ISSN 2175-6058
DOI: https://doi.org/10.18759/rdgf.v25i1.2539

THE VULNERABILITY OF DATA GENETICS HOLDERS IN THE BIOTECHNOLOGY REVOLUTION

A VULNERABILIDADE DOS TITULARES DE DADOS GENÉTICOS NA REVOLUÇÃO DA BIOTECNOLOGIA

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ABSTRACT

Technological advances in the genetic area arouse interest, as they make it possible to diagnose and eliminate genetic diseases at an increasingly earlier stage, even at an embryonic stage. However, the use of data obtained from testing may lead to discriminatory consequences. The purpose of this work is to analyze the degree of vulnerability of genetic data holders in the information society, in a context in which personal data are at the center of struggles for power. The increase in the economic value of information, combined with the ease of acquiring, maintaining and storing data, such as genetic data, makes a global debate on data protection, the potential for economic exploitation and the protection of its holders essential.

Keywords: Genetic data. Biotechnological revolution. Information society.

RESUMO

Os avanços tecnológicos na área genética despertam interesse, pois permitem diagnosticar e eliminar doenças genéticas numa fase cada vez mais precoce, mesmo em fase embrionária. No entanto, o uso dos dados obtidos nos testes

pode levar a consequências discriminatórias. O propósito desse trabalho é analisar o grau de vulnerabilidade dos titulares de dados genéticos na sociedade da informação, num contexto em que os dados pessoais estão no centro das lutas pelo poder. O aumento do valor econômico da informação, aliado à facilidade de aquisição, manutenção e armazenamento de dados, como os genéticos, torna essencial um debate global sobre a proteção dos dados, o potencial de exploração econômica e a proteção dos seus titulares.

Palavras-chave: Dados genéticos. Revolução biotecnológica. Sociedade da informação.

1 THE RISING OF GENETIC DATA

Biotechnology is currently seen as the great milestone at the turn of the century; and its innovations, divided in different areas are capable of changing dramatically the way humans live and the future of humanity. That's where the importance of contextualizing the advances and having criticals thoughts about the future comes from.

With constant technological advances and consequent increasingly ambitious and innovative possibilities in the sense of making definitive changes in the nature of the human species, there is a growing need for decision-making that limits inconsequential impulses, while not rejecting the benefits generated. by new technologies.

Simultaneously, the increasingly important role that information has been playing is observed, with the emergence of terms that describe the current stage of technology in society as "the information era" which takes it to a level of today's central economic good.

In that sense, the development of information technology, on the one hand, aggravated the situation, by enabling the mass sharing of personal data that began to generate great economic interest while exposing their holders to various consequences in case of inadequate treatment.

On the other hand, the development brings the ability of improving the population's quality of life, in general, by creating techniques and health treatments that are gradually more modern and efficient. In the field of biotechnology, specifically, there is a need to establish a balance between the benefits generated by biotechnological evolution and the

potential harm linked to the commodification of human biological material, discrimination and threat to the future of the next generations.

Genetic tests, which are becoming more and more sophisticated and accurate, are the object of interest of large laboratories that quickly dominate them, starting to offer them predominantly to the population with greater economic power. Concomitantly, genetic engineering is on the rise, conquering space in scientific research, since biotechnologies have made genomic editing feasible.

Thus, it is essential for the growing innovations to be subject of extensive studies and multidisciplinary discussions so that the decisions to be taken in the near future consider the risks arising from the use of the technique in its diverse degrees, as well as ways to make them accessible.

Technological advances in the genetic area arouse interest in the population as it makes it possible to diagnose and eliminate genetic diseases at an increasingly early stage, even in an embryonic stage. However, the protection of data obtained through tests is also increasingly sought, and can lead to discriminatory consequences.

From the development of techniques that made genetic editing possible, and mainly, after the first genetically modified babies were born in China, the subject has become viral not only in the scientific community, but also in the social media.

The research proves to be necessary, based on the importance of the theme, given its notability in the present as well as in the future that is built from innovations, considering the transcendental matter of the advances in biotechnology in the current computerized society by different aspects.

Thus, an attempt is made to analyze the extent of vulnerability of holders of genetic data in the information society, in a context in which personal data are at the center of power struggles. In search of getting answers as to how to regulate the economic exploitation of genetic data without exposing vulnerability and guaranteeing respect for the fundamental rights of their holders.

Hence, the goal is to analyze the extent of vulnerability of genetic data holders in the information society, in a context in which personal data are at the center of power struggles. In search of getting answers

as to how to regulate the economic exploitation of genetic data without exposing vulnerability and guaranteeing respect for the fundamental rights of their holders.

2 LEGAL GENETIC DATA PROTECTION

The legal protection of genetic data is regulated, in Brazil, by International Declarations and Resolutions from the National Health Council for decades. Recently, Brazil has approved the General Law of Data Protection, which regulates the subject more specifically and provides legality to norms previously existing in the resolutions.

Some international statements guarantee that patients submitted to genetic tests have the right to know or not to know the results. It is the case of the International Declaration on Human Genetic Data, of 2003, which, taking into account the genetic revolution and the growing importance of genetic data in the economic and commercial domain, declares at the first article " (a) [...] guarantee respect for human dignity and the protection of human rights and fundamental freedoms in the collection, processing, use and conservation of human genetic data" (Unesco, 2003, p. 4).

Thus, it defines human genetic data as "Art. 2nd (i) information relating to the hereditary characteristics of individuals, obtained by analysis of nucleic acids or by other scientific analyses" and conditions the collection, processing and use of consent, understood as: "Art. 2, (iii) any specific, express and informed agreement given freely by an individual for their genetic data to be collected, processed, used and preserved".

It also defines the purposes for which it authorizes the collection, treatment and use; considering, in all circumstances, health, medical and scientific research or purposes compatible with the precepts of the Declaration and Human Rights, carried out in a transparent and ethically acceptable way (Unesco, 2003, p. 6). The declaration allows the use of genetic data as evidence in court proceedings or in forensic medicine, however, it demands their destruction as soon as they become unnecessary.

The 1997 Universal Declaration on the Human Genome and Human Rights had already provided for the protection of genetic data by prohibiting

discrimination based on genetic characteristics; prohibiting research with data associated with identifiable individuals without due confidentiality; conditioning research on respect for human rights and fundamental freedoms; and requiring the benefits of advances to be made available to all (Unesco, 2001).

The Declaration describes the human genome by its evolutivity, since it mutates, and by its extra-commerciality, since financial transactions involving it are forbidden; it also classifies the genome - as the basis of the fundamental unity of the human species - as heritage of humanity (Unesco 2001).

When dealing with research, treatment and diagnosis involving human genetic code, the declaration adopts the principles of beneficence, linked to the idea that research must always aim to maximize benefits and minimize harms; and autonomy, which gives people the power to decide about their own lives and their own data. However, it waives the author's consent and confidentiality when there is public interest.

The Convention on Human Rights and Biomedicine, proposed by the Council of Europe in Oviedo in 1997, which entered into force in 1999 and regulates interventions in the health area in general, paying special attention to consent for interventions; prohibits discrimination based on genetic heritage and, among others, the selection of the sex of the baby in assisted human reproduction (Naves; Naves, 2008, p. 338).

There are also the Japanese Inuyama Declaration on genetic mapping, genetic experimentation and gene therapy of 1990, the Bilbao Declaration on the Right before the PGH of 1993 - intimacy as personal heritage and genetic data for discriminatory purposes (Naves; Naves, 2008, 338), the Charter of Fundamental Rights of the European Union of 2000 that deals with personal data, among others.

In Brazil, there are Resolutions and Guidelines proposed by the National Health Council (CNS) that deal with regulating scientific research since 1996 and constitute important regulatory mechanisms, although they lack legal force.

CNS Resolution No. 196 of 1996 approved a series of guidelines and regulatory standards for research involving human beings. This resolution already brings in its text the guarantee of confidentiality and privacy of

research participants. In addition to prohibiting the use of data obtained from participants for any purpose other than those provided for in the research protocol (CNS, 1996).

In 2004, the CNS published Resolution No. 340 as a complement to Resolution No. 196/96, due to technical and scientific advances that made the previous resolution insufficient to regulate research conducted with human beings (CNS, 2004).

The Resolution shows concern on the stigmatization and discrimination of individuals, thus giving them the right to access the data obtained through research, as well as the prerogative to block their storage and use at any time (Bernasiuk, 2021).

Still, the document reiterates the purposes to which research in genetics should be directed: scientific knowledge capable and with the purpose of alleviating suffering and improving human health (CNS, 2004).

A new Resolution, No. 466/2011, has once again complemented Resolution No. 196/96, specifically regarding the storage and use of biological material for research purposes. Thus, it conceptualizes the means of storage, namely, biobanks and biorrepository, as well as human biological material and research involving human beings (CNS, 2011).

At the legal level, the Biosafety Law (No. 11.105/05) already adressed stem cell research, transgenic foods and in vitro embryos, and proposed ethical limits for research, but was not specific about the human genome and genetic data, which generated a gap in Brazilian legislation (Cardoso, 2018).

Although the approval of a data protection law in Brazil has been discussed since the 2000s (Bernasiuk, 2021), it was only published in August 2018. The General Data Protection Law (LGPD, No. 13.709), which came into force in 2020 and has the scope of protecting personal and sensitive data. This has become a milestone in the Brazilian legal system in advancing the protection of personal data, including genetic data.

The law regulates the processing of personal data, "including in digital media, by a natural person or by a legal entity under public or private law, with the aim of protecting the fundamental rights of freedom and privacy and the free development of the personality of the natural person

[1]" (Brasil, 2018). Taking as a basis, among others, "IV - the inviolability of intimacy, honor and image[2]"; and, "VII - human rights, the free development of personality, dignity and the exercise of citizenship by natural persons[3]" (Brasil, 2018).

The validity of the LGPD has as its cornerstone, the consent, which is essential for the concretization of the holders' autonomy and dignity (Sarlet, 2017). The law allows a uniform regulation of research, as well as gives legal certainty to data holders (Fornasier; Knebel, 2021, p. 1018).

The patenting of genes, on the other hand, is undeniably prohibited in Brazil under the Industrial Property Law, which provides, the disregard of any part of living beings or biological material as an invention, in addition to the explicit non-patentability of living beings in whole or in part.

The Brazilian prohibition on patenting the isolation and sequencing of genes goes against an international trend of granting this type of patent. In an attempt to bring Brazil into line with this trend, Deputy Antonio Carlos Mendes Thame proposed Bill 4.961 in 2005 to amend Articles 10 and 18 of the Industrial Property Law (Freitas, 2015).

It is easy to note that the inspiration of the proposed bill is Directive 98/44/EC of the European Union, which classifies as a patentable invention isolated element of the human body, when produced by means of a technical process, including, expressly, gene sequencing (European Parliament and Council, 1998).

In the meantime, before the entry into force of the General Data Protection Law in Brazil, in 2020, the Civil Code already granted the protection of private life, the Consumer Protection Code (CDC) promoted regulation of databases, the Penal Code (CP) protected the right to secrecy, and, therefore, through the right to intimacy, personal data were already under protection (Colussi; Santos, 2018).

However, the development of biotechnological advances combined with new communication tools, demanded specific protection with regard to the already established fundamental right to the protection of personal data. Thus, strongly influenced by European legislation, in 2018 Brazil approved the LGPD.

2.1 COMMENTS REGARDING THE PROTECTION OF PERSONAL DATA UNDER THE GENERAL DATA PROTECTION REGULATION (GDPR)

In 2016 the European Union published the General Data Protection Regulation (GDPR), which replaced a 1995 regulation and entered into force in May 2018. The GDPR has come to be seen as the most advanced regulation in the world in the treatment of personal data and protection of its holders (Ferreira; Silva, 2020).

The regulation provides guidelines for European or foreign companies offering services to residents of European Union countries, including Brazilian companies operating in EU countries (Derbli, 2019).

It is valid in all European Union Member States, but grants each one the autonomy to interpret the regulation, and to create its own national legislation according to the specific local needs (Paulo, 2021).

Among the considerations cited in the regulation that are part of the basis for its creation, are globalization and technological developments, which have resulted in the use of personal data on an unprecedented scale by private companies and public entities (European Parliament and Council, 2016).

Data protection has come to require greater attention and stricter enforcement. Thus, "(7) [...] legal certainty and practical certainty for individuals, economic operators and public authorities should be enhanced[4]" (European Parliament and Council, 2016).

Through the GDPR, the EU seeks to respect the freedom of companies, with the aim of strengthening the economic market, while encouraging research and ensuring the protection of data subjects (Paulo, 2021).

In recognition of the damage, whether social, physical or economic, that the leakage of personal data can cause to data subjects, the GDPR provides for a 72-hour deadline for notification of a breach in data processing by the data controller to the supervisory body and data subjects, with the exception of proof of the absence of risks to individual rights and freedoms (European Parliament and Council, 2016).

However, the protection of personal data, conceptualized as information relating to an identified or identifiable person, "directly

or indirectly, especially with regard to geographical location, online identification, as well as physical, psychological, genetic, economic, cultural or social data of the individual" (Colussi; Santos, 2018, p. 16), is not absolute.

The GDPR regulates the "collection, storage and use of information that identifies or enables the identification of European individuals, such as [...] elements specific to the physical, physiological, genetic, mental, economic, cultural or social identity of the natural person" (Derbli, 2019, p. 183). It determines that any clash between fundamental rights must be guided by the principle of proportionality (European Parliament and Council, 2016).

It also stipulates that personal data must be processed in accordance with the principles of lawfulness, fairness and transparency. For it to be lawful, it must follow the provisions of Article 6(a) to (f); loyalty relates to a sense of fairness and transparency to clear and honest action with regard to information, communication and rules (European Parliament and Council, 2016).

European Union legislation has been emphatic in protecting sensitive data, considering that by their nature the processing is capable of entailing significant risks to fundamental rights and freedoms. As such, it linked the consent of data subjects to five requirements: in addition to being express, consent must be free, explicit, unequivocal, informed and specific.

Although it establishes a strict regime for the processing of sensitive personal data, it includes exceptions to the prohibition according to ten circumstances, "ranging from the protection of the vital interests of the individual to reasons of substantial public interest, without, however, exemplifying or specifying what these hypotheses would be concretely considered." (Mulholland, 2018, p. 167).

The GDPR ensures the right of data subjects to have information relating to their genetic data protected, prohibiting the sharing of personal data by companies without their consent (Bernasiuk, 2021).

This shows that the regulation is concerned with ethical aspects when it comes to the lawfulness of data processing in research, while also encourages development by providing for data sharing in scientific research (Chassang, 2017).

2.2 COMMENTS REGARDING THE PROTECTION OF PERSONAL DATA UNDER THE BRAZILIAN GENERAL LAW OF DATA PROTECTION (LGPD)

The entry into force of the Brazilian General Data Protection Law is a milestone in national legislation, as it is the first to address in detail the processing of sensitive data for research purposes.

The data leakage and espionage scandals, which even targeted the then Brazilian President Dilma Rousseff, highlighted the data protection gap in national laws and brought the right to personality and the principle of privacy to the forefront (Paulo, 2021).

In addition, the international scenario, especially with the entry into effect of the European Union's Regulations on Data Protection, ends up putting pressure on other countries to also adopt regulations, at the risk of becoming the target of economic barriers due to difficulties in negotiations (Pinheiros, 2021).

The LGPD sets out the principles that should serve as the basis for the processing of personal data, regulates the protection of data, including sensitive and children's data, authorizes its processing by the Government for public policy purposes and provides for sanctions in cases of violation (Brasil, 2018).

It considers as processing various operations carried out with data, such as "collection, production, reception, classification, use, access, reproduction, transmission, distribution, processing, archiving, storage, elimination, evaluation, control, modification, communication, transmission, dissemination or extraction" (Pinheiro, 2021, p. 76).

It also provides rules for the international transfer of personal data to be considered legal, in the sections of article 33[5], in a precept inspired by the GDPR, with the aim of minimizing the risks of data subjects (Paulo, 2021).

According to the law, sensitive data is included among those "concerning genetic or biometric data, racial or ethnic origin and information on religion or party affiliation" (Colussi; Santos, 2018, p. 15), which expose the holder to discrimination.

The condition of data subject provided for in item V of article 5, as: "natural person to whom the personal data being processed refer" is attributed to the person able to provide the information contained in the genetic data, by means of "a free, informed and unequivocal manifestation in which the data subject agrees to the processing of their personal data for a specific purpose", according to item XII of the same article (Brasil, 2018).

The aim of the legislation is to find balancing mechanisms so that data subjects are not exposed in terms of their individual rights, rather than to condemn the use of personal data by private companies. As Pinheiro states, "the guideline is the guarantee of freedom, but the basis is transparency" (2021, p. 82)

The law stipulates that, within the framework of consent, the data holder must receive information from the controller about what is happening with his or her data, and also provides for specific cases where data processing can take place without the consent of the holder, such as for research purposes. In this case, the law recommends anonymizing the data so that the identity of the data subject cannot be identified (Cardoso, 2018).

However, it is considered that genetic data can hardly be anonymized, so the protection granted in the law, in relation to genetic data, has limited effectiveness in terms of guaranteeing privacy (Cardoso, 2018). Once anonymized, the data is not considered personal and is no longer protected by law (Pinheiro, 2021).

Under the LGPD, in 2018, the National Data Protection Authority (ANPD) was created by Provisional Measure No. 869, a body linked to the Federal Public Administration, endowed exclusively with technical autonomy, and therefore without normative, adjudicatory or supervisory autonomy (Derbli, 2019). Among the ANPD's duties is the promotion of actions that encourage cooperation between international authorities and other countries regarding the protection of personal data (Paulo, 2021).

The LGPD has economic, social and political effects as it seeks control mechanisms in a context of digital business without borders. It is also a response to the challenges that technology imposes on society, and should be followed by improvements and the creation of other laws to meet the new demands caused by the great impact of advances in technology.

3 STUDY CASES OF GENETIC DATA PROTECTION

The patenting of genetic data, as explored throughout this paper, generates controversy as it confronts different individual, collective, political, social and economic rights and interests. For the US patent office, USPTO:

> When patents for genes are treated the same as for other chemicals, progress is promoted because the original inventor has the possibility to recoup research costs, because others are motivated to invent around the original patent, and because a new chemical is made available as a basis for future research (USPTO 2001, p. 1094).

The United States occupies a prominent position among the countries that have chosen to allow the patenting of human gene isolation and sequencing and has a notable number of patents on human genes, which has led to some controversial cases regarding legal protection.

In order to deepen the discussion on the protection of genetic data, two cases have been selected to illustrate the vulnerability of data holders: the first, involving US researchers, with implications in several countries, concerns intellectual property and aims to emphasize the importance of finding a balance between the right to economic research and the right to health; the second presents a more human perspective, as it relates to the right to free affirmative self-determination and cultural respect.

The American case, in turn, is so relevant that it has generated discussions about the ethics of patenting human gene sequences all over the world, so one can't discuss gene patenting without mentioning it. The Brazilian case, on the other hand, had global repercussions and sparked discussion about ethics in research with human beings, as well as the right to the human genome and the genome.

3.1 THE MYRIAD GENETICS CASE IN THE UNITED STATES AND THE EUROPEAN UNION

An important case, as notable as it was controversial, which drew attention to the way genetic data was protected in various countries around the world, is the case of the American company Myriad Genetics, the American company that applied for patents in several countries in order to obtain a monopoly on tests involving the BRCA1 and BRCA2 genes.

In 1991, the company began as a small start-up at the University of Utah, interested in developing genetic diagnostic tests (Sherkow; Scott, 2014). Three years later, in 1994, the researchers managed to sequence the human gene BRCA1 and BRCA2 and published the results in the journal Science in an article called "A Strong candidate for the breast and ovarian cancer susceptibility gene BRCA1" (Joly; Tonin, 2014).

Thus, once the location and sequencing of the gene, which acts to suppress tumors, was known, it was possible to develop predictive tests that detected mutations in the regulation of cell division, which helps in the early identification of breast and ovarian cancer risk (Santos *et al*., 2016).

Depending on the population tested, 10 to 20% of breast and ovarian cancer cases occur in carriers of genes that have mutations, among which the chance of developing breast cancer is up to 80%, compared to 10% risk in women who do not have mutations; while the chance of developing ovarian cancer is up to 60%, compared to 1% in women who do not carry mutations (Joly; Tonin, 2014).

Therefore, the discovery of the genes and the development of tests to identify mutations was highly promising in terms of identifying the possible development of breast or ovarian cancer at an early stage (Joly; Tonin, 2014).

As a result, the Company filed a patent application with the USPTO for the sequencing and isolation of the BRCA1 and BRCA2 genes and for the methods used to carry out the tests developed. The application was granted in 1998, giving Myriad exclusive commercial rights to exploit predictive genetic tests to detect mutations in the genes (Morais *et al*., 2018).

In addition, it managed to obtain 19 patents for the discovery of the location of the genes, between the United States, Canada, Australia,

Japan, the United Kingdom and France, so that any genetic tests capable of detecting mutations in the BRCA1 and BRCA2 genes were covered by the company's patent[6]; which, in addition to hindering research, imposed economic limitations[7] on patients (Santos *et al*., 2016).

The granting of the patents, coupled with the way in which the company decided to carry out the economic exploitation of human genes and the control policy adopted by them, preventing other researchers from carrying out research or genetic tests predictive of breast and ovarian cancer, raised criticism as to the legal validity of the patents, equitable access to testing and the ethics of the economic exploitation of human genes (Morais *et al*., 2018).

Thus, in 2009, the American Civil Liberties Union (ACLU) and the Public Patent Foundation (PPF) filed for the invalidation of the patents on the grounds that genes are a product of nature and that the isolated gene does not differ from that contained in the body, arguing that, in order to be patentable, the gene should be manipulated (Santos *et al*., 2016).

The judge granted the plaintiffs' motion and invalidated the patents at first instance. The company appealed and succeeded in overturning part of the decision (Morais *et al*., 2018). However, on further appeal, the US Supreme Court invalidated Myriad's patents in 2012 (Sherkow; Scott, 2014).

The ruling was that the company had not created or modified the information contained in the BRCA1 and BRCA2 genes, nor had it created or altered the genetic structure of the genes (Santos *et al*., 2016), so the genes did not constitute patentable subject matter.

After years of controversy over whether or not isolated genes could be patented, in 2013 the US Supreme Court extended its decision and declared that isolated DNA segments could not be patented, on the grounds that DNA segments existing in nature did not meet the requirements of novelty and usefulness (Morais *et al*., 2018).

The U.S. Supreme Court held, based on an analysis of the case, that discoveries of nature could not be patented, thus requiring that the product being patented: was not identical to a pre-existing one derived from a new source, as it would no longer meet the criterion of novelty; was not just extracted without changes being made to it, as it would not meet the criterion of the necessary structural alteration; and, the

substance, isolated, should be demonstrably more useful than its natural form (Dias; Cerda, 2017).

The decision on patents for the sequencing of the BRCA1 and BRCA2 genes went against the US majority position, which had a considerably more liberal precedent. The definition of the invention requirement remains undefined, but it has been made clear that, despite the uncertainty as to whether the requirements will be rigid or flexible in future decisions, isolated genetic sequences do not constitute inventions (Lai, 2015).

In the European Union, in 1998, Parliament approved the Biotech Directive, after 15 years of debate on how biotechnology patents should be dealt with. Article 5 of Directive 98/44/EC deals with the legal protection of biotechnological inventions and the granting of patents for human biological materials:

> 1. The human body, at the various stages of its constitution and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, may not constitute patentable inventions.
>
> 2. Any element isolated from the human body or otherwise produced by a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.
>
> 3. The industrial application of a sequence or partial sequence of a gene must be specifically set out in the patent application.

Thus, despite allowing the patenting of isolated elements of the human body, including gene sequences, it is necessary to clearly demonstrate in the application that it exists and what the technical effect of the discovery is, i.e. even if it is present in nature, the industrial application, in this case of the gene sequence, must be demonstrated for it to be considered patentable (Lai, 2015).

The issue addressed by the directive is complemented by the European Patent Convention (EPC), which provides for the creation of the European Patent Office (EPO), responsible for granting patents in EPC member states. The body even has decision-making powers, bringing together a Board of Opposition and a Board of Appeal. The rights granted, however, are subject to the legislative adequacy of each country (Cacciammi, 2018).

The office is responsible for granting patents through a single procedure for all member states, though it does not grant a unitary European patent, but a patent with national patent effect in the member states selected by the applicant (Lai, 2015).

European legislation deals with patents in the biotechnology area in a more flexible way, by expressly allowing the patenting of gene sequences. The decision is justified by the claim that patenting would result in improvements in public health. However, the case of the company Myriad demonstrated the opposite link between public health and innovations (Cassier, 2004).

The EPO ruled on patents for the BRCA1 and BRCA2 genes for the company Myriad, on which occasion it demonstrated an interpretation contrary to that of the CJEU, which stated that it was not possible to patent isolated genetic sequences, except in relation to their function in a specific invention.

After the EPO granted the patents to the American company Myriad, three French medical institutions (Curie Institute, Gustave Roussy Institute and the Assistance Publique Hôpitaux de Paris) and a European Consortium of eleven societies for Human Genetics asked for the patents to be revoked in order to prevent restrictions on their medical practices and a monopoly on predictive tests (Cassier, 2004).

This is because, while the gene sequencing dates back to 1994 and 1995, patents were granted in Europe in 2001 and 2002, allowing laboratories to develop and offer predictive genetic tests to patients while sequencing was not legally protected. By granting the patents, the American company aimed to centralize the production of genetic tests, which would drastically reduce the activity and autonomy of European laboratories (Cassier, 2004).

In addition, by preventing the production of tests by any other companies or laboratories that used the BRCA1 and BRCA2 genes, European laboratories, which for years had sophisticated their own tests (three times cheaper than the patented method) would have to charge their patients more for the same services already offered, restricting access to tests (Cassier, 2004).

Furthermore, there were concerns about the privacy of patient data, which would be analyzed on the other side of the world to obtain the test results; not to mention the likely unnecessary and costly delays resulting from centralization (Joly; Tonin, 2014).

Following the aforementioned arguments, and without modifying the legislation that allows the patenting of genetic sequences in Europe, the patents were revoked or modified, so that European laboratories could continue their activities following their own methods and without the payment of royalties.

3.2 YANOMAMI BLOOD

The case of the Yanomami blood collected and taken to the United States for storage and research was a leading case in the process of recognizing both the individual right to genetic identity and the diffuse right to the genetic heritage of humanity. It allowed the Indians' demand for the return of ancestral blood to be conceived as a claim for both (i) the right to the genome exercised collectively by the Yanomami people and (ii) the diffuse right, relating to the interest of Humanity in general, for the genetic material to be returned, given the specific intangible value it had for the indigenous community, not a scientific interest, but a symbolic one (Xavier; Campello, 2017, p. 168,169).

Between northern Brazil and southern Venezuela, in a territory of more than 9.5 million hectares, live the Yanomami indigenous people, who are considered to be one of the most isolated peoples in the world (Xavier; Campello, 2017). It was only in the 1950s that the first contact between the Yanomami and non-indigenous people was recorded, and from the 1960s onwards the region attracted religious missionaries, researchers and anthropologists (Diniz, 2007).

Between the 1960s and 1970s, anthropologist Napoleon Chagnon and geneticist James Neel traveled to indigenous lands and collected at least 12,000 samples, including blood, urine, feces and saliva, from around 3,000 indigenous people (AAADOCFUL, 2004).

Among the reasons for collecting the samples were "for future genetic research; to test a new measles vaccine protocol; to include the Yanomami as a control group for research into the after-effects of radioactive exposure in Japanese populations after World War II" (Diniz, 2007, p. 287), as well as speculation that the research was intended to check whether there was direct descent between the Yanomami and the first people to cross the Bering Strait (BBC NEWS, 2015). And finally:

> Neel and Chagnon were part of a team of researchers whose main objective was to investigate the genetic basis for violence and its relationship with reproductive practices. The Yanomami became the ideal population for this type of research for a number of reasons: a) because they were described as a violent and savage people; b) because of the profound isolation in which they lived, which guaranteed the genetic homogeneity of the population; c) this was a time when the debate on research ethics was still in its infancy, and ethical protocols for the conduct of research were rare[8] (Diniz, 2007, p. 285).

The samples were labeled Archival Anthropological Samples and were subjected to modern techniques in laboratories, for the extraction and reproduction of DNA fragments, which were later used in various research studies (Xavier; Campello, 2017, p. 165), as well as being stored in laboratories at different North American universities, including those dedicated to the Human Genome Project (Diniz, 2007).

The case gained repercussions after the publication, in 2000, of the book *Darkness in El Dorado: how scientists and journalists devastated the Amazon* by Patrick Tierney, because it was only through the book that the Yanomami learned that their blood samples were stored "in refrigerators in the United States", as described in a letter from Davi Kopenawa to the Attorney General's Office in 2002, asking for the return of the blood vials (Xavier, Campello, 2017).

According to Yanomami cultural tradition, after death, all traces of the person must be eliminated. According to Kopenawa, the dead must be mourned, the body burned and everything that was used or planted destroyed. Thus, the fact that the samples are largely from people who have already died makes their storage even more outrageous for Yanomami cultural values (Diniz, 2007).

There is therefore a clash between informational self-determination, the right to genetic heritage and a collective interest in research with the samples, considered by the researchers to be of great value to the Human Genome Project:

> [...] the importance of informed consent and its challenges in vulnerable populations; the boundary between research and biomedical treatment; post-research ethical obligations in biomedical sciences and human sciences and the use of secret, private and confidential information. In this sense, the case of Yanomami blood can be considered a paradigmatic example of the controversy surrounding ethics in research with human beings in various areas of knowledge[9] (Diniz, 2007, p. 295).

In April 2015, an extrajudicial agreement was signed between the University of Pennsylvania and the Brazilian Federal Prosecutor's Office, through which 2,693 vials of Yanomami blood were repatriated (Xavier, Campello, 2017). After the return, there was a large ceremony in which the samples were buried in Yanomami territory (Kátia Brasil, 2015).

This shows the growing importance of defending fundamental rights related to the protection of personal and sensitive data, in the face of the growing possibility of this data being exploited in different sectors and for different purposes, exposing its holders to vulnerability and discrimination.

International declarations and internal directives, as well as judgments made domestically and by international courts, especially with regard to complex cases that generate great debate among scientists, jurists and society as a whole, have the power to influence future decisions, also influencing the course of application of existing innovations, as well as the new paths to be followed with innovations to come in the short, medium and long term.

Thus, the growth in the economic value of information, coupled with the ease with which increasingly complex data, such as genetic data, can be obtained, maintained and stored, makes a global debate on how data should be protected, the possibilities for economic exploitation and the protection of data subjects essential and urgent.

4 CONSIDERAÇÕES FINAIS E PERSPECTIVES ON THE RISING OF GENETIC DATA'S IMPORTANCE AND ECONOMIC VALUE

The biotechnological revolution, techno scientific evolution and the new parameters of the right to information were crucial factors for a series of changes observed in society's way of life in the last few years.

The research on biotechnology raises new controversies in each and every finding, as a reflex, the world and international legislations are divided based on chosen parameters, whether in a predominantly materialist or humanist trend.

In that context, as innovations allow for more radical changes in the very essence of human beings and modify ways of life, more responsibility is needed to regulate research and the application of new techniques, so that the ethics of the past had to be transformed in a modern ethic to encircle all the new elements that it started to achieve.

The development of research and new technologies made nature itself more vulnerable to the actions of men, thus, rethink ethics as a limit to actions that could compromise the future of new generations, as to how they would relate to their own genetic characteristics and the environment, become inevitable.

Furthermore, IT development has led to the storage and sharing of data to a new level, in a way that has enabled the creation of massive databases, whether personal or sensitive. Opening up a promising path for the commercialization of data.

The understanding of human beings' biology has changed since it became possible to collect and store biologic data. The digital information of biologic data follows the explosive growth of the importance of information in today's society.

Among the aspects of intellectual property, such as copyright, industrial property and sui generis protection, industrial property includes patents, which constitute an agreement between society and the State, in which the protection grants privileges to the creator and constitutes a source of information for society (Boff; Pereira, 2018).

In this context, the granting of patents in the biotechnology field is a subject of great discussions, which raise questions with no correct answer, the responses are yet to be determined, so each country adapts to the way believed to be more advantageous, whether from an individual, collective, economic or humanitarian perspective.

The limit between law, research, development, the creation of new techniques and respect for ethics and morals should be based on the fundamental right to human dignity, which serves as the foundation for all fundamental rights, but here, specifically, the right to genetic intimacy, privacy and free informational self-determination.

In other words, biotechnological and information techonology development must respect privacy and genetic intimacy, so that the data holders aren't exposed to genetic discrimination; not to make changes in the genetic inheritance of the next generations, once the consequences are unknown; not to collect, store or make any kind of data control without the agreement of the holder, who must be informed about all the processes to be carried out.

Following from that, the importance of existing legislation is highlighted, as it provides protection, although not absolute, to data holders, guaranteeing consent for collection, research or any intended use of data, as well as against leaks that could expose holder's vulnerabilities.

The use of human genetic data for economic purposes, whether as genetic ancestry tests; diagnostic tests for prevention or therapy; or through patents, must be analyzed, regulated and carried out with special caution, since sensitive and genetic data are at stake and any mismanagement is capable of hurting the most intimate sphere of their holders.

Therefore, it's imperative to analyze the understanding of national and international courts that have judged specific cases in different countries, as well as the different legislations at the international level regarding the protection of personal and genetic data, as well as the possibility of obtaining profit by through human genetic data.

The isolation of the BRCA1 and BRCA2 genes made it possible to create tests for the early diagnosis of ovarian and breast cancer. Patents involving the tests were requested and granted, but they became a

monopoly of the Myriad company, which, due to the high costs of each test, became an impediment for several people to perform them.

The case raised some issues, which were only resolved, in the US, by the Supreme Court, in 2013, when the judges decided not to allow the patent requested by Myriad. However, the same company had already been granted patents, which had been economically exploited since 1998.

While some people advocated that gene sequencing should belong to each patient, others proposed that it should be considered a global public good, and therefore should not be used for economic purposes.

The courts, in general, tend to agree to guarantee the protection of data and the privacy of their holders above the economic aspect. But they ensure the non-absolute character of the fundamental right to data protection, which must be relativized, in specific circumstances, in the name, for example, of public utility.

Myriad Genetics' case has demonstrated greater flexibility in terms of the patentability of technologies related to the human gene within the European Union than in the United States.

Even further, it has been demonstrated that the broader the scope of the patent, the greater the possibility of a monopoly. Which, in the opposite direction of the justification for granting patents, generates public health problems by restricting access to innovations and hindering the development of new techniques.

Another important example is the creation of genetic databases, with different purposes, such as research, criminal investigation and use by fertilization agencies to generate new lives, often through the objectification of the human being, which becomes part of a kind of menu in which parents choose specific characteristics of the biological father.

The creation of each databank and the choice of its purposes give rise to different discussions and confront different rights that require careful consideration in order to ensure that the continuity of data processing takes place in the most balanced manner possible, with respect for fundamental rights at all times.

Thus, it's possible to see the growing importance of defending the fundamental rights related to the protection of personal and sensitive data, in view of the growing possibility of exploiting these data in different

sectors and for different purposes, placing their holders in a situation of vulnerability and discrimination.

International declarations and internal directives, as well as judgments made internally and by international courts, especially in complex cases that provoke great debates among scientists, jurists and society as a whole, have the power to influence future decisions and also the course of application of existing innovations, as well as the new paths to be followed with the innovations that will come in the short, medium and long term.

The increase in the economic value of information, combined with the ease of acquiring, maintaining and storing increasingly complex data, such as genetic, makes a global debate about the protection of data, the potential for economic exploitation and the protection of its owners, essential and urgent.

NOTAS

1 Original: Art. 1º. [...] inclusive nos meios digitais, por pessoa natural ou por pessoa jurídica de direito público ou privado, com o objetivo de proteger os direitos fundamentais de liberdade e de privacidade e o livre desenvolvimento da personalidade da pessoa natural. (BRASIL, 2018).

2 Original: Art. 1º. IV - a inviolabilidade da intimidade, da honra e da imagem. (BRASIL, 2018).

3 Original: Art. 1º. VII - os direitos humanos, o livre desenvolvimento da personalidade, a dignidade e o exercício da cidadania pelas pessoas naturais. (BRASIL, 2018).

4 Original: "(7) [...] deverá ser reforçada a segurança jurídica e a segurança prática para as pessoas singulares, os operadores econômicos e as autoridades públicas" (PARLAMENTO EUROPEU E DO CONSELHO, 2016).

5 Art. 33. A transferência internacional de dados pessoais somente é permitida nos seguintes casos:
I - para países ou organismos internacionais que proporcionem grau de proteção de dados pessoais adequado ao previsto nesta Lei;
II - quando o controlador oferecer e comprovar garantias de cumprimento dos princípios, dos direitos do titular e do regime de proteção de dados previstos nesta Lei, na forma de:
a) cláusulas contratuais específicas para determinada transferência;
b) cláusulas-padrão contratuais;
c) normas corporativas globais;
d) selos, certificados e códigos de conduta regularmente emitidos;
III - quando a transferência for necessária para a cooperação jurídica internacional entre órgãos públicos de inteligência, de investigação e de persecução, de acordo com os instrumentos de direito internacional;
IV - quando a transferência for necessária para a proteção da vida ou da incolumidade física do titular ou de terceiro;
V - quando a autoridade nacional autorizar a transferência;
VI - quando a transferência resultar em compromisso assumido em acordo de cooperação internacional;
VII - quando a transferência for necessária para a execução de política pública ou atribuição legal do serviço público, sendo dada publicidade nos termos do inciso I do caput do art. 23 desta Lei;

VIII - quando o titular tiver fornecido o seu consentimento específico e em destaque para a transferência, com informação prévia sobre o caráter internacional da operação, distinguindo claramente esta de outras finalidades; ou
IX - quando necessário para atender as hipóteses previstas nos incisos II, V e VI do art. 7º desta Lei. (BRASIL, 2018).

6 The patents were broad and interlocking, covering BRCA genomic DNA, cDNA, methods of diagnosis and systems detecting mutations. Myriad also filed for diagnostic 'toolbox' patents, including two claiming any DNA primer or probe sharing 15 nucleotides with the wild-type BRCA1 or BRCA2 it first sequenced. (SHERKOW; SCOTT, 2014, p. 620).

7 It charged as much as $4,000 for its flagship test BRCAnalysis—not uniformly covered by health insurers—where similar, unpatented tests cost as little as $100. (SHERKOW; SCOTT, 2014, p. 620).

8 Original: Neel e Chagnon compunham uma equipe de pesquisadores cujo principal objetivo de pesquisa era investigar as bases genéticas para a violência e sua relação com as práticas reprodutivas. Os yanomamis transformaram-se na população ideal para esse tipo de pesquisa por algumas razões: a) porque eram descritos como povo violento e selvagem; b) pelo profundo isolamento em que viviam, o que garantia uma homogeneidade genética da população; c) esse era um momento em que o debate sobre a ética na pesquisa era ainda incipiente, sendo raros os protocolos éticos de conduta da pesquisa (DINIZ, 2007, p. 285).

9 [...] a importância do consentimento livre e esclarecido e seus desafios em populações vulneráveis; a fronteira entre pesquisa e tratamento biomédico; as obrigações éticas pós-pesquisa em ciências biomédicas e ciências humanas e o uso de informações secretas, privadas e confidenciais. Nesse sentido, o caso do sangue yanomami pode ser considerado exemplo paradigmático da controvérsia que envolve a ética em pesquisa com seres humanos nas diversas áreas do conhecimento. (DINIZ, 2007, p. 295).

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Recebido em: 4 – 12 - 2024
Aprovado em: 18 – 12 - 2024

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