REVIEW ARTICLE

IJAMB JOURNALAMB.COM
INTERNATIONAL JOURNAL OF ADVANCES IN MEDICAL BIOTECHNOLOGY

The pharmaceutical patent process: National Health Surveillance Agency and National Institute of Industrial Property act differently in the process

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Received: 10 dezember 2024; 10 february 2024.

Abstract: The National Institute of Industrial Property (INPI) is the government body responsible for granting patents in the national territory; in the case of medicines, they need to be registered with the National Health Surveillance Agency (ANVISA) in order to be marketed. There was a divergence in legal interpretation (of Art. 229-C of the IPL) which caused damage to entrepreneurs, laboratories and the community in general, as there was no express provision as to whether ANVISA's opinion would be binding on the INPI's decision on patent issues. The aim of this research was to analyze this problem, raising its main points and demonstrating how dangerous and damaging bureaucracy and inefficient and obscure normative acts that give rise to dubious interpretation can be, based on the application of hermeneutic and dialectical methods. In 2021, the Superior Court of Justice (STJ), in Special Appeal n. 1543826, held that ANVISA's opinion would be a valid prerequisite for granting patents for pharmaceutical products or processes. It was found that the STJ decision increased ANVISA's "powers", but with the repeal of Art. 229-C of the IPL, the dilemma was extinguished and the competencies of each body re-established. It is therefore of the utmost importance to fill legal gaps and issue clear and specific laws so as not to leave room for harmful interpretations, guaranteeing original competences and legal certainty.

Keywords: Medicines. ANVISA. INPI. Patents.

Introduction

Health is one of the areas in which biotechnology operates and, specifically for this study, the pharmaceutical area, which uses biotechnological techniques to produce medicines such as antibiotics and biopharmaceuticals, e.g. using genetically modified cells to produce therapeutic proteins such as recombinant insulin for diabetic patients and monoclonal antibodies to treat cancer, for example [25].

The Institute of Science, Technology and Industrial Quality (ICTQ), based on research carried out, has verified the growth trend of the global biopharmaceuticals market, which is worth around US$160 billion a year. In Brazil, there are pharmaceutical companies with biopharmaceutical development projects, such as Libbs, Cristália, Recepta and BioNovis (a joint venture created by Aché, EMS, Hypermarcas and União Química laboratories)[25].

Due to the importance of medicines for the protection of human life, materializing the right to health and, as well as national economic development through the production and marketing of drugs, this research addresses the problem involving the two responsible bodies: the National Institute of Industrial Property (INPI) which protects property rights and the National Health Surveillance Agency (ANVISA) which grants registration for the marketing of drugs.

It should be noted that as part of the state's obligations, it is the government's role to establish policies and laws aimed at protecting human health, and there is a particular concern involving the process of registering drugs by the ANVISA and the analysis of patent applications by the INPI in the area of drugs.

ANVISA is the public body responsible for analyzing drug registration applications and defining the criteria and stages necessary for the release of a new drug in the national territory; only after the registration has been granted will the drug be released for sale[9]. The INPI is a federal authority responsible for granting patents and registering other intellectual properties, as well as supporting the technology transfer process[10].

What is the relationship between these two bodies when it comes to medicines? As a result of the amendment to the IPL and the insertion of Article

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https://doi.org/110.52466/ijamb.v6i1.116

229-C, a problem arose, involving the question of competence, as to whether or not ANVISA's opinion was binding on patent applications for medicines filed with the INPI, leading to a clash of competences between them. The Superior Court of Justice (STJ) was asked to give its opinion, taking the view that the opinion was binding. However, in the same year (2021), Law 14.195 was enacted, resolving the impasse and separating the competences, in the sense that the INPI is not bound by ANVISA's opinion when granting patents for pharmaceuticals.

The aim of this research is precisely to discuss the current rules for granting patents and registering medicines in Brazil, so that they can contribute to innovation and entrepreneurship in the area of pharmaceuticals. This is a literature review, carried out on the basis of journals, the government, the STJ and its decision on the matter, presented from the perspective of the hermeneutic and dialectical methods.

Materials and methods

A bibliographical survey was carried out, a literature review, with a documentary approach and analysis of data contained in literary, scientific and technical works, on the official websites of the Ministries of State, the INPI, ANVISA, the STJ and current legislation related to the subject.

The methods used were hermeneutic and dialectic. Hermeneutics, or the interpretative method, aims to understand a text or discourse, verifying its sense (its meaning). The dialectical method considers the permanent transformation of society. Through discourse based on reasoned arguments, with a view to transforming and improving antagonistic relations, criteria are established for the practice of conduct and the adoption of mechanisms aimed at the evolutionary process[20]. Thus, the dialectical method, following the Hegelian conception with the formulation of a thesis (initial statement), antithesis (refutation of this statement by contrary aspects) and synthesis (a new thesis based on logical convergence or this dialectical logic) was applied to organize the arguments and draw up the conclusions.

Relationship between drug registration and patents

According to Igor Simões[27], the government is concerned about the pharmaceutical sector, both in terms of registering drugs and granting patents. However, the sector is faced with the constant concern of the government compulsorily licensing patents (promoting patent infringement). In addition, Simões says that the problem involving the sector (registration, granting of patents for medicines and possible compulsory licensing) lies much more in the lack of investment and serious and effective public policies in the area of health, much more than in the granting of patents, and the population has the most to lose in this process of divergence.

In order to give the population greater access to medicines, the government is promoting incentives for the generic drug industry. The world market for generic drugs has grown by an average of 11% a year and consumption of these drugs in Brazil has also grown by approximately 220% since they were first made available in pharmacies in 2000. This is due to lower research and marketing costs, which is reflected in the value of the product to the consumer, representing savings of up to 40%[27]. However, the generic drug can only be manufactured and marketed if there is no patent in force and other rights that guarantee exclusivity rights.

Patent protection gives the holder a monopoly on the exploitation of the product for a certain period of time. It is worth noting that the LPI considers an invention patent to be a product or process that meets the following requirements: inventive step, novelty and industrial application. The patent granted is valid for 20 (twenty) years from the date of filing. Utility model patents are for objects of practical use, or part thereof, susceptible to industrial application, which present a new form or arrangement, involving the inventive act, which results in a functional improvement in its use or manufacture; it is valid for 15 (fifteen) years. And finally, the certificate of addition of invention translates an improvement or development introduced into the object of the invention, even without inventive step, but still within the same inventive concept; it is considered an accessory to the patent, which is why it has the same expiry date[8].

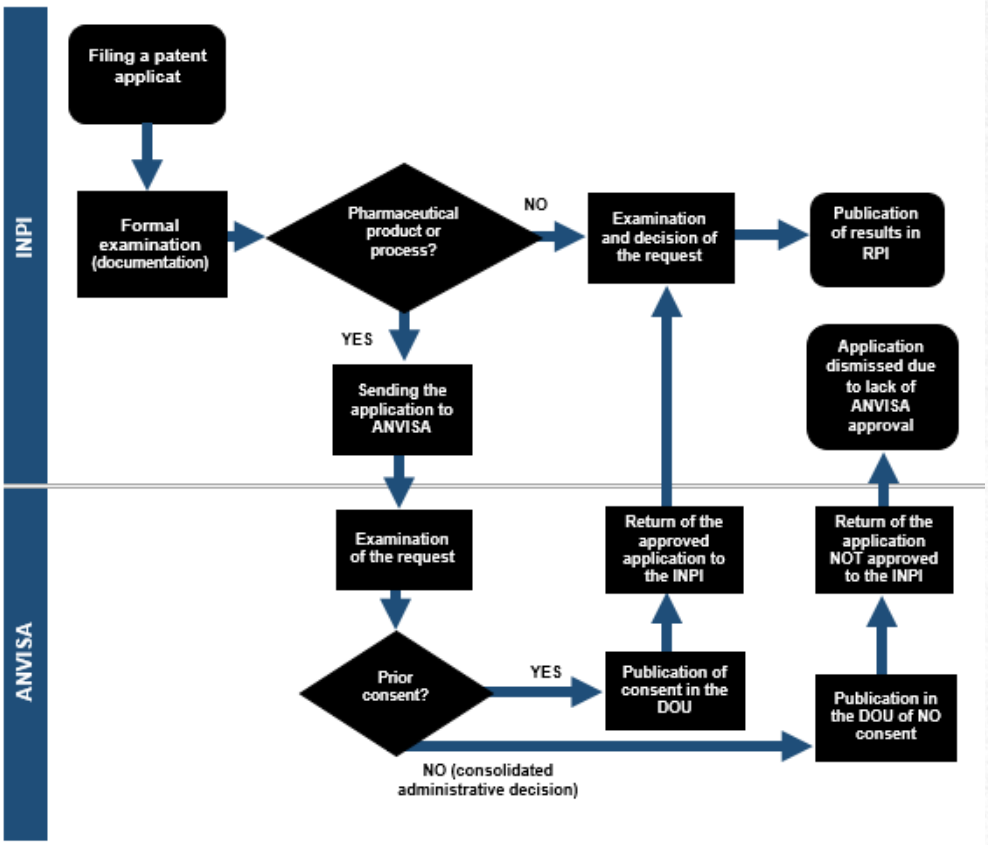
But in the case of medicines, the granting of the patent would be linked to the prior consent of ANVISA. The process follows the stages described in Figure 1.

Until 2001, the INPI examined drug patents without interference from the ANVISA. With the advent of Law n. 10.196, which came into force on February 14, 2001, Art. 229-C was included in Law n. 9.279/1996 (Industrial Property Law - LPI), determining that the granting of patents for pharmaceutical products and processes would henceforth depend on ANVISA's prior consent.

Thus, the granting of a patent does not authorize its holder to commercialize the medicine, it only protects and guarantees the property rights over the product, and may enter into contracts for the assignment of rights, for example. However, the drug cannot be made available on the consumer market, as this requires registration with ANVISA.

The legislative change has sparked discussions,

Figure 1 - Analysis of patent applications for pharmaceutical products/processes.



Source: Adapted from the Report of the Interministerial Working Group on Public Administration[apud 24].

especially regarding the constitutional right to property, which includes the right to patent protection. Therefore, if the requirements are present and the legal requirements for granting the patent by the INPI have been met, it would not be possible to include a new restriction, in this case the prior consent of ANVISA, which would be reflected in the consent of the Federal Government, thus hindering the exercise of this right.

For Denis Borges Barbosa[1], it is not possible to interpret Art. 229-C as ANVISA having the power to deny or admit patents, based on the judgment of convenience and opportunity inherent in the discretionary power of the Public Administration, because in this case, it would be totally incompatible with Art. 5, inc. XXIX of the Federal Constitution of 1988, which establishes that the legal requirements for granting a patent, in a binding procedure, can only be created by ordinary law. The INPI has a duty to listen to ANVISA, which will make a technical analysis aimed at protecting life and health, but it cannot bind the INPI's decision.

However, ANVISA's understanding with the legislative change was that it had the power to analyze the technical requirements for patentability and not only the issues inherent to efficacy and risks to life and health [24]. This discussion was taken to the Federal Attorney General's Office (AGU), which confirmed the Agency's role of analyzing only product/process issues associated with health risks[21].

In a patent application denied by ANVISA, the Federal Regional Court of the 2nd Region (TRF2) ruled that the Agency's legal powers had been overstepped, as they were restricted to examining potential health risks. ANVISA appealed the decision to the STJ, which held that ANVISA's favorable opinion was a prerequisite for the granting of patents for pharmaceutical products or processes, a discussion that will be revisited below.

In practice, from 2001 to 2017, the INPI only analyzed drug patent applications after ANVISA's analysis and approval. As long as this consent was not forthcoming, the processes remained stalled. This procedure meant that at the time, more than 21,733 patent applications for medicines remained paralyzed at the INPI for this reason[22].

In an attempt to resolve this issue and speed up the analysis of processes involving pharmaceuticals, the INPI and ANVISA formalized an agreement in March 2017. The rule included prior analysis by ANVISA, with the aim of ensuring that the drug was effective and did not pose any health risks, but did not bind the INPI in its analysis of the merits of the patent, and it could grant it even if ANVISA issued an unfavorable opinion, which was defined in Joint Ordinance n. 01, of April 12, 2017 (regulating the

procedures for applying Art. 229-C of the LPI).

In summary, Joint Ordinance n. 01/2017 determines the processing of patent applications for pharmaceutical products and processes:

►Art. 2: once the patent has been formally examined by the INPI, the procedure for granting ANVISA's prior consent will take place after the request for examination has been made (in accordance with Art. 33 of the LPI);

►Art. 2, §1°: the INPI will publish the notification of the forwarding of patent applications to ANVISA in the Electronic Industrial Property Magazine (RPI) and, when necessary, the decisions on examination priority;

►Art. 2, §2°: the INPI will make the updated full contents of patent applications available, together with the publication of the referral;

►Art. 3: The INPI will provide ANVISA with access to the information contained in its database;

►Art. 4: After receiving the patent applications forwarded to the INPI, ANVISA will analyze them taking into account aspects inherent to public health, issuing a technical opinion;

►Art. 6: When the INPI disagrees with ANVISA's opinion, it must state the reasons for its disagreement in a reasoned technical opinion;

►Art. 7: At the end of the INPI's examination of patent applications with ANVISA's consent, an official list of patent applications granted and published in the RPI will be sent to the Agency by the INPI;

►Art. 9: An Interinstitutional Articulation Group will be set up, with members from the INPI and ANVISA, with the aim of exchanging technical information and harmonizing understandings.

►Art. 11: the ordinance came into force sixty days after its publication (04/13/2017).

In 2017, the Interinstitutional Articulation Group (GAI) was created with the aim of analyzing and suggesting instruments, mechanisms and procedures for coordinated action between the INPI and ANVISA in the analysis of patents for pharmaceutical products and processes, under the terms of Joint Ordinance no. 2, of October 20, 2017. On March 26, 2018, the first technical meeting of the GAI was held by videoconference, the main purpose of which was to establish the Group's working methodology. On May 24, 2018, the Group's second meeting was held at the INPI's headquarters in Rio de Janeiro. At this meeting, the main results obtained over the period were presented, among them: the optimization of the flow of patent applications, the current methodology for forwarding letters and opinions, the creation of pages on the portals of both the INPI and ANVISA for greater transparency of the GAI's work[7].

In 2021, the 4th Panel of the Superior Court of Justice (STJ) ruled that ANVISA's opinion is a prerequisite for the validity of patents for pharmaceutical products or processes. According to Justice Luís Felipe Salomão, rapporteur of the case (REsp. No. 1543826), the best interpretation of Article 229-C of the IPL is to understand it as a prerequisite for the validity of pharmaceutical patents granted by the INPI. With this understanding, the justices annulled the decision of the Federal Regional Court of the 2nd Region (TRF2), which considered, in a patent application denied by ANVISA, that it had exceeded its legal powers, which were restricted to examining potential health risks[16].

ANVISA's negative opinion in cases where it is shown to be contrary to public health policies is binding and does not support the INPI's decision. ANVISA's attributions are restricted to examining potential health risks, and it is ANVISA's responsibility to determine before the INPI whether the granting of exclusivity rights (production, use, commercialization, importation or licensing) could lead to a situation that is harmful to public health[16].

However, Law n. 14.195, of August 27, 2021 (Conversion of Provisional Measure n. 1.040/2021) revoked Art. 229-C of Law 9.279/1996, establishing the end of ANVISA's prior consent for patent applications for pharmaceutical products and processes (Chart 1).

In a note, available on the official website of the Ministry of Development (2022), the INPI announced the procedures to be adopted:

a) the extinction of the flow of patent applications between the INPI and ANVISA since August 27, 2021;

b) applications that are returned by ANVISA will be processed normally at the INPI;

c) the applications concluded by ANVISA and forwarded to the INPI before the revocation of Art. 229-C were published in the Industrial Property Magazine (RPI) n. 2763;

d) the applications that were at ANVISA were returned to the INPI on August 30, 2021, a total of 1,284 applications, of which 54 already had the consent published by ANVISA before the revocation of the article, so they would be published in the RPI;

e) the INPI is awaiting the return of 19 patent applications that were under requirement or had already been denied;

f) the applications filed by December 31, 2016, included in the Backlog Combat Plan, have been forwarded for examination[10].

Chart 1 - INPI and ANVISA: chronology of the dilemma.

Law n. 10.196/2001 inserted Art. 229-C into the LPI: "The granting of patents for pharmaceutical products and processes will depend on the prior approval of the National Health Surveillance Agency - ANVISA."	
From 2001 to April/20	The INPI only analyzed patent applications after ANVISA's opinion and consent.
From April/2017 to July/2021	Agreement signed between the INPI and ANVISA - Joint Ordinance No. 01, of April 12, 2017 (regulates the procedures for applying Art. 229-C of the IPL).
On August 5th, 2021	The 4th Panel of the Superior Court of Justice (STJ) has ruled that ANVISA's opinion is a prerequisite for the validity of patents for pharmaceutical products or processes. According to Justice Luís Felipe Salomão, rapporteur of the case (REsp. no. 1543826/RJ).
Law n. 14.195/2021 repealed Art. 229-C of the LPI: extinguished the dilemma - re-established the competence of the INPI in granting patents.	

Source: Own authorship, 2023.

The issue of ANVISA's approval, the granting of patents by the INPI and compulsory licensing of medicines

Blocking the analysis of the patent application because of the wait for ANVISA's favorable opinion created insecurity; for the company it makes no sense to invest in a product/process without guarantees of commercial exclusivity. With the application distributed, the principle of prior art guarantees the right from the moment it is filed, but while the criterion was to wait for ANVISA's prior approval before adding it to the application, the risk was greater: in addition to the delay, the «secret» could fall into the public domain (leak out in some way) and be used by generic manufacturers.

The government can compulsorily license the patent in cases of lack of exploitation in the national territory, and how can you exploit it economically (market the drug) without ANVISA's approval? Since medicines cannot be marketed without authorization through the relevant registration with the Agency.

One term used by the informal media is that the government will authorize the «breaking of the patent» of a certain drug, which is nothing more than authorizing the compulsory licensing of the drug, i.e. the government authorizes another company to exploit the drug, implying the loss of exclusivity of economic exploitation by the patent holder.

The compulsory license is provided for in Art. 68 of Law 9.279/1996 (Industrial Property Law - LPI), and will be applied to the patent holder in the event of abusive exercise, abuse of economic power (proven by administrative or judicial decision), in the absence or insufficiency of manufacture of the product and in the absence of full use of the patented process, except in the case of economic infeasibility. This is because patent protection, as a protective reflex and guarantor of industrial property rights, must fulfill a social function and if it does not, i.e. if it is used outside the legal limits, the patent may be compulsorily licensed at the request of the government or an interested third party.

The legal hypotheses that give rise to compulsory licensing of patents are summarized below:

The exercise of a right in an abusive manner (abuse of rights): this is the exercise of a right by its holder that goes beyond the limitations imposed by its economic or social purpose, by good faith or by good customs (Art. 187, CC/2002), characterizing an unlawful act subject to reparation.

Abuse of economic power: unlawful conduct by an economic agent who has market power or who assumes a dominant position in the market exorbitates this power with a view to dominating the market, eliminating competition and arbitrarily increasing its profits, which are prohibited by Brazilian legislation (Art. 173, §4 of the Federal Constitution/88 cc. Art. 36 of the Antitrust Law - Law n. 12.529/2011). It is worth mentioning that the abuse of economic power must be recognized by the Administrative Council for Economic Defense (CADE), the competent administrative body, or by the Judiciary, in a sentence handed down.

Failing to exploit the object of the patent in Brazilian territory, due to the lack or insufficiency of manufacture of the product or lack of full use of the patented process: reveals the «misuse of property». It will be necessary to manufacture the product or use the patented process in Brazil, and importation will only be authorized in cases of economic infeasibility, which is highly subjective - there is no objective concept of what «economic infeasibility» means, making it seriously difficult to grant a license for this reason[19].

When marketing does not meet the needs of the market: when production is insufficient to meet the needs of the market.

In cases of emergency or public interest, declared by the Federal Executive Branch, if the patent holder or its licensee does not meet this need: through collective interest, usually occurs in patents for products and processes involving health, for example in the pharmaceutical industry in 2007 with Efavirenz, a drug for the treatment of HIV[26].

The compulsory license must be requested by a third party with a legitimate interest and the technical and economic capacity to exploit the patent effectively, with the aim of supplying the domestic market. It will be granted ex officio by the Federal Executive Power, exceptionally in cases of national emergency or public interest and, even in these cases, only if the patent holder is not meeting the needs of the market; the grant is exclusive and sub-licensing is not allowed[19].

The request for a compulsory license may be rejected by the INPI. It is the right of the patent holder to be notified of the request and to have a period (60 days) in which to respond, proving with documents the reasons for the disuse (the reasons must be legitimate) or that they are taking steps to start production and/or increase it, justifying the problems they are facing, or that they are not producing due to force majeure, explaining them. In this sense, if the arguments are proven and accepted by the INPI, the compulsory license will not be granted, and exclusivity will remain with the holder of the Patent Letter. In the event of inertia on the part of the owner, once the deadline for manifestation has passed, the request for a license will be granted under the conditions under which it was filed.

If the owner contests the license request, the INPI may carry out due diligence, appoint a commission (including external experts) to support the arbitration of the remuneration due, since there was no consensus between the parties. The arbitration will take into account the circumstances and peculiarities of the specific case, without forgetting to consider the economic value of the license granted[28].

Bill 12/2021 was converted into Law 14.200/2021, amending the LPI to enable the compulsory licensing of products to combat Covid-19, a necessary measure to deal with public health emergencies. It is now possible to compulsorily license patents or patent applications in cases of national or international emergency or in the public interest and in the face of a state of national public calamity (new wording of Art. 71 of the LPI). The compulsory license may be granted ex officio, on a temporary and non-exclusive basis, guaranteeing the rights of the holder to compensation, with the holder's remuneration being set at 1.5% of the net sales price of the product until its value is effectively established (Art. 71 and its §13 of the LPI).

Compulsory license versus patent revocation

A compulsory license should not be confused with patent revocation. The section above defined compulsory licensing and the legal hypotheses for requesting it. In this section we will summarize the hypotheses of patent termination, which is different from compulsory license,

According to Fabio Ulhoa Coelho[21], the industrial right protected by a patent will be extinguished by virtue of the expiry of its term, forfeiture, non-payment of the amounts due to the INPI, the resignation of its owner, the absence of a legal representative in Brazil, if the owner is domiciled or has its headquarters abroad.

The doubts that can arise regarding the termination of a patent are recurrent in the case of forfeiture. Forfeiture arises from abuse or disuse in the exercise of the right, which can be declared by the INPI ex officio or if requested by an interested third party, after the compulsory license has been granted (3 years from the grant), after two years of the license, the patent will fall into the public domain, if the abuse or disuse of the product or process is still verified. The defense and the adversarial process are guaranteed in the forfeiture claim, an administrative process with the INPI (LPI, Arts 80 to 83).

It is important to note that the law protects the rights of third parties in the event of the owner renouncing a patent (a unilateral act). Franchisees and/or licensees, for example, must decline to accept the act, and the INPI must prove that there is no damage to the others involved (interested contractors).

Art. 217 of the IPL states that «The person domiciled abroad must appoint and maintain a duly qualified attorney domiciled in the country, with powers to represent them administratively and judicially, including to receive summonses», failing which the patent will be extinguished.

As you can see, compulsory licensing is an institute for fulfilling the social function of property and protecting the market and the consumer, while termination is another instrument that will operate in hypotheses other than those, the main effect of which is to definitively end the right of the holder of the Letters Patent to the exclusive exploitation of industrial property.

Conclusion

Despite the «tug-of-war» between ANVISA and the INPI, the joint ordinance eliminated (until 2021) the contradictions and speeded up the registration procedure in each body, establishing objective

criteria, which culminated in a greater benefit to health. In 2021, the STJ ruled that ANVISA's opinion is binding and must be observed by the INPI when granting patents on medicines in the event that it contradicts public health policies.

It is clear that the STJ's decision had given ANVISA greater power, conditioning its favorable opinion on the granting of a patent by the INPI, especially given the lack of regulations on what «contradiction to public health policies» would mean, which is subjective.

Then, also in 2021, Law 14.195 repealed Art. 229-C of the LPI and extinguished the dilemma and legal uncertainty, re-establishing the competence of the INPI to grant patents and speeding up the process, which had been too slow.

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