Genetic research with human beings and the distribution of economic benefits derived from biopatents: bio-juridical perspectives for public health policies in Brazil

Pesquisa genética com seres humanos e repartição de benefícios econômicos decorrentes de biopatentes: perspectivas biojurídicas para políticas de saúde pública no Brasil

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Abstract

The possibility of sharing economic benefits from biopatents derived from genetic research with human beings is analyzed. One starts from the following question: what is the current scenario of the distribution of economic benefits stemming of biopatents from genetic research with humans and the perspectives for public health in Brazil? The main objective is outlining a current panorama on the subject, both internationally and in Brazil, as well as establishing a prognosis of public health possibilities in the country. To do so, bibliographical and documentary research procedures are employed. Experiences from other countries are presented as a possible basis for analyzing the researchers' economic rights and for maintaining a sustainable public health system. Nationally, one can conclude that the Law of Access to Biodiversity is a possible route, as it determines that the distribution of economic benefits should occur only in case of commercial exploitation of the invention, and not with the bio-patent deposit. As the main result, it is concluded that, due to the need for materializing the human right to health, thinking about the possibility of sharing economic benefits derived from biopatents is a matter of public health, leading to the construction of a universal and sustainable public health system.

Keywords: Biopatents; Public health; Research with Human Beings; Public Health System; Sustainability.

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Resumo

Analisa-se a possibilidade de repartição de benefícios econômicos decorrentes de biopatentes advindas de pesquisas genéticas com seres humanos. Parte da pergunta: qual o cenário atual da repartição de benefícios econômicos das biopatentes decorrentes de pesquisas genéticas com seres humanos e as perspectivas para a saúde pública no Brasil? O objetivo principal é delinear um panorama atual sobre o tema, internacionalmente e no Brasil, bem como estabelecer prognóstico das possibilidades para a saúde pública no país. Para tanto, utiliza os procedimentos da pesquisa bibliográfica e documental. Apresenta experiências de outros países, como possível base para análise de direitos econômicos dos pesquisadores e a manutenção de um sistema sustentável de saúde pública. Nacionalmente, conclui que a Lei de Acesso à Biodiversidade é um caminho possível, uma vez que determina que a repartição de benefícios econômicos ocorra somente em caso de exploração comercial do invento e não com o depósito da biopatente. Como resultado principal, conclui que, em virtude da necessidade da concretização do direito humano ao acesso à saúde, pensar a possibilidade de repartição de benefícios econômicos decorrentes de biopatentes é uma questão de saúde pública e da construção de um sistema público de saúde universal e sustentável.

Palavras-chave: Biopatentes; Saúde Pública; Pesquisa com Seres Humanos; Sistema Público de Saúde; Sustentabilidade.

Introduction

Commonly, what determines the patients' choice for taking part in a research involving human beings[1] and their consequent exposition to unknown risk and/or risky or invasive procedures is the possibility of having access to a new treatment or medicine that can cure or mitigate the sequelae of the disease they are affected by.[2]

However, during the 20th century, this participation was based on gratuity and most world legislations have prohibited the remuneration of research participants. To make this matter even more complex, these regulations have not made implemented their right to access medical treatments or medicines developed based on the researches they have been subjected to.[3]

This context of lack of economic benefits distribution[4] happens mainly in less developed countries, where the number of vulnerable people or groups is higher. This happens due to poverty, illiteracy, limited resources, insufficient health care and lack of familiarity or experience with medical researches (Dainesi, 2011).

This legislation choice has as a consequence the lack of access to medical treatments and medicines, which violates the human right to health and currently is set as a severe public health issue. This matter becomes even more prejudicial when considered patented procedures or products. Their costs are usually higher, and it can be observed a sharp rise in them when patents are obtained. As a result, millions of people are excluded from the access to health.

When approach specifically the theme of genetic research with human beings and the products

1 See the Resolution no. 466/2012 by the National Health Council (Brasil, 2013), item II. 14, which determines that research involving human beings are those that, individually or collectively, have as the participants human beings, in the complete study or parts of it, and involving directly or indirectly, including their data handling, biological information or material.

2 See the Resolution 466/2012, by the National Health Council (Brasil, 2013), which stablishes that a research participant is the individual who, being informed and voluntary, or after having their legal guardians informed and authorized it, accepts to be researched.

3 An example of a regulation that determines free participation is the Universal Declaration on the Human Genome and Human Rights (Unesco, 1997), which Brazil has signed, and that bases most national legislations and stablishes, in its 4th article, that the human genome, in tis natural state, cannot cause economic profit. Other examples are the Resolution 196/96 and 466/2012, both by the Brazilian National Health Council, which stablish the general rule of free participation in the research. On the lack of funding for medicines based on the research, one can mention the case of the Canadian legislation – cited in this article –, which does not guarantee to the participants the right to medicines created based on the researches they have taken part in.

4 See the Resolution no. 466/2012 by the National Health Council (Brasil, 2013), item II.4, which stablishes that "research benefits" are the direct or indirect, immediate or later, profit gained by the participants and/or their community due to their participation in the research.

and processes created and patented, the issue is equally alarming. The 21st century is experiencing the exclusion of a large share of humanity from the benefits of technological development, simply because this share of population does not possess the means to pay for necessary health treatments and medicines.

Considering the presented context, to think, plan and deal with themes as the access to Brazilian genome, the funding to patented genetic treatments and medicines must be in the spotlight of public policy designers' attention, since they affect Brazilian population on a daily basis. Moreover, to ponder on alternatives for distributing the economic benefits arising from the concession of a biopatent, which is based on a genetic research with human beings, is a matter of public health.

Thus, this article performs an initial analysis on the distribution of economic benefits arising from biopatents acquired from genetic researches with human beings. It focuses on Brazil and uses the term "distribution" of benefits, since it is the one used in the Law of Access to Biodiversity (Brasil, 2015).

Although this legislation deals only with the access to fauna and flora genomes, expressly excluding the issues related to the access to the Brazilian population genetic heritage, the term can be applied to the case of patents resulting from genetic research with human being. This happens because it is understood that this legislation could be the regulatory basis for stablishing rules on the access to the Brazilian population genome.

The guiding research question is: what is the current scenario of distribution of economic benefits resulting from genetic research with human beings and what are the perspectives for public health in Brazil? As the main goal, the study aims to outline an initial panorama of the matter of the distribution of economic benefits resulting from biopatents and human genes internationally and in Brazil, as well as to stablish a prognosis of the possibilities for public health in the country.

As for its nature, the investigation is an applied one, since it intends to create practical application knowledge on the discussed theme. Regarding its objectives, it is an exploratory analysis, since it aims to make the discussed issue more explicit and to analyze examples that may stimulate its understanding. As for its procedures, it is a bibliographic and document research, using as its bases articles written on the theme and the legislation pertinent to the case.

The distribution of economic benefits and biopatents: an analysis on the international perspective

The matter of patents resulting from genetic research with human beings is still little regulated, be it in Brazil[5] or other countries. The regulation basis used for this theme is, overall, the same used for any medical research with human beings.

Among the scarce international regulations approaching the theme, it is highlighted the *Universal Declaration on the Human Genome and Human Rights* (Unesco, 1997). Specifically, the first article defines that the human genome is the fundamental unit of the human family and, in a symbolic sense, its heritage. Thus, it characterizes human genome as a shared human heritage. However, the 4th article institutes that the human genome, in its natural state, should not cause financial profits (Unesco, 1997). This is exactly the state of the genome of subjects in medical researches. On the other hand, is the researched genome is qualified by human work, a transformation in its natural state occurs and a great market value is added to it: patenting products and procedures resulting from the research is allowed.

Based on these mechanisms, one can verify that a person's participation in a medical investigation, as the subject of experimentation, has traditionally been placed in terms of voluntariness. However, this regulation outlines a serious contradiction, which puts the interests of the researcher and the patients in conflict, since it is adopted a model that allows the private appropriation of profits obtained by the onerous circulation of biotechnological products in

5 See the general prohibition of living beings patenting stablished in the article 18, III, of the Brazilian Industrial Property Code (Brasil, 1996).

the market, in contrast to the free way the organic elements common to the whole humanity are conceded by the researched subjects (Gediel, 2000).

However, this paradigmatic understanding on the gratuity of participation in the research was stablished previously to the *Universal Declaration on the Human Genome and Human Rights* (Unesco, 1997) and had its origins in a decision by the U. S. Supreme Court: the emblematic "Moore case".

John Moore was diagnosed with a rare type of leukemia. He looked for medical counselling with the specialist in oncological hematology dr. David W. Golde. In August 1976, he became patient of the Medical Center of the University of California (UCLA), where the doctor taught. To treat the disease, the removal of the spleen was suggested, since this procedure seemed to extend the patient's life. Moore agreed to it and signed a standard form to consent to the surgery and his clinical state stabilized.

The great twist in the case happened in 1983, when the lawyers hired by Moore discovered that, after the procedure of spleen removal, without his consent, dr. Golde had determined that his research assistance obtained a sample of the spleen in order to study the characteristics of the cells and its substances. They also found out that, in 1979, these researchers immortalized the cells extracted from the spleen in a new lineage of cells called "Mo cell line". With these cells and using recombinant DNA techniques, they were able to produce lymphokines and make them a patentable product (Myszczuk, 2012).

Lastly, the lawyers discovered that, in August 1979, the UCLA and Golde required the patent for subproducts of the Mo cell line. The patent was given in 1984 and licensed for the Genetics Institute and the Sandoz Pharmaceutics. The doctor started to work as a payed consultant of the Genetics Institute, receiving actions and other benefits in exchange for their exclusive access to his research results (Myszczuk, 2012).

Dissatisfied, Moore looked for the Justice of California against the UCLA and dr. Golde, claiming he had the right to share the profit gained with the production of patented products, since they were created from his genetic material. In the first instance, the matter was decided in favor of UCLA, based on the fact that there were no remarks in the consent form signed by Moore, who authorized the performance of medical intervention in an university research hospital and authorized the doctor, in a general way, to exert all his activities and have commercial interests, besides medical and scientific ones (Myszczuk, 2012).

In the Appeals Court, the judges, divided, inverted the decision. The court's major opinion was that the human tissue surgically removed were the private body property of the patient. Thus, without the express permission by Moore, the use of his tissue by the UCLA constituted a misappropriation (Myszczuk, 2012).

In 1990, the final decision was taken by the Supreme Court of California, which understood that determining the existence of misappropriation could mean giving to Moore the property of the lymphokine genetic code, which has the same biochemical constitution for all human beings.

The majority decided that Moore had no property rights on the cells taken from his body and that there were serious political reasons to not make a extensive interpretation of the law in this case and grant him rights over the cells. It was understood that this could prevent the free flow of biological material among researchers and that they could be constantly concerned if the donor had consented or not to the research's purposes Myszczuk, 2012).

After this precedent, the regulations, commonly influenced by the lobby of the pharmaceutical industry, started to adopt the position that research participation should be free and that genetic contents are not cause for profiting. Frequently, national regulations have not guaranteed the access to research benefits for researched participants and denied the distribution of economic benefits (Myszczuk, 2012).

In the 21st century, however, this paradigm seems to be tested, with a new practice adopted by some research subjects in the United States and Canada. This is a consequence mainly of the initiative taken by NGOs that represent people with Canavan disease, a neurologic disorder that cause the degeneration of the myelin sheath, the protective isolation of nerve cells, and the patient's death during the infancy (Knoppers, 2003).

Researches on this disease have been developed initially in the United States, after a lot of pressure

by the parents of bearers and the Miami Children's Hospital Foundation. A lot of things were discovered. In 1997, the researchers sought to patent and license products and processes, besides charging royalties. As consequence, many children were left without access to the medicines resulting from researches, for not being able to pay for the treatment. This has reopened the discussion on the gratuity on participation and the possibility for research participants and researchers to discuss intellectual copyrights before the performance of the research (Knoppers, 2003).

After the failed experience for subjects of researches on Canavan disease, other groups sought to prevent and predict the researchers' actions in relation to patenting procedures. For example, bearers of psoudoxanthoma elasticum (PXE), a genetic disorder that cause tissue calcification, have created the PXE International, a NGO to represent them for researchers and to create a genetic material of disease bearers (Knoppers, 2003).

Given that, the researchers that want to access information in this database must previously agree that the rights to biopatents that may arise from the research and the access to the database will be share between researchers and the PXE International. The aim of this initiative is to guarantee that treatments resulting from these researchers may be accessible and funded by the disease bearers (Myszczuk, 2012).

Another interesting example is the biopatent of the BRCA1 and BRCA2 genes, by the Myriad company. In 1994, in the USA, the company required the patent for the BRCA1 gene, and, in 1995, for the BRCA2. Both genes are associated to a higher predisposition than normal to develop breast cancer. The patent requirement included the normal sequence of BRCA1 and BRCA2, various mutation, diagnostic exams for the detection of mutations and for methods of sample analysis taken from tumors (Sheremeta; Gold; Caulfield, 2003).

The approval of these patents created a major bio-judicial issue for the Canadian government and public health system. In 2001, Myriad began the process of patenting the genes in Canada and the search for the protection of its rights against laboratories of public health foundations, which were performing detection test using the BRCA1 and BRCA2 genes. Myriad affirmed that, after a certain date, the continued use of these tests would be considered an infraction to the rights granted by the letter patents they had (Sheremeta; Gold; Caulfield, 2003).

After the marked deadline, it determined that the tests should be performed exclusively in the labs affiliated to Myriad, with the cost of C$ 3800.00 (three thousand and eight hundred Canadian dollars). This made provinces as Ontario, Alberta and Quebec not have financial and budget conditions to pay for the tests anymore. This lead to a decision in the sense of ignoring the warning and/or opposing to the patents granted to the company. Other provinces, as British Columbia, simply did not pay for the tests by the public health system (Myszczuk, 2012).

In 2002, in the context of this public health issue, the province of Ontario required the revision of the Canadian patent law, in order to accommodate the situation of how could or should a patent affect the public health system. To base the request, it formulated a report directed towards all provinces, in which it proposed it should be considered that, in critical situations, the benefits for public health should be reasonably measured when rewarding the inventor with a patent. Any granted monopoly should be extraordinary and happen only in situations in which new inventions resulted on significant benefits for the public and the inventor (Sheremeta; Gold; Caulfield, 2003).

It can also be mentioned that, in the 2000s, the USA have begun discussing the responsibility on the provision of medicines developed by medical researches, patented ones or not. In 2006, in the first round-table discussion in the 42nd Drug Information Association (DIA) Meeting, with the theme "Post-trial access to study medication: is it feasible?", representatives of the Bioethics Department of the National Institute of Health (NIH), of the academia, and the pharmaceutical industry have participated (Dainesi, 2011).

In the event, it was argued that, on the one hand, research participants were already benefited by the special care dispensed to them. On the other, it is unfair to use participants to develop a medicine and them make them buy it (Dallari, 2015).

All cases presented allow one to trace an international panorama about biopatents and the distribution of economic benefits between inventors and subjects of genetic research. This panorama demonstrated that currently the paradigm of free subject participation is going through a phase of many questions. Alternatives to this gratuity, such as the elaboration of strategies to guarantee rights to the patients and the impossibility of granting biopatents in fac of public health interests, are presented as understanding and adoption possibilities by the regulations.

This new scenario opens the possibility of reflecting on a more democratic distribution of benefits. Many perspectives can be considered when pondering on the fundamental right to health and the economic profits coming from the intellectual property based on genetic research with human beings.

Perspectives for the analysis of the distribution of economic benefits resulting from biopatents and public health in Brazil

The experiences and many paths that other countries have run can be used as bases for the discussion and design of a potential Brazilian regulation, considering the researchers' economic rights, the human right to health and the maintenance of a sustainable public health system. Besides, some Brazilian experiences, as the judicialization of conflicts in the health field, the public program for AIDS treatment, and the Brazilian legislation of access to biodiversity, may by a guiding North for dealing with this theme.

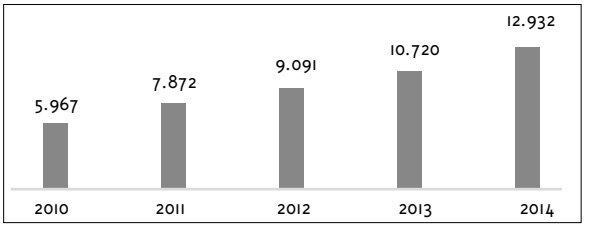
Biopatents, genetic research, conflict judicialization, and public health

In Brazil, even with the express prohibition of patenting human genes, a result of the article 18, III, of the Industrial Property Code[6] (Brasil, 1996), many effects of international disputes concerning genetic research and biopatents can already be observed. To contextualize the extent of the problem and its consequences for public health, one can take into account the perspective of the judicialization of conflicts in public health.

But one can ask: how are the judicialization of conflicts and the distribution of economic benefits resulting from biopatents related to public health? Well, it is exactly the acquisition of medicines for treating genetic diseases - which are, as a rule, patented - the main objects of demands concerning health issues.

Graph 1 shows the number of judicial processes received by the Brazilian Ministry of Health from 2010 to 2014 related to health:

Graph 1 – Number of judicial processes received by the Ministry of Health from 2010 to 2014



Source: Brazilian Court of Auditors (Brasil, 2017)

It is possible to observe, in Graph 1, a sharp rise in the number of judicial processes, which consequently leads to a sharp rise in public expenditures for this area. According to the Brazilian Court of Auditors (TCU) (Brasil, 2007), from 2008 to 2015, the expenditures for executing judicial decisions for the acquisition of medicines and supplies have risen from R$ 70 million to R$ 1 billion, representing a more than 1,300% increase for the Union.

Graph 2 shows the values spend by the Ministry of Health to executed judicial decisions from 2008 to 2015.

Among the most requested medicines to the Justice are those destined to treat genetic diseases (Souza, 2017). Soliris® is indicated to treat two rare diseases:

6 Art. 18. Not subject to patents: III - a living being whole or part of it, except for transgenic microorganisms that meet the three patentability requisites - novelty, inventive activity and industrial application defined in the art. 8th and that are not merely a discovery (Brasil, 1996).

the Paroxysmal Nocturnal Hemoglobinuria (PNH) and the atypical Hemolytic-uremic syndrome (aHUS). In their turn, the medicines Naglazyme® and Elaprase® are indicated to treat mucopolysaccharidoses (MPS), degenerative genetic diseases that manifest during childhood and reduce the patients' life expectancy (Brasil, 2017).

Graph 3 shows information on the three most bought medicines by the Brazilian Unified Health System while executing judicial decisions, between 2010 and 2015. From 2010 to 2012, the medicines Elaprase® and Naglazyme® were responsible for more then 57% of federal expenditures on the judicialization, and, after 2013, Soliris® has become the main purchase in the federal sphere, surpassing R$ 125 million (Brasil, 2017).

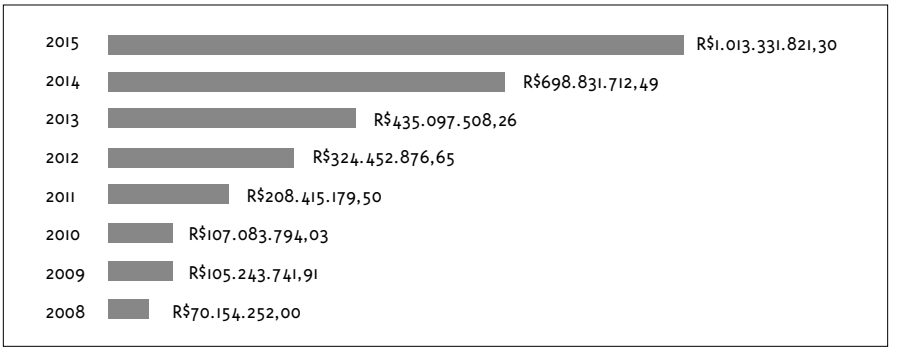
Besides these medicines, among the ten most requested to the Justice, are the medicines Proscyby, for treating the nephropathic cystinosis, a rare and genetic kidney disease; Translama, which treats Duchenne muscular dystrophy; and Replagal, for treating the Fabry disease, a hereditary disorder (Souza, 2017).

Currently, the theme of judicialization is so important for Brazilian public health that many Federation States have promoted judicial actions to discuss if State entity is responsible for paying high cost medicines and/or treatments. Among the many actions, are highlighted: the one with the provision of medicines that are not part of the public entity's program and the one dealing with the provision of medicines that do not have the foreign origin registry in the Brazilian National Sanitary Surveillance Agency (ANVISA). Both processes are being discussed in final instance in the Supreme Federal Court (STF).[7]

However, in these judicial requests, the opportunity for discussing the distribution of economic benefits was missed, as well as the possibility of granting patents or not giving the high costs for the public health system. The matter was limited to the conflict between the extension of the Brazilian citizen's right to health and the principle of reserving the possible, which governs public administration. Wider matters, as why are the costs high or what is the influence of pharmaceutical patents in this process, were not discussed.

Still, regardless of a wider analysis by Brazilian governmental authorities, the country lacks a deeper discussion on the possibility of maintaining a sustainable and inclusive public health system, specially when considering bearers of genetic diseases, which are usually the most vulnerable[8] ones in the process.

Graph 2 – Values spend by the Ministry of Health to execute judicial decisions from 2008 to 2015

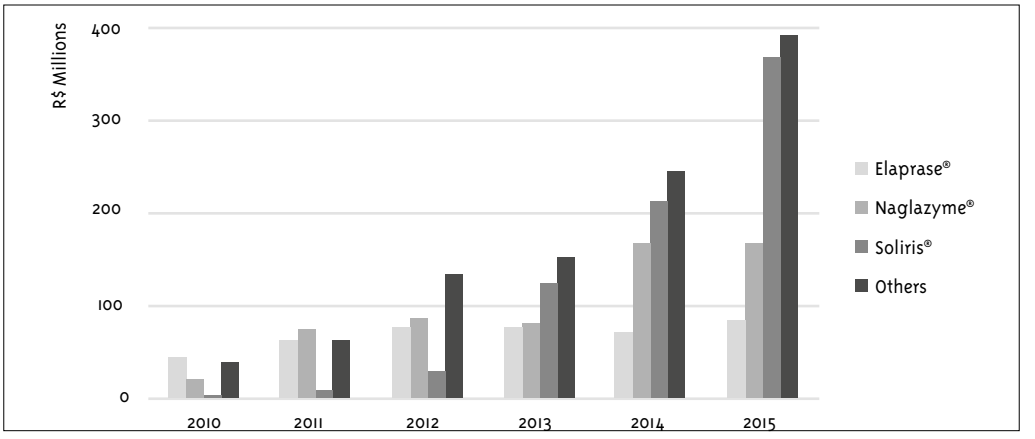


Source: Brazilian Court of Auditors (Brasil, 2017)

7 See the Extraordinary Resource 566.471, available from: <https://bit.ly/2NIbkxx>, accessed on: October 10, 2018; and the Extraordinary Resource 657.718, available from: <https://bit.ly/2AaIWRp>, accessed on: October 10, 2018.

8 See Resolution no. 466/2012, by the National Health Council (Brasil, 2013), item II.25: vulnerability is the state of people or groups that, for any reasons or motives, have their self-determining capacity reduced or prevented, or are anyhow restrained from posing resistance, specially regarding the informed consent.

Graph 3 – Distribution of Ministry of Health expenditures for judicially determined purchases, from 2010 to 2015, highlighting three medicines (in millions of R$)



Source: Brazilian Court of Auditors (Brasil, 2017)

Regarding only rare genetic diseases, in 2013, the country had already 13 million patients, bearing any of the seven thousand diseases catalogued as rare, with 80% of them having genetic origins. Of these patients, only 2% could be benefited of specific medicines and required specialized rehabilitation services. Only 3% counted on treatments that were already stablished for other diseases and that helped to reduce their symptoms. Lastly, 75% diseases are manifested in the beginning of life and affect, most of all, children up to five years-old (Falcão, 2013).

Thus, by analyzing the cost of judicialization, one can observe that the formulation of a public policy discussing the researchers' fundamental right to profiting from their work and from the application of their skills, which considers the human right to health and that can reflect on the costs of biopatents for the public health system is increasingly more crucial.

It is possible to also notice that this matter cannot be reduced to the diminution of fundamental rights. New paths, new alternatives, beyond the judicialization, are indispensable. And these choices will necessarily have to go through the discussion of the distribution of economic benefits given due to biopatents resulting from genetic researches on human beings.

Distribution of economic benefits, social function of biopatents and public health

The Brazilian Federal Constitution (Brasil, 1988), in its 5th article, XXIII,[9] stablishes that the property must fulfill a social function.[10] Likewise, the Brazilian Civil Code (Brasil, 2002), in its article 421,[11] rules that contract freedom must be exerted in observance to and bound by the limits of social function.

9 "Article 5. all persons are equal before the law, without any distinction whatsoever, Brazilians and foreigners residing in the country being ensured of inviolability of the right to life, to liberty, to equality, to security and to property, on the following terms: [...] XXIII - property shall observe its social function (Brasil, 2010).

10 We highlight the Supreme Federal Court understanding on the theme: the right to property is not shrouded in an absolute character, on which the social mortgage can be applied, that is, when its inherent social function is not fulfilled (FC, art. 5th, XXIII), the state intervention on the private sphere will be legitimated, considering, however, for that end, the limitations, forms, and procedures stablished in the Republic Constitution. The access to land, the solving of social conflicts, the rational and proper use of a rural property, the proper use of natural resources available, and the preservation of the environment are elements for performing the social function of property (Brasil, 2004).

11 Art. 421. The freedom to hire will be exerted in observance to and bound by the limitations of the social function of the contract (Brasil, 2002).

Therefore, the social function is a final commandment, meaning that the benefits resulting from property cannot be gained solely by the owner of the property, but some benefit must be given to society. Thus, the existence of property must be limited to the necessity of being useful to society, and not only for its owner (Carvalho, 2007).

In this regulatory context, the custody of industrial property guided by the social function principle both encourages research and investing in new technologies, since its owners profit on the exploration of the invention, as well as it propagates technological knowledge and scientific progress. Moreover, the products and procedures are provided for the whole population, which may be freely served by them after they become public domain (Portella, 2006).

Thus, there is no reason for the existence of a patent that benefits solely its owner, without having the society also benefiting from the invention. Due to that, the intellectual property has as its main reason to exist the fact that it is the source of resource and wealthy for those who own and those who need it. This determination becomes even more important when dealing with patents involving biotechnology, considering all the polemic on the extraordinary economic advantage given to its owner and the need for it to be also reverted to society (Myszczuk, 2012).

Brazil has already analyzed the intellectual property in light of the social function of property, when performing the compulsory licensing, in 2007, for medicines that were part of the AIDS treatment. Through the Decree no. 6.108/2007 (Brasil, 2007),[12] Brazil has licensed compulsorily the medicine Efavirenz, an antiretroviral used in the combat to the HIV/AIDS virus, produced by the Merck, Sharp & Dohme lab.

Since 2006, the Brazilian government was trying to negotiate with the lab the reduction of the Efavirenz price, from US$ 1.59 to US$ 0.65 per 600mg pill. However, no deal was reached. Therefore, the Ministry of Health declared the medicine was **public interest** and announced the intention of buying the generic version produced in India, costing US$ 0.45 per pill. Besides that, the Ministry implemented a compulsory license to enable the purchase of generic medicines that were pre-qualified by the World Health Organization (WHO).

The objective was to reduce up to 72% of the medicine's price; besides saving about US$ 30 million per year. The goal was to save about US$ 237 million until 2012, a value that should be reinvested and guarantee the sustainability of the Brazilian anti-AIDS program. Brail has continued to destine 1.5% of the value spend with the importation of the generic medicine for paying the royalties for Efavirenz, Merck, Sharp & Dohme (Martins, 2011).

This shift in the public health policies was made aiming to maintain the excellence and sustainability of the Brazilian anti-AIDS program, considered one of the bests in the world. Besides guaranteeing the care and medicine supply for infected people. With that, the Brazilian government aimed to reduce mortality rates, an accomplishment that outweighs the economic interests of the North-American lab (Storer; Machado, 2007).

This means that, by determining that the **public interest** outweighs the economic interest of the pharmaceutical industry, the instate of social

12 Art. 1. It is officially conceded the compulsory licensing for public interest of the Patents no. 1100250-6 and 9608839-7.

§ 1st The compulsory license defined in the caption is conceded without exclusiveness and to non-commercial public use ends, in the scope of the National DST/AIDS program, in the terms of the Law no. 9.313, of November 13, 1996, having five years as its period of validity, being possible to prorogate it for the same period.

§ 2nd The compulsory licensing defined in the caption will be extinguished by an act of the State Ministry of Health, if the public interest circumstances that determined it are ended.

Art. 2. The remuneration of the owner of the patents in the Art. 1 is fixed at one and five decimal percent of the medicine produced and finished by the Ministry of Health or the medicine that is delivered to it.

Art. 3. The owner of the patents licensed in the art. 1 is obliged to give to the Ministry of Health all sufficient and needed information for reproducing the protected objects, being the Union's responsibility to duly protect this information against unfair competition and dishonest commercial practices (Brasil, 2007).

function, which guaranteed that the industrial property did not have only an economic function or that it should override the its inherent social function, was applied (Storer; Machado, 2007).

The concern with the social function when exerting the rights granted by the industrial property must be observed, considering that the owners should explore their invention and make it accessible to the society. In case they do not observe it, the State, in the person of the Judge-State, can interfere on it to repress or sanction this behavior, significantly interfering in the right to property on behalf of the collectivity and the common good, the objectives of the Constitutional and Democratic State (Storer; Machado, 2007).

After that, in 2008, the National Intellectual Property Institute (INPI - *Instituto Nacional de Propriedade Intelectual*) denied the request for patenting the antiretroviral medicine Tenofovir, for understanding that there was no inventive activity. At the time, the Ministry of Health had declared it a public interest medicine, aiming to speed the analysis of the process up, which was in the INPI since 1998. At the occasion, about 30,000 patients were using the medicine, costing US$ 43.4 million (Brasil, 2008). In the same year, the medicine's request for patent was also denied in the United States.

The same theme was brought back in 2015, with the rejection of the patent request made by the Gilead lab for the medicine Truvada, an antiretroviral that combines the drugs tenofovir and emtricitabine. The INPI understood that there was no inventive activity in the creation of this medicine since the drugs used in it were already known in 2004, when the request was registered. Likewise, the institute understood that there was no innovation in the manufacturing procedure, which is limited to the combination of both drugs (Buscato, 2017).

This rejection made room for the medicine to be included in the Brazilian anti-AIDS program. Truvada is considered a high cost medicine and granting the patent would make the values even higher. In the USA, a treatment month with this drug can cost US$ 1,000 (a thousand dollars). After the rejection, the free competition and the law incentives to generic medicines, the prices can lower and funding it may be possible (Buscato, 2017).

The same rules that are the base for the program for funding AIDS treatments in the country could support the discussion on the distribution of economic benefits between researchers and the subjects of genetic researches, specially when there are already biopatents granted or when they are requested by the researchers. This is a precedent that may combine the principles of public interest, social function and the guarantee of the researcher's economic rights.

Perspectives for public health and ways of distributing benefits

In Brazil, the Resolution no. 466/2012 by the National Health Council (Brasil, 2013), which regulates the researches involving human beings, does not directly discuss the possibility of distributing economic resources among participants and the study's researchers/sponsor. As previously discussed, it chose to determine that the participation in a research should be free, with the exception of the financial reward for phase I clinical researches, when medicines are test in a small group of healthy people; or in bioequivalence studies for the registration of generic medicines. So, the general rule is gratuity in participation.

On the other hand, the Law of Access to Biodiversity (Brasil, 2015) discusses the access to the genetic heritage of Brazilian fauna and flora, the protection and access to related traditional knowledge, and the distribution of benefits for the conservation and sustainable use of biodiversity.

In article 17, it stablishes that the benefits resulting from the economic exploration of a finished product or reproductive material that comes from the access to the genetic heritage of species found in *in situ* conditions or connected to related traditional knowledge, even if it still produced outside Brazil, will be distributed equally and fairly, where in the case of a finished product, the component of the genetic heritage or the related traditional knowledge must be one of the main value-aggregating elements (Brasil, 2015).

These different public policies lead us to an interesting paradox: the profits gained by the commercial exploitation of products or procedures based on Brazilian biodiversity must be shared between researchers and Brazilian society; while the access to the population genome is free and its profits belong only to the inventors of the processes and/or products.

As it can be seen, the Law of Access to Biodiversity (Brasil, 2015) is very innovative and, besides that, cannot be considered an obstacle to scientific development, since the focus on the distribution is stablished only in the commercial exploitation of the inventions. Only when profit is obtained from a certain genetic resource the distribution is imposed.

Another innovative point in the matter is the INPI guideline (2015) for requesting patents using resources from Brazilian biodiversity. The requesting person must fill a form in, informing the origin of the genetic material and related knowledge, as well as the number of the authorization of access to biodiversity. This happens because the distribution of benefits is only required for the ones exploring the product economically. Thus, a person may request a bipotent and license for another one to perform the commercialization, which then will be responsible for executing the fair and equal distribution (Santos, 2015).

Observing this legislation's innovations and considering the future perspective of authorizing human gene patenting in the countries, it is possible to glimpse an alternative path for the free participation in genetic researches, which could have important consequences for the funding of public health and the construction of a sustainable public health system.

The same criteria used for distributing the profit resulting from Brazilian biodiversity can be adopted for the distribution of economic benefits in the case of the access to the genetic heritage of Brazilian populations. This way, the principle of equality will be covered, which stablishes that equal situations must be ruled by equivalent dispositions and unequal situations by different dispositions, in the proportion of its diversity, aiming for the equal distribution of costs and benefits.

If human beings are right subjects and if the Brazilian legal framework was formulated in order for human dignity to be materialized, it does not seem right for the legislation protecting the Brazilian genome biodiversity to be more comprehensive, inclusive and protective than the legislation ruling the participation and granting access to the Brazilian population genome.

Based on this example of Brazilian legislation, policymakers can have a guide that allows researchers to be rewarded by their work and effort, but that, at the same time, Brazilian society to be benefited by its own genetic resources. Thus, the concretization of the human dignity principle can be connected to the thoroughly affirmation of the principle of social function of the intellectual property.

Final remarks

Despite being known that the Brazilian legislation forbids patenting inventions based on human genes, there is a strong market pressure for that. Since this possibility may become real, it is much more efficient for the planning of public policies to reflect on which path the country will follow.

Although the participation of subjects in genetic researches follow, as a rule, the paradigm of gratuity, issues as the difficulty in finding resources for funding the public system, the concretization of that fundamental right, and the judicialization of conflicts in the health area create many questions on the pertinence of this regulation choice.

Given that, to discuss the possibility of distributing economic benefits resulting from biopatents is a matter of public health and of the construction of an universal and sustainable public health system. The various international examples given show that great discussion currently fought on how to equalize the right to intellectual property of researchers to social justice principles.

To plan Brazilian development and public health policies demands great attention to genetic researches with humans and how will they bring benefits for the society as a whole. The principles of

solidarity, sustainability, and human dignity must guide the responsible ones for the formulation of public policies and the consequent regulation on patenting and benefit distribution criteria.

In the current scenario of human being researches, numerous approaches with commercial ends are searched to guarantee benefits, but humanistic parameters must be imposed in these approaches. The possibility of commercial exploration must be thought and restricted from to reference points: the guarantee of the fundamental right to scientific research, and the recognition of the right for economic benefits on the inventions. Limitations to these rights will be imposed only when the clash with fundamental rights, judicial goods that are constitutionally guaranteed, or international judicial tools, including the declarations of rights.

It is important to also reflect that to adequate the system of patent protection to the criteria of human living matter, it is necessary to balance the requirements of the right to patents itself to the requirements of protection to human beings detailed in the judicial framework. In this sense, no international or foreign legislation could serve better as the marker for Brazilian policymakers as the Law of Access to Biodiversity (Brasil, 2015).

This regulation has found an important point of balance: it is only distributed the economic benefits of what is commercially exploited. Adopting this same parameter for the case of the access to the Brazilian population genome will not make genetic researches with human beings or the request of patents unfeasible, and scientific information will be able to circulate. Only when there are profits with the exploitation of patents based on genetic resources of the Brazilian population will the distribution be imposed.

Along with the analysis, there is the fact that most genetic resources are in developing countries, but that only developed countries have the technical knowledge and economic resources to exploit them. Besides, manufacturing the products is a business for companies in developed countries and distributing the benefits is not in their concerns (Muller; Macedo, 2013).

Lastly, we highlight that this text performs only an initial reflection on the issue of biopatents, distribution of economic benefits, genetic research and public health in Brazil. For that, it outlined a panorama of the main obstacles to the theme, posing questions and discussing possible paths and solutions.

However, it is still suitable, considering all the arguments presented and to think on new studies, to leave a final question: in a increasingly more technological society, in which billions of people are excluded from the possibility of accessing the human right to health, which will be the possible path for Brazil?

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Authors' contributions

Myszczuk designed the study and analyzed the data. Meirelles dealt with the theoretical bases. Both authors have contributed in writing the article.

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