v. 5, n. 25, 2025

International Journal of Health Science

PATENT INFRINGEMENT IN THE CONTEXT OF A PUBLIC HEALTH EMERGENCY

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Acceptance date: 11/07/2025

Abstract: The research addresses the relationship between intellectual property and health in the Brazilian context, focusing on the possibility of patent infringement during international emergencies. The general objective is to discuss compulsory licensing in health crisis situations, considering the conflict between the right to industrial property and the protection of public health. The justification is that the COVID-19 pandemic has highlighted the precariousness of healthcare in Brazil, raising questions about the exclusivity of drug patents. The problem aims to understand whether it is possible to reconcile the guarantee of patent rights with the interests of the community in health emergencies. The approach used is the hypothetical-deductive method, with bibliographical and documentary analysis.
Keywords: 1. patents; 2. right to health; 3. patent infringement; 4. compulsory license; 5. international emergency.

INTRODUCTION

Patents are the way in which the modern world has made it possible to guarantee intellectual and industrial rights in the most varied branches of society, enabling the commercialization and growing production of products and services whose formula and characteristics are protected by domestic and international laws. In the pharmaceutical field, this fundamental guarantee for the free development of intellectual rights has unique peculiarities that have no simple answer and are frequently debated, pitting against each other the feasibility of a price that is less affected by the commercial bias of exclusivity, and the right guaranteed to the company or laboratory to succeed with its innovation, in order to obtain the benefits of exclusivity, even for a medicine that is inevitably accessible globally, often due to the hype of an emergency, as happened in the coronavirus pandemic.

Governments, seeing the imminent problem that the pandemic has brought socially and economically, have had various strategies to find a middle ground between economics, law and public health. In Brazil, on September 2, 2021, Law No. 14.200/2021 was passed with vetoes, allowing the temporary breaking of patents on vaccines and supplies during this period of public calamity. Thus innovating the way in which coronavirus-related problems are dealt with in terms of patents, distributing an amount of 1.5% of the net price of the product to the holder of the broken patent in a compulsory manner.

Even though the law was sanctioned, the provision of the necessary and sufficient information to produce the object of reproduction was vetoed, on the grounds that such an act would not be feasible, since it would harm the pharmaceutical and pharmacochemical industries, and their *know-how* is exclusive, and it is up to the industry to license it or not.

The moral dilemma characterized by the debate on breaking patents and making medicines viable comes mainly from the precariousness of the care needed for public health in Brazil, a problem that has been shown to be at its most critical during the pandemic. The exclusivity of the rights to reproduce medicines, as much as they aim to guarantee the intellectual rights of the pharmaceutical industries, unfortunately end up being a way of leveling prices upwards in a pandemic situation, where demand is very high, and variety is very low, and the real dilemma is knowing at what point the state should intervene, when it should intervene, and whether its intervention is feasible, given that patents are an important part of industrial law and are deeply respected globally.

Although antagonistic from the point of view of profit, the right to a patent fully guaranteed by law and the objective right to health guaranteed in the constitution need to be

reconciled in order to recognize that their coexistence is a fundamental pillar of the right. Without profit, private investment in research is disinterested in finding a solution to a social problem, and the state, by guaranteeing investment in research, is unable to generate the innovation needed to deal with these moments of crisis, But even with this clash, the private sector achieves many innovations by sticking to state investment, and the state manages to maintain itself by guaranteeing the full right to health of its population using the results of technological innovation that, even with its help, came from the sector that seeks to guarantee its legal monopolization of the medicine, method or product that brings the solution in times of crisis.

The biggest challenge is to guarantee full patent rights at the same time as solving the problems faced in public health, without giving in to what common sense tends to make antagonistic. In this sense, the problem must be solved taking into account the importance of both intellectual rights and the viability of maintaining them in times of emergency.

The general objective of this study is to discuss compulsory licensing in health crisis situations, considering the conflict between the right to industrial property and the protection of public health. This scope will be achieved through the following specific objectives: a) Describe how Brazilian law approaches and regulates intellectual property rights and patents; b) Understand how the extraordinary context of the pandemic has affected social and collective values; and c) Discuss the weight between intellectual property rights and public health, analyzing which should prevail in situations of conflict.

To this end, the deductive method will be adopted, with descriptive and exploratory purposes. The means of research are bibliographical (using secondary sources already written on the subject) and documentary (with reference to normative texts), with access to materials already published.

THE LEGAL TREATMENT OF PATENTS IN BRAZIL

In the Brazilian legal system, patents function as a mechanism designed to regulate the protection of intellectual property and guarantee its full use and enjoyment. The issue of intellectual property has intensified worldwide in recent times, and the Paris Convention for the Protection of Industrial Property, of 1883, can be considered its main milestone. Its agreements and themes were introduced into Brazilian law with the aim of ensuring intellectual property rights in the face of growing international concern about their protection and equality with regard to both domestic and imported products (MACEDO and BARBOSA, 2000). With the creation of the World Intellectual Property Organization (WIPO), the National Congress approved decree 75.572/1975, which aimed to instrumentalize this commitment to intellectual law. With the solidification of national and international interest in protecting patents and their creators, Brazilian legislation arrived at what we have today as the main normative reference on the subject, the 1988 federal constitution, the Industrial Property Law (Law No. 9.279/1996) and Patent Law No. (10.196/2001).

Our current legal system is committed to the need to protect this right, which is so relevant to the international ties established by the country. The Federal Constitution of 1988 defines the legal framework for the protection of industrial, scientific, artistic and technological creations, including pharmaceutical patents, in its article 5, item XXIX. The purpose of this protection is to ensure the research and development of new initiatives and medicines (SANCHEZ E GIALLUCA, 2000).

The TRIPS Agreement, managed by the World Trade Organization, is one of the most

important international instruments in the area of intellectual property. Among its guidelines are the minimum rules for patents on medicines, aimed at stimulating technological development and cooperation between the signatory countries (RODRIGUES and POLIDO, 2007).

Dealing with the growing need for regulation on the subject, Brazilian patent legislation was instituted, consolidated mainly in Law No. 9.279/1996, which was the direct result of a movement to adapt Brazil to international requirements for harmonizing intellectual property regulations (OLIVEIRA, 1996). In particular, adherence to the TRIPS Agreement in the context of the World Trade Organization imposed on the country the commitment to strengthen patent protection in terms compatible with the standards adopted by developed countries (CARVALHO, 2000).

This legal restructuring, although presented as a technical-normative advance, was marked by strong diplomatic and economic pressure from central nations, particularly the United States and the countries of the European Union, which were concerned about guaranteeing the protection of their technological and pharmaceutical assets in the Brazilian market. The impact of this new approach not only changed the content of the legislation, but also redefined Brazil's role in the international intellectual property system, demanding a regulatory compliance stance that sometimes conflicts with the country's social and economic priorities.

Even though the 1988 Federal Constitution guaranteed the protection of industrial and technological creations in its article 5, item XXIX, this provision was made within the framework of valuing the social function of the invention, and this characteristic is an intrinsic part of the need for regulation on the subject, given the importance of the social function of the patent, which cannot be ignored and is highlighted in various studies, such as by the authors Dean Baker, Arjun Jayadev and Joseph E. Stiglitz (2017, p. 70):

> Intellectual property rights are a social artifice. Like other property rights, they are subject to a certain set of limitations and restrictions. We argue here that it is increasingly clear that the main reason for supporting this device, at least in its current form - the idea that it will increase welfare and innovation - is questionable both theoretically and empirically.[1]

However, infra-constitutional legislation has ended up leaning heavily towards the logic of exclusivity and extensive protection, meeting international standards that often disregard the structural asymmetries between developed and developing countries (VICENTE, 2020).

This permanent tension between normative sovereignty and multilateral commitments defines, to this day, the contours of the Brazilian patent regime: legislation built on the promise of access to innovation and the transfer of technology, but which often proves dysfunctional in the face of internal social demands. The challenge, therefore, is not just to apply the law, but to rebalance it in the light of national needs in the face of the impositions of the global system.

THE PANDEMIC CONTEXT OF PATENT INFRINGEMENT

At the beginning of 2020, a public health challenge unprecedented in our history began in Brazil, a disease with a high rate of transmission in a short period and a very high lethality, especially in risk groups. The rate of hospitalizations resulting from Covid-19 far exceeded the capacity of Brazilian hospitals, and forced

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the population into a social isolation that has hardly been repeated in history, generating, in addition to the serious problems resulting from Covid-19 infection, many psychological and economic problems in the population in general (LIMA *et al*., 2020).

The scarce resources, especially in the interior of our country, ended up generating a humanitarian crisis that was difficult to control, with products related to protection and hygiene inflating their values exponentially, the use of medicines without a doctor's prescription, and irresponsible encouragement of treatment methods without scientific proof by political figures in this historical context. In this way, the humanitarian crisis and the lack of government coordination reinforce a cycle of vulnerability and social inequality, according to Lima *et al*. (2020, p. 97):

> On the other hand, public managers lack articulation between the powers and between the federative entities, reneging on Social Justice and making the less favored dependent on charity, which has no right time, increasing instability within families and fomenting conflicts.

In order to combat this scenario in which it was not economically possible to deal with the spread of Covid-19 in Brazil, with very low rates of immunization by the second dose of the vaccine in the respective period, Bill 12/2021 was proposed by Senator Paulo Paim (PT-RS), which was approved by the plenary, thus generating Law No. 14,200/2021, which brought important changes to the legal regime of compulsory patent licenses in Brazil, establishing a legal framework for national emergencies.

Its measures caused a clear tension between the exclusive right of the patent holder and the collective interest in health, as already addressed by international treaties such as the WTO TRIPS Agreement and the Doha Declaration, both internalized by the Brazilian legal system, but it proved to be decisive in facing the state of pandemic calamity, and opened the door to the discussion of the state's obligation to ensure the right to health even in crises.

In this context, the compulsory license established in article 71 of Law No. 9,279/1996 went from being a distant legal exception to becoming a central tool in the debate on the balance between innovation and public health. The amendment brought in by Law 14.200/2021 expanded the practical applicability of this provision by reducing bureaucratic obstacles and reinforcing the role played by the State as a regulatory agent and promoter of the collective interest (RODRIGUES, MENEZES and MORAES, 2022).

Among the changes promoted by Law 14.200/2021 is the possibility of ex officio compulsory licensing during a state of national emergency, facilitating its enactment without the need for prior negotiation with the patent holder, as previously required.

The rapid distribution of prevention methods such as disposable masks and the distribution of vaccines was a determining factor in the drop in the number of victims, and was only possible thanks to these emergency measures related to the breaking of patents on medical supplies, medicines and vaccines.

The health crisis has thus laid bare how dysfunctional the traditional patent system can be in developing countries, even if it is necessary for technological progress and investment, especially when public health is at stake. What once seemed impossible, such as temporarily breaking the exclusivity of large laboratories, has become not only legally feasible, but politically necessary. However, this new situation has not developed without resistance. The suggestion of loosening intellectual property rights, even on an emergency basis and limited in time, provoked vigorous reactions from segments linked to the pharmaceutical industry, which began to mobilize arguments in favour of the current patent system. The main justification involves safe-

guarding the financial return on private investment in research and development, which they see as crucial for innovation and agility in responding to health crises. They also point out that the legal protection offered by patents is crucial to preserving the competitiveness, predictability and stability of the global medicines market (VICENTE, 2020).

The international pharmaceutical business and industry defends itself against the loss of profitability triggered by patent infringements, highlighting their importance in the agility and quality of the supply of medicines and vaccines, developed through private investment. In this debate, which is relevant to both legal and economic discussion, the companies argue that, through research and historical contextualization, private investment bears the greatest economic fruit, ignoring state investment in the scientific industrial sectors themselves, using a marketing metric that cannot be sustained without ignoring the less financially surprising advances achieved through state investment, as we can see from the author Mariana Mazzucato (2013, p. 28):

> Public venture capital, for example, is very different from private venture capital. It is willing to invest in areas with much greater risk, while offering greater patience and lower expectations of future returns. By definition, this is a more difficult situation. However, the returns of public and private venture capital are compared without taking this difference into account.[2]

INTELLECTUAL PROPERTY AND COLLECTIVE HEALTH

It is the state's responsibility to ensure the protection of public health, and it is not possible to place it in the intellectual law field as a mere victim of the unpredictable pandemic state. It is the state's responsibility to draw up detailed provisions that do not destroy industrial rights or make them irreducible, since in an emergency it is not possible to fully protect such rights.

In this context, it is important to recognize that during an emergency, such as a pandemic, it is difficult to guarantee full protection of intellectual property rights. However, this does not imply the complete destruction of this right, but rather the need for exceptional measures aimed at promoting the public interest and protecting collective health.

Since the state is responsible for protecting fundamental rights, it is its duty to place one of the two guarantees above the other (the right to industrial property and/or public health), as Lima *et al*. (2020, p. 153 and 154) make clear:

> This is a classic case of fundamental rights in collision, the state's choice is - evidently - to respect and prioritize the right to life and health, in accordance with the international recommendations of the World Health Organization.

The pandemic has set a benchmark in Brazil's health system, demonstrated the strength of the single health system and its importance for the entire population, and shown that it is not just a question of the lack of investment by the government, but also of the commitment and training of the professionals within this structure.

The best way to adapt the right to intellectual property to the exponential improvement in the treatment of new or pandemic diseases is not simply to pass a law that only discusses solving for the time being what the state has not prevented. What is needed is a detailed, mediated and, above all, comprehensive elaboration that seeks to strike a balance between undermining the pharmaceutical industry's guarantee when it comes to innovating and providing studies that are often privately

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International Journal of Health Science ISSN 2764-0159 DOI https://doi.org/10.22533/at.ed.15952525250612

funded, and, at the same time, without undermining the right to health for the sake of profits that are not accounted for in a humane way, in circumstances where demand takes precedence over ethics.

In Brazil, various legal provisions and normative instruments establish the duty of the state to guarantee equal and universal access to health services, thereby guaranteeing the right to health. These certifications are supported by norms and rules in the 1988 Federal Constitution, infra-constitutional regulations and global agreements to which the country is a signatory (DMYTRACZENKO and ALMEIDA, 2016).

In order to ensure that everyone has equal access to health activities and services, Article 196 of the Federal Constitution states that health is a right and duty of the state. The Unified Health System (SUS) is established by article 198 as the comprehensive, universal and free set of health actions and services provided by the state (NIELSEN, 2023).

In Brazil, various normative instruments also support the right to health, such as Law No. 8.080/1990, which contemplates the circumstances of advancement, safety and recovery of well-being, establishing the norms and rules of the SUS.

The country is a member of agreements such as the ICESCR (International Covenant on Economic, Social and Cultural Rights), which consolidate health guarantees as a fundamental right. This pact establishes the obligation of states to adopt progressive measures to guarantee the right of everyone to the highest attainable standard of physical and mental health.

In jurisprudence, the Federal Supreme Court (STF) has reaffirmed the importance of the right to health and positioned the state to guarantee it. In several judgments, the STF has recognized that the right to health is of a fundamental nature and that guaranteeing it involves making financial resources available, offering medicines and treatments, and organizing efficient public policies (LIMA *et al.*,2020).

Likewise, the set of norms, international treaties and legal principles serve as a basis for guaranteeing the right to pharmaceutical patents. Protecting and encouraging innovation in the pharmaceutical industry, fostering the creation of new medicines and treatments that improve public health.

The guarantee of the right to pharmaceutical patents is based on fundamental legal principles, such as the principle of legality, which determines that the patent system must be governed by law, establishing that the criteria for granting patents must be met.

The principle of intellectual property protection values the economic and social impact of pharmaceutical inventions and aims to encourage their creation and exploitation.

Pharmaceutical patents give inventors and pharmaceutical companies exclusive rights to market their products, which encourages investment in the research and clinical trials needed to create safe and effective medicines.

It is essential to bear in mind the importance of harmonizing the protection of the right to health and the protection of intellectual property rights with regard to patent protection. In certain circumstances, such as public health emergencies, it is essential to weigh up public interests and guarantee access to necessary medicines and treatments, even though patents are a legitimate means of protecting innovation and encouraging research and development.

Thus, if other legitimate interests are properly balanced, some principles of the right to health highlight points of interest that support extensive patent protection. These include the following principles:

Principle of equality: The right to health implies the guarantee of equal access to health services and adequate treatment. By protecting patents, the aim is to encourage innovation and the supply of new medicines, helping to spread access and improve the quality of available treatments.

Principle of progressiveness: The right to health is progressive, i.e. we constantly seek to improve and expand access to health services. Patent protection can stimulate research and the development of more effective and innovative treatments, boosting scientific and technological progress in the area of health.

Principle of solidarity: The right to health involves a collective responsibility to ensure the health of all individuals. Patent protection, by encouraging innovation and the development of new treatments, contributes to strengthening the health system, benefiting not only patent holders, but society as a whole.

In order to guarantee timely and equitable access to essential medicines, national legislation and international treaties establish mechanisms to make patents more adaptable during public health emergencies.

The search for benefits in pharmaceutical companies is justifiable, as innovative work on medicines requires a lot of speculation. However, fair and equitable access to medicines for those most in need must not be compromised.

WIPO has carried out studies that show a strong correlation between the effective protection of intellectual property rights, including patents, and investment in research and development (R&D) (WIPO, 2024). These studies show that countries with greater patent protection generally attract more investment in R&D and consequently experience greater innovation and technological development, but not partly antagonistically. A study published by Mariana Mazzucato, an economist and professor at University College London, argues that the state plays a central role in promoting technological innovation (MAZZUCATO, 2013). The study analyzes the history of important technological advances, such as the internet and the digital revolution, and shows that much of the initial research and development was funded by government agencies, thus showing that as much as the state depends on the industries that legally monopolize certain medicines, the industry benefits and maintains itself from state investment.

The state in turn guarantees the breaking of these patents in public health emergencies, very unique cases that reflect the way in which these two agents relate. We can see the guarantee of the right to break pharmaceutical patents in Brazil in cases of public health crises based on a series of legal principles and instruments that aim to protect the public interest, universal access to essential medicines and the promotion of collective health (RODRIGUES, MENEZES and MORAES, 2022). For example, the consolidation of the aforementioned Law No. 14.200/2021, which aims to provide a legal tool to guarantee access to essential products, such as medicines and medical equipment, in crises where the supply of these products is limited or prices are prohibitive due to patent protection. This includes medicines to treat diseases, as well as items related to the COVID-19 pandemic, such as tests, mechanical ventilators and medicines.

Patent infringement is considered when patented products are unavailable or insufficiently supplied on the market, especially when this results in high prices or difficulties of access for the population. Providing that the main focus, which is the right to health, is a determining factor in the institutional focus on providing the use of all the tools necessary for the health sector, thus bringing the most advanced treatments possible that not only provide adequate treatment for patients, but also help the government stabilize access to hospitals, which during the pandemic were the epicenter of the chaos generated by the volume of patients.

Thus establishing specific criteria that must be met in order to grant compulsory licenses, such as notification and adequate compensation to the patent holder, determined on the basis of specific criteria established in the

law. These criteria include, for example, the market value of the patent and the profits the patent holder would have made if the compulsory license had not been issued. Before issuing the compulsory license, the government can negotiate the terms and conditions of the compensation with the patent holder. This may involve discussions about the amount of compensation, the form of payment and other related aspects. But without losing the agility provided by the legislation.

This legislation balances the protection of intellectual property rights with the need for access to products that are essential for public health, and paves the way for a future situation that can be avoided if brought up in the present as an agenda to be resolved and not drawn up in the heat of the moment.

The measure to break patents must be proportional to the seriousness of the emergency, taking into account the interests of both patent holders and the public interest in health. It cannot be ignored that the legislation is a success in the sense of bringing balance and not harm, knowing that the holders of patent rights are mostly the main funders of research and evolution of the means of treating various diseases, even having their previous influence on research that facilitated the creation of medicines and vaccines suitable for Covid-19.

In the context of the isolation and collapse of the Brazilian health system, the Compulsory Licensing Law was proposed and approved as a way of providing a legal tool that would allow the Brazilian government to act quickly in guaranteeing access to essential products, even if this meant temporarily breaking patents. The idea behind the legislation was to balance the protection of intellectual property rights with the adjustment of the public health system during the pandemic, ensuring that companies could produce and distribute necessary products without being hindered by patent issues.

Being essential for the proper management of Covid-19 patients, patent-protected drugs were essential for controlling the spread of the virus during the pandemic, and this law is a Brazilian step towards stabilizing the health system, and a step towards "normal" life.

The law regulates, brings flexibility and agility when it comes to making decisions that lead to a reduction in the volume of serious cases of Covid-19, since they bring the drug, equipment and adequate and cutting-edge treatment to affected patients, and all this in a free system available to the entire population, which is the single health system, being a model and example for the rest of the world.

Breaking patents, in emergency contexts, allows companies other than the original holders to produce medicines that are essential to public health. This measure has a direct impact on speeding up production and expanding access to treatments, especially at critical times, such as during the Covid-19 pandemic. By allowing different manufacturers to operate simultaneously, the market becomes more competitive, which tends to reduce prices and make it easier for the population and public health systems to access previously inaccessible medicines. However, this is an exceptional measure, restricted to the period of a health emergency, precisely to preserve the balance between the public interest and private rights.

For pharmaceutical companies that have invested in research and development, the temporary relaxation of patents represents a significant challenge. The measure could be perceived as a threat to legal certainty and the protection of intellectual property, fundamental pillars for the economic sustainability of innovation. These companies may be pressured to cooperate with governments or other manufacturers, which, while necessary in humanitarian terms, raises fears about the continuity of investments in innovation in the long term. How the pharmaceutical industry

International Journal of Health Science ISSN 2764-0159 DOI https://doi.org/10.22533/at.ed.15952525250612

responds to the breaking of patents in emergencies can affect its willingness and ability to invest in research and development of new drugs in the future. This can have long-term implications for innovation in the pharmaceutical industry. Therefore, the law can close doors when it comes to investment in the national territory, and the criteria and compensation for the use of medicines previously protected by patent are extremely important.

Prior to the Covid-19 pandemic, there were times in history when other countries had to face this problem mitigated by Law 14.200/2021. Such as in 2001, when the South African government faced an HIV/AIDS crisis and decided to issue compulsory licenses to reduce the price of patented antiretroviral drugs, expanding access to treatment (ELLEN, 2009). This led to a significant reduction in the price of antiretroviral drugs, allowing more people to have access to treatment. However, the pharmaceutical industry naturally criticized this decision, arguing that it could undermine the protection of intellectual property rights and discourage future innovation. In Egypt, where hepatitis C is a major public health concern, the government issued compulsory licenses for patented drugs as a way of treating the disease. This allowed several local companies to produce generic versions of the drugs at lower prices, thus increasing access to treatment for millions of people, as indicated by a WHO report (WHO, 2016). Brazil also had an emblematic episode related to the issuing of compulsory licenses, in 2007, in the context of the fight against HIV/AIDS. That year, the federal government decided to issue a compulsory license for the drug Efavirenz, an antiretroviral patented by the US pharmaceutical company Merck (RODRIGUES, MENEZES and MORAES, 2022). The decision was taken after lengthy attempts to negotiate a reduction in the price of the drug, which was widely used in the treatment provided by the Unified Health System (SUS). The Brazilian government's central argument was based on the need to guarantee universal access to treatment, one of the pillars of the national AIDS policy. Faced with the company's refusal to offer the drug at a price considered compatible with the sustainability of the public program, then president Luiz Inácio Lula da Silva signed a decree allowing the import of generic versions of Efavirenz, produced in India, at a significantly lower cost.

This measure had international repercussions and was legally supported by the TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights). As part of its regulatory framework, the World Trade Organization establishes that compulsory licenses can be granted in the face of national crises or when justified by the common good. In addition, the episode consolidated Brazil as one of the most active developing countries in defending access to essential medicines, reinforcing the legitimacy of using the flexibilities provided for in international law to protect collective health.

In his thesis, Matheus Ferreira Bezerra states that the breaking of pharmaceutical patents in public health emergencies is based on the principle of the supremacy of the public interest over the private interest (BEZERRA, 2009).

This means that in the event of pandemics or other welfare crises, such as the Coronavirus, the state has an obligation to act in the interests of aggregate welfare, even if this means limiting the intellectual property rights of patent holders.

FINAL CONSIDERATIONS

These studies and arguments highlight the importance of state action in promoting innovation. The state plays a key role in providing funding for research and development, establishing appropriate policies and regulations, fostering partnerships between the public and

private sectors, and encouraging the adoption of innovative technologies. By investing in innovation, the state contributes to economic development, competitiveness and social progress, playing a key role by providing funding for research and development, establishing appropriate policies and regulations, fostering public-private partnerships and encouraging the adoption of innovative technologies. By investing in innovation, the state contributes to economic development, competitiveness and social progress, as well as facing global challenges by not being a mere victim of corporate interests in maintaining a high profit on such innovations, but in many cases being the protagonist of this innovation, and being able to use it to protect those who need it most in times of emergency, It is not interesting in the short and long term to stand with your hands tied in the face of patents, but to move in a promising direction when facing the subjective right over innovation, using its constitutional strength to protect health and human dignity, while continuing to invest and walk side by side with the private sector.

The state innovates alongside the private sector when it invests in new technologies and boosts its scientific and technological sector, but it finds itself in a dilemma when, in wanting to guarantee public health, it wants to go beyond the right to patent protection and its innovations.

The industry behaves as the defender of its cycle of research, investment and market insertion. It doesn't want to be at the mercy of a state that may or may not comply with its demands, even if it is protected by the international scope that knows the importance of its research for the future.

Both the Universal Declaration of Human Rights and other international treaties recognize access to health as a basic human right. Therefore, measures that guarantee access to essential medical treatments, such as breaking patents, are justified on the basis of protecting human rights, including the right to health.

Patent-breaking helps to reduce health disparities by allowing people in developing countries or those with limited resources to access treatments that would otherwise be financially inaccessible. This is crucial to ensure that everyone has the opportunity to achieve the highest possible level of health, as established by the World Health Organization (WHO).

As a way of mitigating the damage caused by public health emergencies, pharmaceutical companies can adopt a tiered pricing strategy, offering lower prices to low-income countries or those with limited resources. This allows medicines to be more accessible in regions where patients are less able to afford them. Governments, meanwhile, could encourage collective purchases of medicines, increasing their bargaining power and obtaining lower prices through economies of scale. This could be done through regional or international agreements.

Commitments by governments to buy medicines in advance, guaranteeing stable and predictable demand for manufacturers, can be an incentive to reduce drug prices in exchange for guaranteed sales volumes. As a long-term alternative, funding non-commercial research, such as that carried out by academic institutions and non-profit organizations, could lead to the development of drugs for neglected diseases and diseases of public interest.

The government can offer subsidies and tax incentives to pharmaceutical companies that invest in research and development of essential medicines for public health. This can include tax credits for R&D expenses, tax exemptions for specific products or direct funding for innovation programs. Or even Public-Private Partnerships, or "PPPs", which are collaborative agreements between the public and private sectors to develop, produce and distribute medicines and treatments.

Looking at the impacts of the legislation on the national economy, patent infringement encourages local innovation in the pharmaceutical industry, since Brazilian companies can be motivated to invest in research and development of new drugs to compete with patented products. This leads to significant advances in the discovery and development of treatments for specific diseases that affect the Brazilian population. On the other hand, patent infringements can also raise concerns among foreign investors about the business environment and respect for intellectual property rights in Brazil. There are good examples of this complex relationship between the common good and the guarantee of intellectual property rights. The Accelerated Access to Tuberculosis Program (Xpert MTB/RIF) is an example of collaboration between industry and public health organizations to increase access to rapid diagnostic tests for multi-drug resistant tuberculosis (MDR-TB). The company that manufactures the test, Cepheid, has agreed to reduce the price of the test for low- and middle-income countries in exchange for guaranteed sales volumes funded by international donors such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (WHO, 2014).

The Global Alliance for Vaccines in Immunization (Gavi) is a public-private partnership that aims to increase access to vaccines in low--income countries. Gavi works closely with pharmaceutical companies to negotiate affordable prices for vaccines and ensure equitable access to vital immunizations for children around the world. This collaboration has been instrumental in increasing the availability of vaccines in regions where they were previously scarce.

The Coalition for Epidemic Preparedness Innovations (CEPI) is an alliance formed by governments and companies to speed up the production of vaccines against emerging infectious diseases. CEPI works with pharmaceutical companies and research organizations to fund research and development of vaccines against threats such as Ebola, Zika and the coronavirus. This collaboration has been key to driving vaccine innovation and preparing the world for future epidemics

Partnerships that include technology transfer, capacity building and infrastructure construction help strengthen local capacities in low- and middle-income countries. This not only increases the capacity to produce and distribute medicines, but also promotes economic development and long-term sustainability.

By collaborating effectively, these partnerships can help tackle complex public health challenges and ensure equitable access to vital treatments for all.

To fully address the connection between patent infringement and public health, this paper employs a mixed methodology that combines qualitative and quantitative components. The aim of the study is to understand the effects and possibilities of harmonizing these two aspects.

Initially, a review of the subject was carried out, looking for relevant reports, scientific books, theses and articles. This bibliographic survey enabled the development of a hypothetical structure, containing the main hypotheses, ideas and discussions linked to licensed innovation, intellectual property, patent infringement and public health.

In addition, data was collected from various sources. Case studies on patent infringement in health emergencies were consulted. The aim of this data collection was to provide empirical support for the study's analysis and arguments.

Content analysis was a qualitative technique used to carry out the research. The data collected in the written survey and the information gathered were subjected to in-depth analysis, with the aim of distinguishing the main topics, examples and related patterns.

International Journal of Health Science ISSN 2764-0159 DOI https://doi.org/10.22533/at.ed.15952525250612

The results obtained from the qualitative and quantitative analysis were presented and discussed in an integrated manner, allowing for a comprehensive understanding of the issues addressed. The results were interpreted in the light of the theoretical framework, seeking to establish connections and identify consistent patterns.

Finally, based on the findings and discussions, proposals and recommendations were made which attempt to reconcile the guarantee of the right to public health with patent protection.

It is essential to emphasize that ethical research guidelines were observed throughout the process, ensuring the correct citation of the sources used and respect for copyright.

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Título do trabalho: Quebra de patente no contexto de emergência de saúde pública.
Autor/a(es/as) (nomes): João Artur Magnaguagno
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Orientador (a): Profº. Mc. Guilherme Maciulevicius Mungo Brasil
Coorientador (a):
Número de páginas: 27 Data de defesa: 16/06/2025
Data de entrega do arquivo à coordenação do curso/TCC: 18/06/2025
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