights, but excluded inventions related to chemicals, alloys, and food products or materials, and medicines of any kind (Section II, Article 8, § 2). The revisions of the Code, in 1969 and 1971 (Decree-Law 1,005 and 1971 and Law No. 5,772), expanded these exceptions and included processes to obtain or modify medicines among the items without the right to protection.

Two elements of these exceptions must be considered: i) the importance of base elements (chemicals and alloys) in the internalization of industrial development; ii) the construction of social protection policies (food and health) based on the non-recognition of patents on food products and medicines. Concerning drug production, one notable example was the creation of Farmanguinhos

(Institute of Technology in Pharmaceuticals, integrated with the Oswaldo Cruz Foundation, Fiocruz, in 1970) in 1956. The laboratory specialized in the reproduction of therapeutic molecules that had already been discovered and protected, permitting the development of products at a lower price than those of private laboratories.

Social protection policies were reinforced with the re-democratization of the country and the promulgation of the 1988 “Citizen’s” Constitution, which had a guarantor bias and established the notion of Social Security (Chapter II, Section I). However, from the 1990s onwards, the country’s accelerated internationalization and the demands for “modernization” gained momentum, leading to ruptures in the patenting exceptions in the medicines and food sector.

THE NEW INTELLECTUAL PROPERTY LAW, THE CENTRALITY OF DRUG PATENTS AND BRAZIL’S PERIPHERAL SITUATION IN THE FIELD OF INNOVATION

Initially vague and ideological, with the election of governments with neoliberal biases in the 1990s, the idea of modernization became a true national theme, although its meaning was not questioned. A new psychosphere (SANTOS, 1996) advanced, replicating values and desires that prepared behaviors for the country’s entry into globalization, including the modification of national intellectual property rules. Under the argument of the lack of “legal certainty”, the participation of corporations in the public debate increased, as did the importance of the American 301 Reports, which underpinned the changes to Brazilian legal documents.

Ano	Classificação	Ano	Classificação	Ano	Classificação	Ano	Classificação
1989	Priority Watch List	1997	Watch List	2005	Priority Watch List	2013	Watch List
1990	Priority Watch List	1998	Excluded	2006	Priority Watch List	2014	Watch List
1991	Priority Watch List	1999	Watch List	2007	Watch List	2015	Watch List
1992	Priority Watch List	2000	Watch List	2008	Watch List	2016	Watch List
1993	Priority Foreign Countries	2001	Watch List	2009	Watch List	2017	Watch List
1994	Excluded	2002	Priority Watch List	2010	Watch List	2018	Watch List
1995	Priority Watch List	2003	Priority Watch List	2011	Watch List	2019	Watch List
1996	Watch List	2004	Priority Watch List	2012	Watch List		

Figure 1 – Brazil’s Classification in the Special 301 Report (1989-2019). Source: USTR, Special 301 Report (Editions between 1989 and 2020). OWN ORGANIZATION.

The Special 301 Reports, prepared annually since the adoption of the Omnibus Trade and Competitiveness Act (Public Law 100-418, of 23/08/1988), translate geopolitics into text, revealing the externalization of American policies. The name refers to Section 301 of the Trade Act of 1974 (Public Law 93-618, of 03/01/1975), which authorized the President to retaliate against countries whose behavior is considered unfair to Intellectual Property. The 301 Reports are produced by the Office of the United States Trade Representative (USTR) and rank countries according to the highest (Watch List) or

lowest (Priority Watch List and Priority Foreign Countries) respect for Intellectual Property under a monopoly of US corporations.

In the 1989-2019 Reports (Table 1), Brazil fluctuated between demotion and promotion in an Intellectual Property ranking that acts as a prize or a punishment to the country in question. The country has been on the Watch List since 2007, but in 1993 it was classified as a Priority Foreign Country, the most serious category and the USTR (1993, p. 04) announced the beginning of an investigation into Brazilian practices. Over the following years, there were ruptures in the traditional Brazilian Intellectual Property laws and a consequent improvement in the country's assessment in the respective Reports. In 1994, Brazil signed the TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights). The country approved the Intellectual Property Law (Law No. 9,279), and the new Copyright Law (Law No. 9,610), in 1996 and 1998, respectively.

According to the 1994 USTR Report, the investigation initiated the previous year had been completed and Brazil deserved a "special mention": "Brazil's welcomed reform efforts in intellectual property rights are important to a broad cross-section of the U.S. private sector. We will closely monitor these efforts with great interest" (USTR, 1994, p. 15. Emphasis added). In 1996, the Intellectual Property Law was considered an "admirable step" and its modernity was praised (USTR, 1996, p. 2; 12). Once implemented, they continue, the Law would help Brazil to stabilize its regional leadership, making it more attractive for investments in technology and innovation.

An analysis of the legislative procedures of the Intellectual Property Law indicates the deepening of the complicity between the national adoption of norms and the country's classification in the USTR Reports. Bill 824/1991, authored by Congressman Ney Lopes (PFL-RN), was chosen to guide the discussions. Brazil's negative assessment in the 1993 Special 301 Report accelerated the Bill's progress, with the patenting of medicines and chemical-pharmaceutical products emerging as a central theme. The legislative process enables the monitoring of other social agents' participation, such as INTERFARMA (Association of the Pharmaceutical Research Industry), which has participated publicly since the 10/12/1991 meeting of the Special Commission³.

In March 1993, INTERFARMA argued that the Bill was necessary since the laboratories aimed to develop research involving Brazilian plants, which would be unfeasible if the patents were not secured. The Ordinary Sessions of April 13 and 15, 1993 were changed into a Special Commission to discuss the Bill. The speeches of the participants alternated between the protection of research and national industry and the defense of "modernization", criticisms of these concepts were defined as "retrograde" and "isolationist"⁴. On 06/02/1993, the text's final version was approved by the Chamber and forwarded to the Federal Senate (PL 115/1993). The spirit of the Project was not only maintained but expanded. Despite resistance, once back in the Chamber the bill was approved and later sanctioned.

Previously, all food, chemical-pharmaceutical, and medical products were subject to patenting, however, with the new law, the processes used to create products could also be patented (Art. 230). Santos (1998, p. 30) argues that this obsession with modernity took the country into a new phase of non-sovereign international insertion. Nature itself, the realm of reproduction, and therefore, the opposite to the notion of invention, became subject to patenting, allowing new forms of primitive accumulation (LENCIONI, 2012; TOZI, 2012), specificities of the current accumulation by dispossession (HARVEY, 2003).

By allowing the patenting of Brazilian biodiversity, part of the territory's natural composition was alienated to corporations. This authorization of biopiracy was inspired by US legislation, although Brazil did not have equivalent social agents and institutions. The Intellectual Property Law permitted extreme situations, such as the bizarre patent application for cupuassu, a fruit native to the Amazon, by the Japanese corporation Asahi Foods⁵.

Among the new regulations for drug patents, one of the most abstruse concerns the retroactive recognition (or revalidation) of existing patents, through a pipeline or "import" of the first deposit overseas (Articles 230 and 231). Despite having the prerogatives to do so, Brazil did not adopt the safeguards provided for in the TRIPS agreement (Articles 65 and 66), which provided for longer periods for "developing" countries in the transition from a planned economy (centrally-planned) to a market economy based on freedom of enterprise (market, free-enterprise economy). Rather than maintaining the Brazilian tradition that preserved medicines from other common patents, it was interrupted and reversed.

Also, it is noteworthy that the provision modified the status of products that were already in the public domain, fundamental to public health policies, and formed national economic sectors. Chaves et al. (2007), observe that the use of the periods foreseen in the TRIPS would strengthen national productive capacity and thus protect against competition from foreign corporations. Unlike Brazil, India chose to use the TRIPS term for retroactive patent recognition and would, years later, become an important exporter of low-cost medicines, including to Brazil, one of its major buyers.

According to Santos (1998, p. 26), this historic moment saw the expansion of biotechnology companies based on thematic convergence and mergers between the industries of the pharmaceutical, agrochemical, and oil sectors. These corporations viewed Brazil as fertile territory for their global expansion but were hindered by the territorial-national normative code that did not adhere to the monopoly rights ensured in their countries of origin. Therefore, Congressman Ney Lopes' project was both the solution to this impasse and a necessary concession to preserve Brazilian exports, which benefited from the customs tariff reductions of the General System of Preferences (GSP), in the face of sanctions threats.

There are indications that the original text of Congressman Lopes' Bill was drafted by INTERFARMA (SANTOS, 1998, p. 27), however, this topic still requires clarification. On the other hand, speeches made at the time reveal converging views. One example can be found in the depositions of Francisco Teixeira, then Executive Vice President of INTERFARMA and the then US Ambassador to Brazil, Edward Verano, as recorded by the Minutes of the Chamber of Deputies of 12 / 11/1991, the General Commission of 04/13/1993, and the Constitution and Justice Commission⁶. Concurrently, Teixeira was the owner of Clever Consultoria, which specialized in pharmaceuticals, chemicals, and biotechnology. The preface to the first edition of his book on patents (TEIXEIRA, 2006 [1997]) was written by the parliamentarian Ney Lopes and was funded by the pharmaceutical laboratory GlaxoWellcome, while the second was sponsored by INTERFARMA. A handbook of corporate ideas about Intellectual Property, the book does not lack ironic comments on the "retrograde ideals" opposed to drug patenting.

Nevertheless, even after the Law was approved, drug patents continued to be one of the central themes of the following editions of the Special 301 Reports, which explains the importance of the topic in US-Brazil relations. Although the legislation was considered a "notable advance" (USTR, 2012, p. 42), the National Health Surveillance Agency's (ANVISA) technical-scientific opinions on patent applications began to be called into question. The 2012 Report encouraged Brazil to adopt procedures to ensure that the Agency no longer had the authority to review the requirements for obtaining pharmaceutical patents.

Indeed, many laboratories have challenged ANVISA's unfavorable opinions in court. However, with the new Intellectual Property Law, the number of drug patents has multiplied rapidly (BICUDO, 2009). Furthermore, after the 2012 Report, an Inter-ministerial Working Group altered the flow of drug patent applications, so that the application is made to the INPI (National Institute of Industrial Property) that forwards the process to ANVISA, which is restricted to only analyzing the health effects. The Agency maintained the prerogative of refusal but is no longer linked directly to the concession.

The change in the Agency's functions exemplifies the growing technical specialization of political decisions and reveals the indirect mechanisms through which one country acts over another, even though the classic definitions of territorial sovereignty have been maintained. The Report was approved by Interministerial Ordinance No. 1,065, of 05/24/2012, while the Special 301 Report, which criticized ANVISA was released in April 2012. The proximity between these dates does not appear to be fortuitous. In its most recent edition (USTR, 2020, p. 78), the USTR continues to express its concerns about ANVISA's role in the analysis of drug patents, while welcoming the limits already imposed on it by the Federal Government.

The Intellectual Property Law was presented as an inevitable step in the "modernization" of the country following the good examples from "civilized countries" and preventing Brazil from continuing to be a "paradise for brand piracy". More than twenty years after it was passed, it is clear that the Law, which avoided creating privileges for the national pharmaceutical industry, ended up prioritizing foreign manufacturers, thereby placing unequal economic agents on an equal footing in an oligopolistic global market controlled by American and European multinationals, as shown by Antas Jr. (2019, p. 10).

Currently, patents guarantee legal certainty in the various national territories, ensuring continuous royalty payments, whilst offshore territories safeguard low duties and taxes on pharmaceutical corporations (MACHADO, 2017, p. 335).

In this sense, Väyrynen's (1978, p. 342) assertion is pertinent. Patents are a means of monopolizing information, thus reinforcing the multinationals' "meta-power" and boosting their ability to manage the relationships between metropolises and technical peripheries. Similarly, Bognár (1968, p. 47) presents patents as new colonizing powers to ensure what he defines as "intellectual monopolies". Graph 1 presents these "technical metropolises" based on the growth of patent applications between 1883 (the year of the Paris Convention) and 2018, the year in which the total valid patents reached 3.3 million.

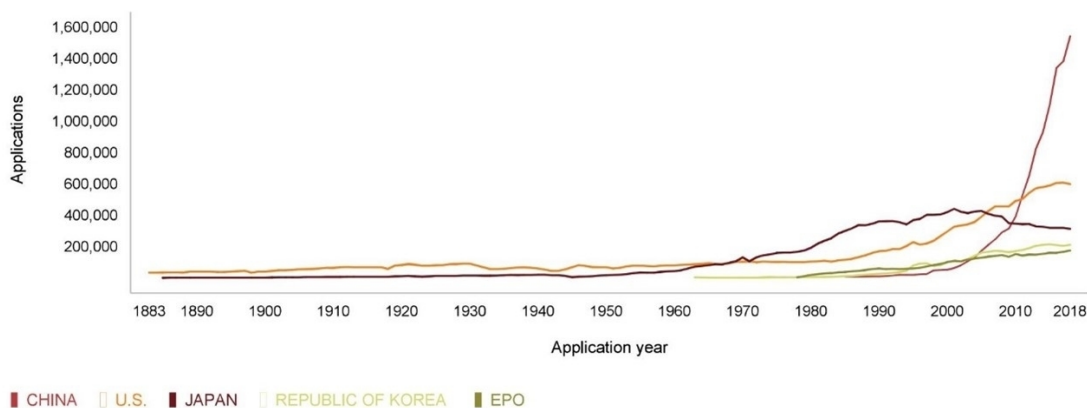


Figure 2 - Patent applications at the five largest Intellectual Property offices (1883–2018). Source: WIPO (2019, p. 14).

Each country has its individual system, with its respective office or institute for the control of Intellectual Property, such as the INPI in Brazil. In Europe, the system became regional with the creation of the EPO (European Patent Office) in 1977. The data make it possible to monitor the importance of patents in each country, enabling an analysis of the international division of labor based on innovation. The top five offices accounted for 85% of worldwide patent applications in 2018, revealing the restricted circulation of innovation.

From 1968 to 2005, the Japanese office had the highest number of applications, when it was surpassed by the American body, which has gained importance since then; the European and South Korean institutes have grown since 1975. Asia has become the most active patenting region and China has led ranking since 2011 (also in the brands and design categories), accounting for 47% of the total applications in 2018. Americans lead patent applications beyond their national borders, followed by Japan, Germany, South Korea, and China. Therefore, these five countries are foremost in innovation developments requiring protection abroad, which indicates the commercial expansion policies aimed at markets in other territories.

Brazil ranked 26th in the world in 2018. Although requests for deposits and the number of concessions have grown in the country since the 1990s (the number of requests more than doubled between 1998 and 2014, from 14,970 to 33,075), most are for "non-residents" (10,233 and 25,779, respectively), showing that foreign applicants are the main beneficiaries of Brazilian Intellectual Property Law. However, since 2014 the number of patent applications to the INPI has fallen, reaching 27,444 in 2018, of which 19,971 were from non-residents. Therefore, despite growth in specific sectors, such as medicines, the country has been passed over by foreign applicants. Also, there is dissatisfaction with the average analysis period of 86 months, which is substantially longer than that of the runner-up, India, with a term of 52 months, while that of the European Institute (EPO) is 22 months⁸.

Universities and public companies, such as Petrobras and Embrapa, are the main agents of innovation and, consequently, the main beneficiaries of Brazilian patents. According to Dagnino (2007, p. 91), the participation of foreign private capital in national innovation reveals that the technological

effort of Brazilian divisions is small, even though they are the majority among the large companies in the country. Besides, most of the patents granted to Brazilians are in the Utility Model category, in other words, they are just an addition to an existing registration. Despite the importance of this category for Brazil, it does not even exist in the leading foreign offices. Therefore, in the territorial division of labor, as a rule, Brazil does not develop new technologies, instead, it buys or expropriates them.

PERSISTENT TENSIONS BETWEEN HEALTH AND DRUG PATENTS: TIMES OF EPIDEMICS AND PANDEMICS

Despite being presented as an advance in “legal security”, more than two decades after its approval there are pending issues involving the Intellectual Property Law and drug patents. The case of patent pipelines has remained undefined for eleven years since the Direct Action of Unconstitutionality (ADI nº 4.234 / DF, 2009), which is still in course at the Supreme Federal Court (STF). Proposed by the Attorney General’s Office, the Action questions the attribution of novelty to products that were already in the public domain and claims that retroactivity would have caused price increases due to the centralization of the offer and/or renewal of royalties. In reality, this is not a secondary issue as it deals with the meaning of patentability in the framework of territorial sovereignty. The ADI ruling was suspended by Minister Carmen Lúcia Antunes Rocha on 5/20/2019⁹, but, when resumed, it will shed light on the procedures of the Intellectual Property Law and how the pharmaceutical sector in Brazil has been oligopolized.

Drug patents also reveal internal contradictions within the state itself: the same government that passed the Intellectual Property Law passed the “Generics Law” (Law No. 9,787, of 10/02/1999) opening up the national market to pharmaceuticals with internationally canceled patents. The next administration deepened this interpretation and revoked an antiretroviral patent (Decree No. 6,108, of 05/04/2007) in the public interest through a compulsory license since the costs of the National STD/AIDS Program had increased due to high drug prices amid the epidemic. This practice has been replicated and remains essential in the universalization of top of the range treatments, allowing for purchase policies or “pirate” production of drugs distributed by the SUS. These state actions are a new theme in the history of the country’s hybrid relationship with drug patents.

Hence, the growing importance of patents does not prevent them from being questioned in times of public health crisis and this phenomenon has gained international dimensions in 2020, with the COVID-19 (SARS-CoV-2) pandemic. Although the process is in the early stages, it is already clear that the debate on innovation, patents, and health has been updated based on the actions of States, corporations, and international institutions. Even before the registration of COVID-19 patents, the Resolution of the 73rd Assembly of the World Health Organization supported their breach, recovering the concept of compulsory licenses found in the TRIPS agreements¹⁰. However, this Resolution has been resisted by the United States, which issued a Communiqué rejecting the passages addressing the issue, informed that it had frozen its financial support of the Organization, and announced that it was considering withdrawing from the WHO. The Communiqué accused the WHO of neglecting the pandemic to benefit China, “Clearly not serving the interests of the United States¹¹”. China, for its part, has pledged to waive patent rights on its future vaccine.

On the other hand, about 500 existing patents are considered potential treatments of COVID-19 (LIU et al., 2020), and health issues end up renewing the commercial importance of valid patents. At the same time, the collaboration between private and public laboratories is defended as essential to speed up tests, treatments, and vaccines, renewing cooperation between the State and the market in pharmaceutical innovation. In July 2020, there were 166 vaccines under development, of which 27 were being tested in humans, and five of which were in Phase III, that is, large-scale efficacy tests (WHO, 2020). An analysis of the headquarters of the companies and institutions that coordinate this research provides data on the international division of labor based on innovation in the field of health.

The United States has the highest number of research projects (27), followed by China (13), Turkey (11), Canada (10), Russia (10), Japan and India (7), the United Kingdom, Thailand, and Spain (6). There are two Brazilian projects, both conducted by public institutions (Fiocruz, Instituto Butantã, and

the University of São Paulo). The same pattern is evident for international cooperation projects, the United States leads the ranking (19 projects), followed by China (7), the United Kingdom (5), France, Germany, and India (4). There are five joint projects involving Chinese and American institutions, so, despite the differences voiced in the WHO, cooperation between the two countries prevails.

These agreements occur because, although the number of studies (166) is significant, this diversity is artificial. As soon as some vaccines are approved in Phase III and licensed, the testing protocols for the others become more rigorous, and thus more expensive, which will reinforce the trend towards oligopolization in the sector. This explains why several countries have signed vaccine purchase agreements when they reached the final testing phase¹². Like war and patents, pandemics have a geopolitical dimension and the strengthening of national policies is observed, making “pharmaceutical and sanitary sovereignty” (RAMONET, 2020) a dimension of territorial sovereignty.

In this sense, three of the five most advanced research ventures (WHO, 2020) are Chinese: one developed by Sinovac Biotech Ltd. and two by the state company Sinopharm in partnership with state institutes. The Anglo-Swedish AstraZeneca is developing its vaccine in partnership with the University of Oxford, while the American Moderna Therapeutics has signed agreements with state agencies, which invested in their research. The fifth vaccine is being developed by the German BioNTech in partnership with Pfizer (USA) and the Chinese Fosun Pharma.

Therefore, public health issues to combat the pandemic do not exclude the fact that these vaccines are patent-protected commodities with hundreds of millions of potential consumers, even if indirectly served by state purchases. After all, a discovery without a patent removes the vaccine from the realm of goods¹³. An innovative capacity also translates into an increase in the market value of corporations, such as Moderna, which gained 300% in four months¹⁴. The share value appreciated when the results of their vaccine were promising, but also, as the American government invested public funds in the company's research, bought its vaccines and diverged from the WHO Resolution on patents. In an example of the geopolitical symbiosis between the State and corporations, Moncef Slaoui, an executive at Moderna, took over as Chief Counsel of Operation Warp Speed¹⁵, a public-private partnership to develop vaccines in the country.

The interface between politics, innovation, and the pandemic has reinforced Brazil's peripheral position. Rather than develop vaccines, its drug research and production infrastructure has mainly been used to produce foreign vaccines under license in agreements to purchase productive technology. The same contingencies observed by Bertollo (2013) during the 2009 H1N1 virus pandemic have been aggravated by the restrictions imposed by Constitutional Amendment 95/2016, which limit investments in public research centers for 20 years. Also, since contagion rates in the country remain high, it has become a favored locus for human testing. Thus, the country renews its peripheral role, regardless of any priority this may confer in the purchase of foreign vaccines.

CONCLUSION

The reconstruction of the central events of Brazilian and international norms to protect Intellectual Property, with emphasis on Brazilian patent laws, is essential in the analysis of the role of innovation in the informational phase of capitalism. In this context, the topic of patents for medicines and drugs stand out; it was possible to identify ruptures in how the subject was treated before and after the approval of the Intellectual Property Law (1996). This normative change is linked to a new phase of internationalization of the national territory and reinforces the country's peripheral role in the international division of labor guided by innovation.

The analysis of the Special 301 Reports gives empirical data on the correlation between the United States government's evaluations and recommendations and the changes to Intellectual Property protection in Brazil, especially the Intellectual Property Law and ANVISA's role in drug patenting. Therefore, a State's action beyond its borders gives new content to the notion of territorial sovereignty and authorizes us to speak of geopolitics based on innovation.

The importance of innovation, knowledge transformed into products and services, is evident in the systematic growth in the number of patents in the five main registration offices worldwide (American, European, Japanese, South Korean, and Chinese). In Brazil, patent applications have grown since 1998,

however, they have fallen since 2014, revealing empirical elements of the country's participation in the international division of labor. Also, the patents registered with the INPI are mostly applications by foreigners, whilst the patent submissions by residents are mainly from public institutions and relate to improvements in patents already in force.

Finally, cooperation and conflict between the State and corporations are manifested in particular ways in times of public health crises. During the HIV / AIDS epidemic, Brazil broke drug patents to ensure treatment by the SUS. In turn, during the COVID-19 pandemic, the transfer of state funds to pharmaceutical corporations is an international phenomenon, as well as the multiplication of cooperation between public and private laboratories. The purchase agreements of potential vaccines by several countries reveal the prevalence of national policies to the detriment of multilateral agreements, despite efforts by the WHO. Last, the analysis of the geographical concentration of research and cooperation in COVID-19 vaccines reveals a division of labor that updates Brazil's peripheral situation concerning innovation.

NOTE

1- The concept of Intellectual Property brought together Industrial Property (inventions, innovations), Intellectual Property (literary and artistic works), Brands (symbols and names) and Geographical Indications.

2-With the popularization of movable mechanical presses (from the fifteenth century) it was possible to produce texts, but also copies and adulterations. This process was central in defining the philosophical and moral sense of the idea of author and authorship, bringing the two lines of European law into opposition. For Kant (1990 [1785]), only written works had authorship, unlike works of art or techniques. However, this conception of authorship changed, and there was a transposition of the idea of authorship to technical inventions.

3-Diary of the Chamber of Deputies, year XLVII, n. 11, of 02/19/1992. Available in: <http://imagem.camara.gov.br/Imagem/d/pdf/DCD19FEV1992.pdf#page=146> . Accessed on: 04/09/2020.

4-Diary of the Chamber of Deputies, Year XLVIII, n. 59, of 04/14/1993. Available in: <http://imagem.camara.gov.br/Imagem/d/pdf/DCD14ABR1993SUP.pdf#page=1> . Accessed on: 04/09/2020.

5-The registration was canceled in 2004 and the cupuassu was subsequently declared "national fruit" (Law 11.675 / 2008). Application for registration at: European Patent Office (EPO), Fat originating in cupuassu seed, process for producing the same and use thereof. Applicants: Asahi foods LTD, ID: JP2001348593A. Available in: <https://worldwide.espacenet.com/patent/search/family/027530763/publication/JP2001348593A?q=pn%3DJP2001348593A> . Accessed on: 01/15/2020

6-Diary of the Chamber of Deputies, n. 11 and n. 59, Op. Cit.

7-Terms used by Esther Flesch and Lélío Schmidt. Caminhos certos, boas escolhas, Editorial, ABPI Newsletter 11/11/2000.

8-Based on the databases provided by INPI, on demand, and WIPO (2019).

9-Available in: <https://portal.stf.jus.br/processos/detalhe.asp?incidente=12879> . Accessed on: 05/03/2020.

10-73rd World Health Assembly - COVID-19 response, World Health Organization , May 19, 2020. Available in: www.who.int/about/governance/world-health-assembly/seventy-third-world-health-assembly . Accessed on: 05/20/2020.

11-DELETAR. Available in: <https://www.whitehouse.gov/wp-content/uploads/2020/05/Tedros-Letter.pdf> . Accessed on 20/05/2020.

12-Among these agreements, we highlight those signed by the United States government, through Operation Warp Speed, with Pfizer / BioNTech, AstraZeneca / University of Oxford, Moderna and

Sanofi / GSK. The European Union, through Europe's Inclusive Vaccines Alliance (IVA), agreed to purchase the vaccine developed by AstraZeneca-University of Oxford. In Brazil, the most important are the technology purchase agreements: i) between the São Paulo State Government, through the Butantã Institute, with Sinovac; ii) between the Union, through Fiocruz, with AstraZeneca / University of Oxford and; iii) between the Paraná State Government, through the Paraná Institute of Technology, and the Chinese state-owned Sinopharm.

13- This was the case for Jonas Salk and Albert Sabin, who waived the patents for their respective polio vaccines in the 1950s.

14-NASDAQ-US shares went from USD 18.13 on 1/6/2020 to USD 73.47 on 5/20/2020. Available in: www.bloomberg.com/quote/MRNA:US . Accessed on 05/25/2020.

15-Trump Administration Announces Framework and Leadership for Operation Warp Speed; US Department of Health & Human Services, May 15, 2020. Available in: www.hhs.gov/about/news/2020/05/15/trump-administration-announces-framework-and-leadership-for-operation-warp-speed.html . Accessed on 05/25/2020.

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