The right to health and the quality of generic medicines

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ABSTRACT

The right to health includes the concept of quality of life. Quality health care is a goal that countries on a global scale and, in the context of sustainable development, want to achieve, since a high level of health is a fundamental element for the well-being because it is from the good health that individuals are able to carry other human rights in particular required, housing, nutrition, dignity, education. The relationship between intellectual property and public health has attracted controversy both in developed countries and in developing countries. The pharmaceutical innovation is an essential part of efforts to improve the quality of life and save humans throughout the world. This innovation not only benefits patients but also prevents new diseases. Thus, access to medicines relating to social welfare, two interesting questions arise: 1. Prices of medicines 2 Quality of medicines. . To join the competition, companies end up producing drugs with sub-standard. Situation that directly violates the right to health. And so, the proliferation of drugs without quality in the world, is an international public health problem.

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INTRODUCTION

The right to health is part of the concept of quality of life, because people in good health are not those who receive good medical care, but those who live in healthy homes, eat healthy food, in an environment that allows them to give birth, grow, work and die. According to Article 25 of the Universal Declaration of Human Rights, access to health becomes an essential guarantee for the individual, as an indispensable condition of human existence. It remains, therefore, for the power of the state to ensure social well-being in every way.

History shows that diseases have always afflicted man. Currently, there are, among others, HIV/AIDS (Acquired Immunodeficiency Syndrome) and cancer. These are diseases that defy science, due to their complexity and, so far, the inability to demonstrate results that favor finding a cure for such diseases, so treatments are often ineffective in addition to being extremely costly.

The relationship between intellectual property and public health has attracted controversy in both developed and developing countries. However, it is important to emphasize that the major problem can be identified, to a large extent, in developing countries, namely those located in Africa, due to the large epidemics that occur in the countries and that end up causing thousands of victims, since the states do not have sufficient financial resources capable of fighting the diseases and even the population of such needy, It does not have the financial resources to meet the needs that arise from illnesses.

As such, it can be confirmed that pharmaceutical innovation is an essential part of efforts to improve the quality of life and save human beings around the world. In this aspect, it should be noted that the process of producing medicines involves important elements of the economy, as they comprise the development of the medicine itself and also both production and commercialization.

It is argued that access to medicines is disrespected due to the arbitrariness of pharmaceutical companies and this occurs precisely as a result of the lack of proactive, progressive and preventive public policies on the part of the States with regard to the production of medicines.

Therefore, problems can be identified more at the national level of the countries, with regard to public policies, to achieve the desire of the collectivity, than at the international level, since there are no imposing mechanisms for the country to do or not to do a certain activity.

In this context, the market for generic drugs in the world has developed strongly, in order to generate asserted competitiveness with reference drugs. The problem of generics is not only limited to the permission or prohibition of their production, it goes a little further, more precisely, with regard to the quality of the medicines, since the imitation of technology to meet local needs is often the basis of an independent local research and development sector.

Currently, this issue has been discussed in drugs manufactured in India, China and even in Brazil, when it comes to similar drugs. Thus, emerging countries stand out in the drug market in the

world, but there are indications of poor quality of drugs placed on the market. In order to reduce the costs of medicines and, consequently, the final value (price worked by the companies for access by the consumer), companies end up investing little, in order not to apply good manufacturing practices for generics and the like, since they will replace them with cheaper ingredients.

In this way, the problem-situation emerges: Is the manufacture of generic drugs in countries of the global periphery an obstacle to the right to health and, consequently, to the right to development? In view of the problem presented, this work has as general objective: To analyze whether the manufacture of generic medicines is an obstacle to the right to health and, consequently, to the right to development and as specific objectives: To identify if generic medicines are obstacles to the right to health; To verify whether there are cases of poor quality medicines in the international scenario and to ascertain the position of international organizations regarding the entry of poor quality medicines into the market.

Thus, the research that is underway has as a background the doctrine in the field of International Development Law, database and documents of the entities that make up the UN system and other associations linked to the subject, such as the WHO, WIPO, WTO, journalistic news, as well as the Universal Declaration of Human Rights, WTO TRIPS Agreement and the Doha Declaration on access to health.

DOHA DECLARATION AND THE RIGHT TO HEALTH

According to Duarte (1994), the right to health is part of the concept of quality of life, because people in good health are not those who receive good medical care, but those who live in healthy homes, eat healthy food, in an environment that allows them to give birth, grow, work and die.

Therefore, quality health is a goal that countries, on a global scale and also in the context of sustainable development, wish to achieve. A high level of health is a fundamental element for well-being, because, as Machado and Raposo (2010) argue, it is from good health that individuals are able to realize other human rights, namely, housing, nutrition, dignity, education.

In general, aspects of health in developed countries are much better than in developing countries. Analyzing the data on the reasons for mortality, it was found that the causes of malnutrition compete with infectious diseases, such as tuberculosis, AIDS/HIV and malaria.

Thus, it can be observed that the right to health has characteristics of human rights, which go back to the United Nations Charter itself, namely in its articles 55 and 56 and also in the Universal Declaration of Human Rights, establishing criteria of social well-being, respect for human rights, economic and social progress, emphasizing, therefore, the elements of the right to health. In this sense, Jónatas Machado and Vera Lúcia Raposo (2010) observe that:

> "In the aftermath of the Second World War, and the human misery that resulted from it, the seeds of the right to health were sown in the Charter of the United Nations, with its emphasis, inscribed in Articles 55 and 56, on the well-being of peoples, respect for human rights, economic and social progress and the resolution of economic and social problems, including health. From the outset, it was enshrined in the Universal Declaration of Human Rights, in its article 25, integrating the original matrix of international human rights law in the twentieth century" (Machado and Raposo 2010. p. 11)

According to Article 25 of the Universal Declaration of Human Rights, access to health becomes an essential guarantee for the individual, as an essential condition for a dignified human existence. It remains, therefore, for the power of the state to ensure social well-being in every way. In the same line of health protection, in the sense of holding governments accountable as the main maintainers of development, the Covenant on Economic, Social and Cultural Rights is identified, more specifically in its article 12, with the following guidelines:

> "The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the best attainable standard of physical and mental health. 2. The measures which the States Parties to this Covenant take to ensure the full exercise of this right shall include the measures necessary to ensure: (a) the reduction of infant mortality and mortality, as well as the healthy development of the child; (b) the improvement of all aspects of environmental and industrial hygiene; (c) the prophylaxis, treatment and control of epidemic, endemic, occupational and other diseases; (d) the creation of specific conditions to ensure medical services and medical help in the event of illness for all persons". On the international scene, we have other normative instruments that are concerned with the right to health, namely: the 1965 Convention on the Elimination of All Forms of Racial Discrimination, the 1979 Convention on Discrimination against Women, the 1989 Convention on the Rights of the Child, the Additional Protocol to the American Convention on Human Rights in the field of economic rights, 1988 as an international instrument concerned with the right to health".

In this aspect, it is interesting to observe that, at the moment when the concept of the right to health is expanded, some essential aspects of the right to development are being clarified, since it is observed that public health is also part of the sector of interest to the State, as it is Human Rights (CARVALHO, 2011). In this way. Winslow notes that:

> The science and art of preventing disease, prolonging life, and promoting health and efficiency, through the organized effort of the community, for a) sanitation of the environment; b) control of communicable diseases; c) education of individuals in personal hygiene; d) organization of medical and nursing services for the early diagnosis and preventive treatment of diseases; (e) the development of a social mechanism which ensures that each person has an adequate standard of living for the preservation of health, and that these benefits are organized in such a way that every citizen is in a position to enjoy his or her natural right to health and longevity. (WINSLOW apud ACOSTA, R.T.K 1993 p 7-8)

History shows that diseases have always afflicted man. Currently, there are, among others, HIV/AIDS (Acquired Immunodeficiency Syndrome) and cancer. These are diseases that defy science, due to their complexity and, so far, the inability to demonstrate results that favor finding a cure for such diseases, so treatments are often ineffective in addition to being extremely costly.

The international characteristic of the Right to Health is possible when one visualizes the extraterritorial element that contaminates the individual, that is, when the individual crosses the borders of his territory, taking with him the risk of a pandemic, which consequently generates the concern on the part of international organizations to contain this problem, so that it does not get out of control.

In this aspect, the relationship between health and sustainable law is observed, since the main role of sustainable development is to improve the quality of life of the population without, however, increasing the use of environmental resources. However, for this connection to occur, it is necessary that there is a balanced action for the economic growth of natural resources, the environment and social development, so that if there is no renewal for the path of development, it will not be possible to speak of sustainable development (WHO, 2001).

The common issue that generates affinity between intellectual property and public health has been discussed not only in developed countries, but also in developing countries. In African countries, specifically, the major problem is identified due to the large epidemics that occur, affecting thousands of victims. There are not enough resources to combat this situation and the population also does not have the conditions to meet the needs that arise with the diseases.

From this perspective, Dutfield observes that:

> High-profile pandemics likes HIV/AIDS understandable attract considerable attention. Millions of peple have died of this terrible diseade-2.6 million in 2003 and 2,8 million in 2005, of which sub-saharan Africa contributed 1.9 million and 2,0 million respectively (DUTFIELD, 2008, P. 312).

In this context, the right to health corresponds not only to medical and hospital care (specialized human labor), but also to access to medicines, so it must be improved according to social, technological and scientific development.

Medicines are one of the most effective tools in the therapeutic arsenal available to prevent, cure or alleviate various diseases. For all these reasons, it represents a very important element of health and administrative policy. Today, they are considered essential products, as they transcend civil rights to reach the level of public affairs (MARQUES, 2013).

Therefore, access to medicines corresponds to one of the elements for the completeness of the right to health and as such must be respected and made available to society, especially in a preventive way, thus avoiding problems that are difficult or prolonged to solve (CARVALHO, 2011).

Therefore, it can be stated that the right to access medicines differs from other rights related to health, because in the latter, it involves public and private interests, since it is a service concession that must be made by the public administration, as it is framed as a fundamental legal element for the individual and for his function of maintaining the needs of the population to be achieved and, also,

In the private sector, research, investment and development will be involved in the manufacture of pharmaceutical products.

As such, it can be confirmed that pharmaceutical innovation is an essential part of efforts to improve the quality of life and save human beings around the world. This innovation not only benefits patients, but also prevents new diseases. In addition, it is very important for a country's health system, as it brings solutions to different public health problems. Consequently, it allows for a more efficient use of resources, resulting in enormous savings for the sector (MARQUES, 2013).

THE PRODUCTION AND PROTECTION OF MEDICINES AS PART OF ACCESS TO HEALTH

The process of producing medicines involves extremely important aspects of the economy, as they include the development of the medicine itself and also the production and marketing of the medicine. From this perspective, Huveneers observes that:

> Development begins with the therapeutic research phase: the synthesis of new molecules, i.e. the production of a substance or chemical composition on a laboratory scale. The synthesis is followed by an analysis of the purity and stability of the new molecules, followed by their screening, i.e. the study of their behaviour using pharmacological and biological tests. At the production level, a distinction must be made between the production of the active ingredient and its galenic form. The launch and marketing stage is the promotion to the medical profession by the teams of medical representatives of the pharmaceutical companies. These promotional activities are very costly. (HUVENEERS, 2000. PP. 17-18)

In view of the above, the issues related to the entry of medicines into the market become very complex, due to the interests that arise in the company-state-individual relationship. There are those who argue that patent protection for medicines is irrelevant in the context of the right to development, since the investment costs are high, a situation that reduces access to medicines. In this sense, we observe what Krishna has established:

> Patents are irrelevant for the development of the products needed to address the diseases prevailing in developing nations…. The extension of pharmaceutical patent protection to developing nations, mandated by TRIPS Agreement, can do very little to prompt the development of such products, while it generates costs in terms of reduced access to the outputs of innovation. (Krishna, 2006, p.10)

However, the issues related to access to medicines are aggravated by the presence of pharmaceutical laboratories, because, in a way, they end up monopolizing the activities of drug production and for this reason, pharmaceutical companies are constantly criticized, since the focus ends up turning more to capital accumulation and less to humanitarian issues.

The criticisms that revolve around drug patents are based on an exclusionary policy, as there will be unavailability of drugs in an equitable manner (developed and developing countries). Thus, it

remains to be seen whether there is a way to reconcile the appeal of society's *well-being* with the general idea of property.

The situation of drug patents becomes more complex when we broaden the field of visualization to the international scenario, because the different interests of different countries are at stake. Thus, as a way to consolidate patent issues in a uniform manner in the international scenario, some agreements and treaties were established between several countries in order to facilitate *patentability* processes within each country, as well as to reestablish international policies and relations between countries.

The TRIPS agreement, according to Carvalho (2011), represents a minimum protection and therefore should be complemented by activities developed by the Member States, as there must be the counterpart of the state to achieve the essential needs of the population through the principle of progressivity. In this sense, Carvalho notes that:

> It is important to reiterate the importance of understanding and acting to implement public policies that provide progressive and sustainable development, through respect for the fundamental human right to access to medicines, even because the greatest needs and budgetary expenditures, related to health policy, are related to the supply of medicines. (CARVALHO, 2011, p.45)

Therefore, the member states will use the flexibilities made available in the international legal scenario, but they will have to comply with a counterpart, that is, they will have to contribute with positive activities on the part of the State.

It is important to take into account that the States, especially those in the process of developing countries, do not have sufficient technical and scientific knowledge to start a process of producing medicines, a situation that harms the country in terms of access to health through access to medicines. Thus, the only viable alternative for achieving the objectives of the rule of law is to resort to alternatives offered by the international legal order, which will consolidate the system of international cooperation, in particular, compulsory licenses.

By their very nature, patents require financial reimbursement in order to obtain the return due on the monetary values invested in drug discoveries. In this sense, medicines are at the highest level of discussions on intellectual property and development at the international level. The prices worked by the pharmaceutical companies are in a certain way abusive and, due to the needs of the population itself, there is a need to interrupt this monopoly, so that the socialization of this medicine occurs.

In this sense, Correa observes the problem of the population's need for access to medicines in different regions of the world:

> With more than 30 million people living with HIV, most of them in the poorest regions of the world, the need toaddress the problem of access to patented medicines has emerged as a global priority. While it is true, as argued by the pharmaceutical industry, that other factors such as infrastructure and professional support play an important role in determining access

> to drugs, it is also true that the prices resulting from the existence of patents ultimately determine how many will die from AIDS and other diseases in the years to come. (CORREA, 2005, p57)

The AIDS crisis, all over the world, brought this need to block the activities of drug companies and began to be discussed about the real need for legal protection for pharmaceutical products, since the population, regardless of its geographical location, needs drugs for survival and that the patent would only limit this access. In this context, regarding the statistics of HIV incidence in the world, it is observed that:

> "More than 35 million people now live with HIV/AIDS; 3.3 million of them are under the age of 15; In 2012, an estimated 2.3 million people were newly infected with HIV; 260,000 were under the age of 15; Every day nearly 6,300 people contract HIV—nearly 262 every hour; In 2012, 1.6 million people died from AIDS; 210,000 of them were under the age of 15; Since the beginning of the epidemic, more than 75 million people have contracted HIV and nearly 36 million have died of HIV-related causes" (AMFAR FOUNDATION, 2013)

Faced with this panorama of the fight against AIDS, Brazil was the forerunner, when it used the edition of a domestic legislation to commercialize the drug *Efavirenz* - antiretroviral drug produced by the Laboratory *Merck Sharp & Dohme*, patent holder, used in the fight against the AIDS/AIDS virus.

With the incorporation of the TRIPS agreement into the Brazilian legal system, Brazil began to grant patents for medicines and, as a result, it was no longer possible to manufacture generic medicines without the payment of *royalties* to patent holders, a situation that overloaded the Brazilian public coffers. Thus, based on the collective interest and the emergency regarding the HIV/AIDS population, Brazil decided to apply for compulsory leave based on the public interest and also on the abuse of economic power Berg (2007).

However, only with the threat of the request for a compulsory license was there a 64% reduction in the value of the reference drug, because the company in question knew that Brazil had enough technology to produce generic drugs. Subsequently, the drug company resumed operating the product at high prices, so that Brazil announced its intention to buy the drugs intended to combat the disease, in generic format, from India. Although there was a counter-proposal from the interested company, for a 30% reduction, Brazil observed that it did not meet the country's public interests.

Thus, from decree 6108, the permission of the legal instrument was announced and, since then, the country has started the process of parallel import of the generic drug company, located in India, and the royalties of the Merck group, in relation to the import of the Indian like product, stood at 1.5% of the value of the drug in India.

In March 2012, India granted the first compulsory licence for a medicine produced by *Natco Pharma*, as the Indian legal system allowed compulsory licences to apply for irrespective of patent control. (BECKETT; POUNTNEY 2013).

It is also important to note that, although other factors exist for the difficulty of access to medicines by developing countries with less relative development, the price of medicines becomes the cornerstone of the problem. In this regard, Berg notes that:

> For example, at the time that a year's supply of a combination of AIDS drugs cost more than $10,000 in the United States under patent, Indian generic producers offered a similar combination for around $300. Although other factors have contributed to the unavailability of essential medicines, for some medicines prices have clearly been part of the problem. (BERG, 2013)

The central challenge of this problem was to try to reconcile economic interests and the fundamental right to health, since there is a direct link with the costs of research and development and market prospects. Thus, since medicines are an essential public health good, they should therefore be treated as a priority and, thus, policies should be established that guarantee access to medicines for the population (HERINGER 2007).

In view of the above, in principle, a conflict of fundamental rights can be observed, namely the right to property and the right to health, represented by access to medicines. However, by establishing an equation between the two legal elements, the advantages and disadvantages that arise with the compulsory license are soon verified, which according to André Ramos would be a comparative valuation of the rights in conflict:

> It consists in the comparative assessment between, on the one hand, the advantages of a measure and, on the other, the sacrifice required of a fundamental right. The cost-benefit analysis has to be done to avoid unbalanced measures, which generate more inconvenience to the holders of the restricted rights than the general benefit." (RAMOS 2005, p.19)

And yet, in relation to the balance between rights, the same author points out that:

> There remains the analysis of the proportionality between the restriction of one right (means) and the benefit of another (purpose), using the three elements of the proportionality judgment (suitability, necessity and proportionality in the strict sense). Therefore, in the collision between rights, it is necessary to prevent a right from being sacrificed uselessly, beyond what is necessary, or in an unbalanced way. (RAMOS, 2005, p.47)

Thus, when verifying the proportionality requirements, it can be observed that access to medicines falls within the issue of collectivity, that is, the need of a portion of the population that does not have sufficient financial resources to acquire certain medicines, thus identifying the social relevance of the right.

On the other hand, the property right inherent to the pharmaceutical patent is focused on an individual issue, thus excluding a large portion of the population, since the benefits will be restricted to a small portion. Therefore, when establishing this balance, in search of a balance of interests, it is verified that the right to health becomes, in fact, a prominent element, because it should not have a

condition and therefore, even though it is a programmatic norm in most constitutions, it should still have priority to the detriment of other rights listed in the constitutions of the countries.

It should also be noted that the TRIPS agreement itself establishes in its text the possibility of using various measures (including compulsory licensing) so that the country can promote public health through access to medicines. And, although the Doha Declaration establishes questions about the Right to health, there was no clarification in its text of the possibility of using compulsory licenses so that the country could promote public health.

The Doha Declaration only stated that the signatory countries should comply with the determinations set out in the TRIPS Agreement, a situation that generated a tightening of the protective rules for drug patents, thus hindering the establishment of a consumer market both domestically and internationally. Thus, in 2003, the WTO Ministerial Council approved the export of medicines through the use of compulsory licensing to the countries most in need, that is, those countries with serious public health problems.

It should also be noted that access to medicines, as part of the right to health, requires quality in the provision of goods and services aimed at achieving the right to health. Thus, it is not only the right to enjoy a healthy life, but also encompasses the right to enjoy a high standard of health care and, therefore, there must be strong control by countries regarding the liberalization of the entry of generic and similar drugs into the market, when using the mandatory license.

However, the lack of adequate patent protection will reduce in an unfavourable incentive structure for the research and development of more technologically advanced medicines, with significant losses for national and global public health. This is all the more so since the development of antibiotic resistance by many viruses requires a continuous research effort, which only adequate patent protection can guarantee (CANOTILHO et al. 2008).

RIGHT TO QUALITY MEDICINES AS PART OF THE GUARANTEE OF THE RIGHT TO HEALTH

In the context of access to quality medicines, Jónatas Machado and Vera Lúcia Raposo (2010) observe that the accessibility of medicines can cause a conflict between two dimensions of access to health, as one privileges the accessibility of medicines, while the other places emphasis on the research and development of new medicines and on the assurance of their quality. safety and efficacy in order to address health shortages and emergencies on a global scale. And without new medicines entering the market, it will be very difficult to make up for the deficiencies that will arise from the lack of suitable pharmaceutical products.

For this reason, the health authorities responsible for the entry of medicines into the market have a great responsibility to adequately supervise medicines, so that they do not fall under one of

the elements of violation of the right to health, namely medicines of poor quality. In this sense, it can be stated that, in fact, the State has the duty to supervise the drugs that will be introduced into the market

Thus, the proliferation of low-quality medicines in the world constitutes an international public health problem of the greatest proportions, hence the great importance of inspection agencies to allow medicines to enter the country (MACHADO; RAPOSO, 2010).

It should also be noted that, although emergency, the compulsory license cannot be used arbitrarily, because the principle of free enterprise and property will be meaningless. From this perspective, BERG observes that:

> The defenders of intellectual property rights— both corporations benefiting from patents and copyrights and governments of the IP-generating developed nations, especially the United States—counter that strong IP protection benefits developing nations and the poor. In the words of a U.S. State Department undersecretary, strong IP protection "will not only encourage innovation, it will provide the level of confidence in an economy needed to attract foreign investment and spur technology transfer." These arguments were among the justifications presented in the 1990s for including intellectual property in general international trade agreements for the first time. (BERG, 2007, p28.)

Thus, the country must seek mechanisms to enforce the right to health and life, through consistent instruments to motivate research and development, otherwise the burden of the state's inefficiency will fall only on the private companies that produce medicines. In this sense, Roberta Remedio Marques observes that:

> The rigidity of this control corresponds to the importance of what is at stake, which is public health and the individual health of each citizen. Thus, only after passing this rigorous examination, in which it is verified that the properties of the product or process do not have any harmful effects on human beings and that they are in fact effective for the purpose for which it is proposed, can the drug be launched on the market. (MARQUES, 2013, p.57)

It is also observed that the temporary monopoly inherent to the granting of a patent is nothing more than the obstacle that the population faces to have access to medicines, which until then is unknown to them.

It is recognized that the protection of intellectual and industrial property plays an important social function, insofar as it fosters the intellectual, cultural and scientific development of States. In the field of the pharmaceutical industry, this protection is an essential condition for the sustained promotion of public health (MARQUES, 2013).

As previously elucidated, in recent years there have been problems involving pharmaceutical patents, namely the reduction of incentives for innovation in the area, due to the vulnerability to imitation of the system. In this sense, Roberta Remedio Marques observes that most of the current medicines launched on the market contain few innovative elements, a situation that does not

collaborate with social development, since it does not follow the evolutionary pattern of society, namely the emergence of diseases.

The need for greater pharmaceutical innovation is undeniable, and the improvement of health (public and individual) globally depends on this innovation. It is linked to constantly evolving public health needs and associated with global phenomena. Therefore, its objective is the continuity of drug innovation, providing greater benefits to humanity. This innovation process, however, is very complex, time-consuming, and fragile by nature. For this reason, the chances of success in the task of placing a new medicine on the market are reduced. In addition, the process is very expensive, a fact that restricts the number of entities technically and financially qualified for the successful search for a new molecule (MARQUES, 2013).

The lack of incentive for research in pharmaceutical innovations to combat diseases is perceived not only in antiretrovirals, but also in drugs to combat and control malaria, tuberculosis, among others. From this perspective, Ganslandt (2005) observes that:

> "the problem, however, is that developing new drugs typically involves substantial investments in R&D. The average cost to develop a new pharmaceutical drug is approximately U$300 million; in some cases, it is substantially higher. These costs are mainly fixed and sunk once the drug is developed". (GANSLANDT et. al, 2005, p.214)

This issue stems precisely from the fragile protection that drugs have in several countries, especially those in developing countries. In this regard, Mattias Ganslandt, observes that:

> HIV/ ADIS is not the only disease plagues poor nations; malaria tubercolosis, and other maladies are equally lethal and debilitating. Indeed, HIV/AIDS is unusual in that strong incentives for pharmaceutical companies to develop treatments for sufferers in high-income economies have resulted in medicines that effectively permit patients to function well years before onset of the disease. Overwhelmingly poor and cannot afford medicines in sufficient quantities to cover R/D costs. The problem is accentuated by weak patent protection in potential markets, further reducing the willingness of pharmaceutical enterprises to develop new drugs and vaccines. (GANSLANDT 2005p.34)

In developed countries, the industry related to Intellectual Property, characterized today as a high value-added good, has been growing continuously at a faster pace than any other segment of the economy. It is a reflection of the new cycle of evolution of industries based on technological dynamism that has knowledge as raw material for the means of production, an element dependent on creativity.

Brazil, among other developing countries, faces the difficulty of locating itself in the international market of pharmaceuticals due to the fragile production system that still exists, because despite having technological incentives in the area, it is not enough to compete directly with the high-level production of medicines originating in developed countries.

However, the developing countries, despite not reaching the level of the developed ones, in the production of original drugs, have managed to develop a high standard of quality for the production of drugs in the generic modality, thus, they are able to supply the domestic market with drugs at a lower cost, with national production of generic products, thus using the same drug formula as the original.

In view of the above, it is important to note that the flexibilities arising from the TRIPS Agreement and praised by the Doha Declaration may not be put into practice due to the organizational difficulties faced by developing countries. Therefore, even if the essential requirements for the establishment of certain flexibilities have been met, countries will not be able to implement them. From this perspective, Matthews (2011) observes that:

> The use of compulsory licensing provisions and other TRIPS flexibilities is also problematic the procedural requirements for implementing the appropriate national legal provisions are complex and burdensome, particularly for developing and least-developed countries that lack the necessary technical and legal expertise and administrative capacity. (MATTHEWS, 2011 p. 423)

It is also observed that, in addition to the structural difficulties faced by developing countries, there are bilateral and regional agreements, as we will see below, which may include restrictive measures that may hinder the development of essential techniques for the production or reproduction of medicines (MATTHEWS, 2011).

Due to the difficulties faced by developing countries in implementing the flexibilities of the TRIPS Agreement, International Organizations have become, as will be seen below, a strong support for identifying viable solutions in the negotiations that take place between countries (MATTHEWS, 2011).

The debate on exceptions and limitations in the field of patents, especially compulsory licensing, has long focused on the area of public health and access to medicines in the developing world. The amendment to the TRIPS Agreement decided in 2005, with regard to compulsory licensing for exports in the pharmaceutical area, is a result of this debate.

The debate also refers to the discussion of whether the patent system, with its current checks and balances built in, remains an adequately balanced system, which is extremely important, as there will be incentives for technical development and economic growth.

This process of competition through the strengthening of trade in developing countries is part of the natural condition of the international trading system. It is also important to emphasize that, with regard to the intellectual property system, the economy of developing countries is experiencing a transition period of substantial importance, as they assume that they do not have sufficient technology to develop their research and, therefore, end up depending on the knowledge and technology of developed countries. In this sense, the existence of generics becomes of fundamental

importance, because it will be from a technology that already exists that a more advanced technology will be developed. As such, Gibbons notes that:

> History teaches that uncompensated intellectual property transfers (piracy) as a developmental policy may have much to commend it because uncompensated transfers may mark an attempt to return to the well-worn paths that led to past successful economic development. Many now-developed nations passed through this stage of taking and exploiting uncompensated transfers of intellectual property.
> (GIBBONS, 2011, p87)

The discussion has now broadened to other areas. Examples are the discussions at the United Nations Basic Convention on Climate Change (UNFCCC) on intellectual property related to "green" technology, the decision of the WIPO Standing Committee on Patent Law to study the area of exceptions and limitations in the patent system, and the WIPO Conference held on 13-14 July 2009 on intellectual property and public policy.

In this sense, for the proper balance between the rights of individuals and the rights of patent holders of objects of greater human need, measures can be adopted to protect the rights of individuals who urgently need the use of such medicines, however, and therefore such measures cannot be abusive, that is, it is extremely important that there is coherence and limits in the measures that are taken.

Thus, a weighted analysis between intellectual property rights and access to public health is necessary, as there is a need for patent protection in the pharmaceutical industry and also the implementation of public policies of differentiated prices for the acquisition of essential medicines in developed countries and those in the process of social development.

The fact is that medicines are becoming mere commodities and health is an extension of the market in which cures and treatments for the diseases that afflict poor communities around the world will only be available in an exclusive way, that is, to those who have sufficient purchasing power to support them (Plaza 2008)

Currently, the issue of drugs manufactured in India, China and Brazil has been discussed when it comes to similar drugs. Thus, emerging countries stand out in the drug market in the world, but there are indications of poor quality of drugs placed on the market.

In order to reduce the costs of medicines and, consequently, the final value (price worked by the companies for access by the consumer), companies end up investing little in order not to apply good manufacturing practices for generics, since they will replace them with cheaper ingredients.

As such, low-quality products can stem from a number of issues, namely, lack of knowledge, flawed manufacturing practice, insufficient infrastructure, containing toxins, active ingredients, and incorrect ingredients. Another important issue refers to the inspection agencies for the entry of

medicines into the market, which are often not so strict and end up facilitating the entry of pharmaceutical products of poor quality.

The consequences of the entry of non-quality medicines on the market are serious, namely: non-treatment of the disease, either because the medicine does not have an effect or even because it develops a resistance of the body to the ingested medicine, it can also generate distrust in the health system, allergies and poisoning. In this sense, it is observed that:

> When patients receive a counterfeit medicines, they are subjected to multiple risks. They often suffer more than just an inconvenience; as they become victims of fraud medicines and are all put at risk of adverse effects from unprescribed medicines or substandard ingredients. Additionally, patients may lose confidence in health care professionals including their physician and pharmacist, and potentially modern medicine or the pharmaceutical industry in general. Counterfeit or substandard (poor quality) drugs pose threats to society; not only to the individual in terms of the health side effects experienced, but also to the public in terms of trade relations, economic implications, and the effects on global pandemics. It is vital for suppliers, providers, and patients to be aware of current trends in counterfeiting in order to best prepare for encounters with suspicious products. (SE, NSIMBA 2008, p4.)

Therefore, it is not the simple access to the drug that will build the idea of equality, but also the quality of this drug that is being made available to the public. Thus, access to medicines will be conditioned to their quality, because if the patient has access to a medicine of poor quality, then their right to health will be automatically violated.

In this sense, the inspection policies currently used by developing countries regarding the permissiveness of the entry of non-quality medicines into the market are very worrying. The problem is not necessarily the copying of the drug, but only the inspection criteria for granting permission for drugs to enter the market. In this sense, Jónatas Machado and Vera Lúcia Raposo observe that:

> A permissive policy on similar and counterfeit medicines for reasons solely related to the low price and accessibility of medicines can prove disastrous for public health, placing those patients who are least able to pay at particular risk and vulnerability. (MACHADO; RAPOSO 2010, p70.)

In the present context, globalization has become a worrisome phenomenon in the international scenario, as the flexibilities resulting from bilateral agreements boost the commercialization of medicines, and may even facilitate the distribution of medicines without due quality in less developed countries (MACHADO; RAPOSO, 2010).

A very recent example of the problem is the anti-malaria drug consumed by people who are located in sub-Saharan Africa and also in Southeast Asia, where some resistance to the drug *artemisinin* has been found, more specifically on the border of Cambodia and Thailand. Studies have been carried out and a large number of low-quality medicines have been found to be falsified. Thus, Nayyar (2012) observes that:

> "Of 1437 samples of drugs in five classes from seven countries in southeast Asia, 497 (35%) failed chemical analysis, 423 (46%) of 919 failed packaging analysis, and 450 (36%) of 1260 were classified as falsified. In 21 surveys of drugs from six classes from 21 countries in sub-Saharan Africa, 796 (35%) of 2297 failed chemical analysis, 28 (36%) of 77 failed packaging analysis, and 79 (20%) of 389 were classified as falsified. Data were insufficient to identify the frequency of substandard (products resulting from poor manufacturing) antimalarial drugs, and packaging analysis data were scarce" (NAYYAR et al. 2012, p.288-496)

Thus, placing intellectual property rights on the margins of society in order to praise, for example, the right to health through access to medicines can generate serious problems, since health policies aimed at overseeing pharmaceutical companies may not be so reliable. Therefore, it incurs in the entry of drugs with no quality and also in the discouragement for the research of new drugs, which generates, therefore, elements that indicate social regression.

Therefore, developing countries should make efforts to control the entry of non-quality medicines into the market, both through the establishment of good laboratories that are committed to producing quality medicines, as well as through the commitment of health agencies responsible for monitoring or verifying the quality control of all locally manufactured pharmaceutical products and those imported (entry) or donated to countries to be used to protect their products. make sure that they meet the set or established international or national standards.

In view of this context, it is apprehended once again that it is the State's own responsibility to achieve *social welfare* , and control attitudes for the entry of medicines into the market through certification methods that guarantee the quality of the drug become of substantial importance. Attitudes that merely block the entry of generics into the market, but only the entry of low-quality medicines, cannot be considered, so that it does not incur in the denial of fundamental rights, that is, the right of access to health, to live with dignity.

CONCLUSION

In view of all the above, the present study was based on the premise that a high level of health is a fundamental element for well-being, since it can be concluded that it is from good health that individuals are able to realize other human rights, namely, housing, nutrition, dignity, education.

Thus, considering that pharmaceutical innovation is an essential part of efforts to improve quality of life and save lives, it was observed that, in order to enter the competition, many generic drug companies end up producing drugs with low-quality substances. This situation directly violates the right to health. And for this reason, the proliferation of poor quality medicines in the world constitutes an international public health problem.

In view of the above and related to what was exposed in the text, it is observed that the manufacture of generic drugs in countries of the global periphery is a real problem, because the lack

of care in the preparation of the drug will cause access to poor quality drugs by less favored countries.

It is known that the central challenge of this problem is to try to reconcile economic interests and the fundamental right to health, since there is a direct link between the costs of research and development and market perspectives. It is not only about the right to enjoy a healthy life, but also the right to enjoy a high standard of health care and, therefore, there must be strong control on the part of countries regarding the authorization of the entry of generic and similar medicines into the market.

In fact, the lack of adequate patent protection will be reduced in a structure of incentives that are unfavourable to the research and development of more technologically advanced medicines, with significant losses for national and global public health. What is certain is that the proliferation of high-quality medicines in the world is indeed an international public health problem of the greatest proportions, hence the great importance of inspection agencies to allow medicines to enter the country.

Therefore, it is concluded that developing countries, mainly, should make efforts to control the entry of non-quality medicines into the market, both through the establishment of good laboratories, as well as through the commitment of the health agencies responsible for monitoring or verifying the quality control of all locally manufactured pharmaceutical products and those imported or donated. Since it is not the simple access to the medicine that will build the idea of equality, but mainly, the quality that is being made available to the public.

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