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# THE LEGAL SYSTEM OF PHARMACEUTICAL PATENTS IN BRAZIL

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**Abstract:**
This study aims to discuss the criteria adopted by the Brazilian legislation on the patentability of pharmaceutical products at the National Institute of Industrial Property, as well as the obligation to submit the application to a prior consent from the National Health Surveillance Agency, due to the great social importance of the theme of access to medicines and consequently access to health, and also to protect innovation, involving the national techno-scientific development.

**Keywords:** Patents; medicines; public health; industrial property; legislation; Brazilian

## Introduction

The development of the industrial property protection occurred concurrently to the evolution of the International law field, in the end of the 19th century. One hundred years later, economy globalization has been producing essential effects on national laws, which until them had several gaps, starting a movement of international knowledge protection. More and more industries and trade relations exceed national borders. The inventor or research institute is no longer limited to its own country, regarding the protection of technological assets.

The right to access to medicines and the right to pharmaceutical patent are initially declared by international organizations and subsequently incorporated by the various national legal systems, that can not form watertight compartments under penalty of compromising the international trade.

This study aims to approach the criteria adopted by the Brazilian legislation on patentability of pharmaceutical products at the National Institute of Industrial Property, as well as the obligation to submit the application to a prior consent from the National Health Surveillance Agency, due to the great social importance of the theme of access to medicines and consequently access to health, and also to protect innovation, involving the national techno-scientific development.

## 1. Brief History of the Rise of Patent Protection in Brazil

The Regent Prince, Dom João, on January 28, 1809, issued a license charter granting patent of invention.
The first Brazilian Constitution, of 1824, in its art. 179, XXVI, assured to inventors the property of their discoveries and inventions, establishing that *"the inventors will have ownership of their discoveries or production. The law will ensure them an unique and temporary privilege or will remunerate them in compensation of the loss that they may suffer due to vulgarization".*
On the other hand, the first Brazilian patent law, after independence, signed on August 28, 1830, granted" privilege to the one that discovers, invents or improves a useful industry, and an award to those that introduce a foreign industry, and regulates its concession". (ALMEIDA, 2011)

The first Republican Constitution, of 1891, maintained the privilege of security for inventors, declaring in article 72, § 25, *inverbis:*

Industrial inventions belong to their authors, to whom there will be guaranteed a temporary privilege by law, or be granted by Congress a reasonable prize, in case it´s convenient to popularize the invention.

According to Gama Cerqueira, to pay a reasonable premium did not correspond to a compensation for expropriation and not even any kind of reward, but a mere substitute for the privilege. If there were convenience in the popularization of the invention, instead of receiving the privilege, the inventor would receive a prize. (CERQUEIRA *apud* FURTADO, 1996)
The Liberal Constitution of 1934 kept almost unchanged the wording of the previous text, art. 113, item 18, while the Constitution of the authoritarian regime that started in 1937 did not express reference to the inventor's rights. Thus, the industrial property would have to seek protection in the broader context of the property institute, as a fundamental right and guarantee.
In 1945, the Decree 7.903 introduced changes to the previous legislation, highlighting the following: deleting the privilege of inventions related to food and medicines, similar exclusion regarding materials or substances obtained by chemical processes and the definition of novelty as a requirement for patents granting.
The 1946 Constitution, again a liberal charter, returned to expressly dispose on industrial inventions, using in § 17 of Art. 141 almost the same wording of that of 1934: "Industrial inventions belong to their authors, to whom the Law will ensure temporary privilege or, if the vulgarization suits the community, just give a reward".

The Constitutions of 1967 and 1969 also expressly ensured rights to the inventor. Finally, with the democratization of the country, the 1988 Constitution brought, like the others, expressed provision on the protection of industrial inventions, featuring article 5, XXIX, *inverbis:*

The Law shall ensure the authors of industrial inventions temporary privilege for their use and ownership and shall guarantee brand property, either commercial or industrial, as well as exclusivity of brand commercial name.

**2. The Legal Protection of Pharmaceutical Patents in Brazil**
Currently, the Constitution of the Federative Republic of Brazil, 1988, as well as the Industrial Property Law (Law 9.279 of May 14, 1996), establishes national rules to protect patents.

Industrial property is an episode of Intellectual Property (which is divided into two branches: the author rights and intellectual property), that deals with intangible assets applicable to industries such as patents of invention and utility model, industrial design registration, registration of products and services brands, repression to false geographical indications and repression to unfair competition.

With respect to the pharmaceutical patents, the technological development of the pharmaceutical industry has never been a priority in Brazil, although considered in many countries as national security. From 1945 to 1969, Brazil only granted patents for pharmaceutical processes, denying them to products[1]. The exclusion was essentially politically motivated, that is, to provide, via appropriation of other people's knowledge,

[1]BRAZIL. Art. 9th Law 5772/71 – Non-privileged: c - substances, materials, mixtures or food products, chemical-pharmaceutical and medication of any kind, as well as the respective processes of obtaining or modification.

Brazilian development in these technology sectors. This plea was supported in the Convention of Paris[2], 1883, which established that any country could exclude from patenting any essential product due to social reasons, threat to health and national security. (LYARD, 2006)

Since patent was denied during the referred period, the lack of an appropriate policy for the sector prevented investments to be made. As a result there was the dismantling of the pharmaceutical industrial park due to the lack of public and private investments in research and development. (LYARD, 2006)

Since Brazil did not recognize, at the time, pharmaceutical patents, it suffered several retaliations because of powerful lobby introduced in the USA by the Pharmaceutical Manufacturers Association with the US government.

In July 1990, retaliation ended, when the minister of economy of that time announced that Brazil would submit to the Congress a bill proposing a revision of the Industrial Property Code, with the objective, among others, of recognizing pharmaceutical patents. (LYARD, 2006)

Brazil started to recognize patents for the pharmaceutical industry in 1997, changing its industrial property legislation in 1996, with Law 9,279 / 96, possibly due to strong pressures and trade sanctions made by the United States since the end of the 80s, adjusting the new rules of the WTO (World Trade Organization)[3], establishing the beginning of an era, in which the protection of intellectual property rights turns to be an official component of the various multilateral trade agreements, among them the TRIPS (Trade Related Aspects of Intellectual Property Rights)[4].

The new law then expanded the scope of patentable subject matters, establishing the possibility of protection for all fields of technology, changing the prohibition of the previous law (Law 5.772 / 71), with respect to, for example, substances, materials, mixtures or food products, chemical-pharmaceutical and medication of any kind, as well as the respective processes of obtaining or modification. (PARANAGUÁ & REIS, 2009)

With respect to patent, this may be an invention or utility model, that is, in terms of purpose, they can be: patents of invention or utility model. So before you define what is a patent, you first must address what are invention and utility model.

Invention, according to Fabio Ulhoa Rabbit (2009), is the original act of human genius. Every time someone designs something unknown, he will be producing an invention. Although all inventions are unique, it may not be always new, that is, unknown to others.

According to Gama Cerqueira (1982), the invention, in terms of origin, is characterized as an intellectual creation, as a result of a inventive activity of the human spirit; by way of its realization, it is classified as a technical creation; and, for its purposes, it is a way to satisfy human practical needs.

Ronaldo Lemos (2010), on the other hand, considered invention the intellectual creation of technical or industrial purpose. Thus, the mere creation of the intellect is not considered invention strictly speaking, in

[2]*Convention dÚnion de Paris pour la Protection de la Proprieté Industrielle* – First multilateral treaty of universal vocation, aiming to improve the mechanisms of internationalization of ownership of technology and the productive sector.

[3] International organization that deals with the global rules of trade between nations.

[4] International treaty that consists of a set of rules that establish minimum standards to be observed by the signatory countries in their domestic law. To internationalize minimum levels of intellectual property protection, the TRIPS Agreement brings profound changes in nationally sensitive issues, as it is the case of pharmaceutical patents, which has become mandatory subject of patentability.

the technical legal sense of the word. According to the teacher, a creation, to be considered an invention, must consist of a new solution to an existing technical problem.

To Gama Cerqueira (1982), it is important to differentiate invention from mere discovery. The invention, in general, consists in creating something that didn´t exist; the discovery is the revelation of an existing thing in nature. The invention is presented as a solution to a technical problem, aims the satisfaction of certain purposes in practical terms; the discovery, on the contrary, is not intended to pre-established practical purposes, it only increases the sum of human knowledge about the physical world.

Thus, the distinction between discovery and invention becomes evident when one has in mind that this is a revelation of something already found in nature, although until them unknown, whereas invention brings out something before nonexistent.

Utility model is an object of practical use, of industrial application, with new format, which result in better conditions of use or manufacture. It is not, precisely, an invention, but it increases the usefulness of a tool, a working tool or utensil by the action of the partial novelty added to it. It is called also a "small invention" and enjoys autonomous protection in relation to the invention that had its utility improved. (COELHO, 2009)

Law 9.279 / 96 determines, in article 10, what is not considered as an invention or utility model, such as discoveries; scientific theories and mathematical methods; literary, artistic and scientific works; schemes, commercial or financial plans or methods; computer programs themselves; game rules; techniques and surgical methods; all or part of natural living beings and biological materials found in nature, etc. Therefore, they are not entitled to have patent protection.

After approaching the concept of invention and utility model, we will discuss now the concept of invention and utility model patents.
Invention patent, in the words of Gama Cerqueira (1982, p. 202):

The patent of invention, issued by the government, subject to the legal procedures and under certain conditions, is the act by which the State recognizes the right of the inventor, assuring him the property and the exclusive use of the invention for the term of the law. It represents the title of inventor property right. It is, at the same time, evidence of law and the legal title for its exercise. Figuratively means the privilege itself.

Thus, the patent of invention, in addition to protect the invention, consists of a title issued by the State, through the agency responsible for that - in Brazil, it is the National Institute of Industrial Property (INPI) that gives to the author the exclusive property and exploitation of the invention for a limited period[5], counted from the filing date in the INPI. (LEMOS, 2010)

If the holder does not require the patent, the right to property and the exclusive exploitation do not exist. The invention, in the Brazilian legal system, will only be recognized as such and thus be protected by our legal system, if it is patented. It is present, then, the attributive effect of the registration rights. (LEMOS, 2010)

Patents of invention, in turn, can be classified according to their object: in procedures or product patents.

[5] BRAZIL. Art 40 - Law 9.279/96 - The period of exclusive use comprehends 20 years from the filing date, or, at least ten years from the grant date, except in the case that INPI is prevented from proceeding to the order of merit examination due to judicial pending matters or force majeure.

Both modes must correspond to mechanisms for obtaining particular technical solution to a problem, as follows:

a) procedure patent: When technology consists of the use of certain means to achieve a technical result through the action upon nature, there has been a procedure patent. Thus, the set of human actions or mechanical or chemical procedures necessary to get to a result (to heat, to insert an acid, to bring a product to absolute zero) will be subject to a patent. In the case of procedure patent, there is a reversal of the burden proof in counterfeiting procedures, such as granting for being extremely costly to the patentee to prove which process is being used by the alleged infringer. (BARBOSA, 2003)

b) product patent: The technology can be, on the other hand, related to a given physical object: a machine, a chemical, a mixture of different substances, a microorganism, an element of equipment, etc. The patent that protects this kind of technology is called "product patent". (BARBOSA, 2003)

Denis Borges Barbosa (2003) also discusses "device patents", that are product patents and their inclusion in a claim does not offend the requirement of unit patent. Thus, it would be possible to reclaim both the product and the apparatus for manufacturing it. Example: industrial mixture preparation device.

As for the utility model patent (UM), its definition can be found in Law 9.279 / 96 in article 9[6]. This patent mode is associated with functional improvement in the use or manufacture of "known objects", that is, it has a smaller level of inventiveness and therefore enjoys a shorter duration of protection than the invention patent[7]. (LEMOS, 2010)

Finally it is worth mentioning that patents of inventions as well as of utility models are subject to the

following requirements:

a) novelty: in order to obtain the industrial right it is not enough for the invention or the utility model to be unique. The creation must be unknown to the scientific, technical or industrial community (article 11 of Law 9.279 / 96).

b) inventive activity:, the law establishes that the invention has inventiveness when it is not an obvious result of the prior art (article 13 of Law 9.279 / 96). In other words, the invention must awaken in the spirit of the technicians of the correspondent area the sense of a real progress. In turn, the utility model meets the requirement if it doesn´t result in a common or usual manner of the prior art, in the opinion of experts (art. 14 of Law 9.279 / 96).

c) industrial applicability: assuming its use in some practical and industrial activity or possible industrial production (Article 15 of Law 9.279 / 96).

d) non-impediment: the law prohibits, for technical reasons or public interest, the patentability of certain inventions or utility models (article 18 of Law 9.279 / 96). Examples: affront to morals, good customs, security, order and public health, substances resulting from transformation of the atomic nucleus, living beings, except those that are gifted with characteristics unattainable by the species under natural conditions (transgenics, GMOs).

After the requested administrative procedure, INPI (National Institute of Industrial Property)[8] will issue its charter, that is the only acceptable proof recognized by law, to demonstrate the right of exclusive use of the invention or utility model. No one can claim the right to exclusively economic exploitation unless it has been obtained, from INPI, the corresponding grant. (COELHO, 2009)

[6]BRAZIL. Art 9th Law 9.279/96 - It is patentable as a utility model the object of practical use, or part of it, susceptible of industrial application, presenting new shape or arrangement and involving an inventive act that results in functional improvement in its use or manufacture.

[7] BRAZIL. Art 40 - Law 9.279/96 – The utility model patent will be valid for 15 years from the date of deposit to 7 years from the grant date.

[8] Industrial rights are granted by the State, through the National Institute of Industrial Property (INPI). The right to exclusive use of the patent object depends on the corresponding concessive act.

It´s important to remember that to be patentable, an invention must meet the requirements of novelty, inventiveness and industrial application. The lack of any of them prevent grant of the benefit, and they can not be listed in the exceptions as prohibitions to exclusiveness, arranged in article 18 of Law 9.279 / 96, namely:
I – that are contrary to morals, good customs, public security, order and public health;

II – substances, materials, mixtures, elements or products of any kind, as well as the modification of their physical-chemical properties and the respective processes of obtaining or modifying them, when resulting from the transformation of the atomic nucleus; and

III – the whole or part of living beings, except transgenic microorganisms that meet the three patentability requirements – novelty, inventiveness and industrial application – provided in article 8 and that are not mere discoveries.

Sole paragraph. For the purposes of this law, transgenic microorganisms are organisms, except the whole or part of plants or animals that express, through direct human intervention in their genetic composition, a characteristic normally not attainable by the species under natural conditions.

Patents are seen by some experts as a scientific promotional tool, given the obligation to make public the descriptive information of inventions, otherwise the patent can even be denied, if the description is not properly done.

A patent, in its classic formulation, is the right conferred by the State, that gives its owner the temporary exclusive exploitation of a technology and, in return, the patent holder must disclose to the public every step of the invention, therefore, later, when the patent becomes part of the public domain, it can be freely produced by any interested party in the form of a similar[9] or generic drug[10].

There are several criticisms addressed to patents, especially with regard to developing countries, due to the difficulty of implementing an effective national policy of protection of their interests in face of other nations, regarding the disparity in the development of technologies and generated knowledge, since they both require high risk and financial resources. (PARANAGUÁ & REIS, 2009)

Among economists there is also criticism towards the patent system with respect to restrictions to free competition, which can be harmful to consumers and to free trade. The big question is whether the reward to innovators and to potential incentives to innovate outweigh the costs of providing legal monopolies islands and if there are prospects of benefits for the developing countries. Another topic of discussion is the standardization of monopolistic rules for essential goods such as cosmetic products and some electronic

[9]Similar Drugs - one that contains the same active ingredients, the same concentration, dosage form, route of administration, dosage and therapeutic, preventive or diagnostic indication of the reference medicinal product registered with the federal agency responsible for health surveillance, which may differ only in characteristics related to size and shape of the product shelf life, packaging, labeling, excipients and vehicles, always identifiable by the trade name or brand.

[10]Generic Drug - drug product similar to a reference or innovative product, which is intended to be interchangeable, usually produced after the expiration or waiver of patent protection or other exclusivity rights, proven its effectiveness, safety and quality, and designated by the DCB or, in his absence, by the DCI.

objects, for example. This standardization would perhaps better balance the regulatory frameworks, respecting the different levels of development of each country. (PARANAGUÁ & REIS, 2009)

Deardorff (Deardorff *apud* CORREA, 2005) elaborated a model to extend patent protection from one country to another. He demonstrated that when protection is extended to a country that "does not invent," the well-being of this country decreases, while the country's well-being that "invents" is extended. He demonstrated that while patents involve compensation in research and development, in practice, the establishment of protection should be performed only in part of the world. That is, for him, the protection of a patent worldwide may not be desirable, and that at least the very poor countries should be relieved of any new agreement within the GATT.

It is important to emphasize that all property in this constitutional system is subordinated to its social function. For this reason, professionals and researchers, especially from the most affected countries, must know all rules of industrial property in order to use them the best possible way, aiming technological and social development of enterprises, universities and countries. The extent of protection of a patent depends fundamentally on national law, and particularly of the judging criteria of patenting inventions.

**3. Prior Consent of the National Health Surveillance Agency (ANVISA)**

The process of granting pharmaceutical patents (products and procedures) differs from the conventional procedure of other technological fields. Medicines, cause of its social importance, led the legislature to create the institution of prior consent, consolidated in Article 229-C of the Industrial Property Law.

The article 229-C of Law 9.279 / 96 determines that deposits of pharmaceutical products and processes will only be approved and receive the patent after the prior consent of the National Health Surveillance Agency – ANVISA. This consent is granted or denied after the evaluation of the application by the National Institute of Industrial Property – INPI, considering aspects of form and merit.

The course of a process framed in article 229-C is done as follows: INPI makes a technical evaluation, and the processes respecting the patentability conditions are referred to ANVISA for analysis, that declares, in form of a report, its understanding of the object in question and if it is capable or not of protection. Both institutions provide the right to legal defense from applicants. Once the expert advice of consent is issued or not by the ANVISA, it is forwarded to INPI to be issued the charter in which the right to patent protection was recognized, or even, to publish the rejection for not meeting the statutory patentability requirements.

If the prior consent of the institute is not considered by INPI, the process will be subject to an administrative process or nullity action. Any addiction can give rise to the invalidity of a patent, whether it is related to the matter of the patent itself or to the way in which the claim should have been processed.

Although mandatory the registration within ANVISA for protection of national health and patent rights, the national legal system, with respect to eventual needs, forsees the possibility of exemption from registration provided that in case of imports, this is done through international multilateral organizations for use in health programs by the Ministry of Health or related entities, such as the UN or the OAS. (CARVALHO, 2007)

The exception is permitted due to existing legal provisions. Furthermore, it is consistent with the State purposes, whether at a national or international level, to safeguard, directly, the right to access to medicines and, indirectly, the life, dignity and development.

It should be mentioned that part of the doctrine questions the appropriateness and correct application of Article 229-C of Law 9.279 / 96, which oblige the prior consent of ANVISA to grant patents for

pharmaceutical products and processes, cause it understands that such a device causes unjustifiable delay in granting the privilege, and affects the development of the country. In spite of that, since it´s an issue that affects the dignity of the human person, that is, public health, one should not think only in market interests. (VIZZOTO, 2010)

INPI is responsible for analyzing the existence of all necessary elements for the provision of pharmaceutical patent, while ANVISA is responsible for the protection of public health through intellectual property rights, including knowledge of existing flexibilities in the TRIPS and Doha Declaration[11]. (CARVALHO, 2007)

In order to assure that the combination of these entities really aims the public purpose, they must be timely, since the speed is important for access to medicines and to protect the owner of the invention.

**Conclusion**

The patent system in Brazil is in line with the international rules, since market globalization ultimately leads to legal protection standardization.

The tendency is towards harmonization and internationalization, but that does not prevent from seeking solutions that enable the preservation of a certain level of autonomy of each country with regard to patent applications processing, and therefore it is of great importance the administrative level – INPI and ANVISA – to the issues of access to medicines and protection of innovation.

Regarding the granting of patents for drugs there must be, certainly, greater control from the State, since medicine can not be treated like any other commodity, as it deserves a committed caring for the health of the population.

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