



BIODIVERSITY, GENETIC HERITAGE AND BIOTECHNOLOGY: Legal aspects for scientific development.

Correspondence Authors :

Luana Aparecida Ribeiro. UNA University Center Campus Bom Despacho.

Email: luana457@hotmail.com.

Luciene de Fátima Ribeiro. Centro Universitário UNA Campus Bom Despacho.

Email: fatimaluc_ribeiro@hotmail.com

Eduardo José Azevedo Corrêa. Empresa de Pesquisa Agropecuária de Minas Gerais (EPAMIG)

Email: eduardo@epamig.br

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ABSTRACT

Brazil is one of the 17 megadiverse countries on the planet. It is estimated that the number of known species is between 170 and 210 thousand known species, which corresponds to around 10% of all species already studied by mankind. Such biodiversity is not only of great value because it exists, but also represents a source of possible biopharmaceuticals that moves a millionaire market that, in 2006 alone, generated trillions in exports of medicinal plants in natura. In this sense, Law 13.123 / 2015 instituted strict rules for bioprospecting and studies of new biopharmaceuticals from all the national biodiversity and their indigenous, quilombola or associated traditional knowledge. What is undoubtedly important for the conservation of species in Brazil, however, this law only has action and efficiency within the national territory, not valid for research institutions outside Brazil. Therefore, this article is relevant for evaluating and providing subsidies on the law in question, through scientific articles, books and current legislation.

Keywords: Law 13123/2015; Biodiversity; Genetic heritage; Biotechnology.

INTRODUCTION

The Federal Constitution of 1988, in its article 225, guarantees that: "Art. 225 Everyone has the right to an ecologically balanced environment, a good for the common use of the people

and essential to a healthy quality of life, imposing on the Government and the community the duty to defend and preserve it for present and future generations . " (BRASIL, 1988). Therefore, it is the duty of the State to

guarantee the protection of biodiversity throughout the national territory, as well as the culture of peoples who live and survive from these resources. The biodiversity of a nation not only has an intrinsic value to the very existence of species and life, but it also has great potential for the generation of biopharmaceuticals and bioactive substances for the treatment of numerous human pathologies. From the expansion of pharmacological and biochemical discoveries of various species components and the growing worldwide extinction of natural species and ecosystems, in 1972, the United Nations (UN) convenes all countries for the first UN Conference on the Human Environment, held in Stockholm (Sweden) instituting in chapter I:

“The protection and improvement of the human environment is the biggest task that affects the well-being of the population, economic development worldwide; it is an urgent desire of the peoples of the world and a duty of all Governors”(UN, 1972, p.3).

This was the first international agreement for the protection of ecosystems and the species that depend on it. This resulted in several other conferences throughout the world, including the one that took place in the Brazilian city of Rio de Janeiro and known as the Rio 92 Conference, since it took place in 1992. Among several actions, they established Agenda 21 that establishes a global agenda global lifestyle, including instituting environmental education as a tool for global transformation (UN,

1992) in chapter 35, session 35.1, institutes the role of science and the scientist in conserving the planet: “The role and use of science in supporting prudent management of the environment and development for the daily and future survival of humanity. (...) A role of science will be to provide information to better formulate and select policies and for decision-making processes.” (UN, 1992, p. 311).

In addition to Agenda 21, the Convention on Biological Diversity was also instituted, which, in its article 15, establishes 7 rules for access to genetic resources and in its first article states that: “Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with national governments and is subject to national legislation (...)

(...) Access to genetic resources will be subject to the prior and informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.

(...) Each Contracting Party shall endeavor to develop and carry out scientific research based on the genetic resources provided by other Contracting Parties with full participation and, whenever possible, in those Contracting Parties.

(...) the results of research and development and the benefits arising from commercial use and other genetic resources with the Contracting Party that supplies them. This sharing "must take place on mutually agreed terms."

(MMA, 2019, p.1). Such agreements led Brazil to institute, in 2015, Law 13.123, which establishes strict rules for access to genetic heritage, that is, the resources and derivatives of national biodiversity, as well as their protection and access to knowledge of traditional peoples. associated with this biodiversity (BRASIL, 2015). In this sense, Brazil has instituted the National System for the Management of Genetic Heritage and Associated Traditional Knowledge (SisGen) which not only requires that all national research institutions and their researchers register all their research and research results using genetic resources from biodiversity from a bacterium to the largest trees under penalty of a fine. Such rigor practically stopped national research with biopharmaceuticals and bioactive substances from Brazilian biodiversity. Ethnobotanical research that seeks to test from popular knowledge which herbal medicines are really effective or not in the treatment of diseases were practically extinct, as the researcher by law must now obtain a legal declaration attesting that the entire community that has knowledge about a certain herbal medicine is consulted and that all members allow access and conducting the research . Starting from the premise that such rules and with such rigor were not instituted in other countries like China, Japan, United States etc. We believe that Brazilian national research has lost a lot with the institution of such strict rules for researching its own biodiversity, in contrast to the possibility that other countries carry

out such prospections without such mandatory and rigor. The SisGen (National System for the Management of Genetic Heritage) and the Biodiversity Law (Law 13,123 / 2015) impose new limits on the country's biotechnological development. Could such a law be a setback for Brazilian research and, involuntarily, benefit international research for prospecting new drugs from Brazilian biodiversity?

The increase in the rigor of legislation aimed at national research institutions that study and generate patents based on bioactive principles of Brazilian biodiversity, in contrast, with the low international requirement and less strict rules for institutions outside the country, may lead to an increase in the international use of Brazilian biodiversity in prospecting for new drugs.

BIODIVERSITY AND GENETIC HERITAGE

It is estimated that the existing biodiversity in Brazil represents about 20% of everything that is alive on the planet. In addition, about 12% of the world's available water resources are located in our country. Milaré (2011) explains that biological diversity is the variability of living organisms from all origins, comprising terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part. It also includes diversity within species, between species and ecosystems. Fiorillo and Diáféria (apud ANDRADE, 2013), explain that it is the diversity of life, both for the existence of the planet and for the survival of the human being and this as the main focus

of this diversity, today, and more than ever, it is most responsible for its preservation and the maintenance of life for the future of humanity. The genetic heritage is the one that contains the genetic information of the organisms of a certain country and that can be studied in order to develop medicines, research and other benefits. They are part of a state and Provisional Measure 2,186-16, dated 08.23.2001, was a legal landmark on access to genetic heritage and associated traditional knowledge in the country. Such MP defined the concept of genetic heritage as being: Information of genetic origin, contained in samples of all or part of a plant, fungal, microbial or animal specimen, in the form of molecules or substances derived from the metabolism of these living beings and extracts obtained of these living or dead organisms. Thus, Milaré (2011, p. 722) explains that: "Genetic heritage is the core of all biodiversity".

INTERNATIONAL LEGISLATION AND PROTECTION

The Convention on Biological Diversity (CBD) was a milestone for the protection and regulation of genetic heritage and biodiversity, in addition to traditional knowledge. Before that treaty, there were some international laws such as the UNESCO Convention (1970), the UN Resolution of 1989 etc. But with the advent of the CBD, the sustainable use of components of biodiversity through the conservation of biological resources was determined:

"Protect and encourage the customary use of biological resources in

accordance with traditional cultural practices compatible with the requirements of conservation or sustainable use". (art. 10). In addition, the CBD has come to recognize the sovereignty of States in the use of natural resources and traditional knowledge of local communities and indigenous peoples, while noting, however, the right of these communities to participate in the process and the benefits generated. Brazil became a signatory to this document in February 2011, as explained by Andrade (2013). The Nagoya Protocol to the Convention on Biological Diversity is an agreement complementary to the Convention and seeks to legally and transparently structure the effective implementation of the fair and equitable sharing of benefits arising from the use of genetic resources in order to compel the parties to respect the agreement in the document. This objective is found in his article¹:

"The objective of this Protocol is the fair and equitable sharing of the benefits arising from the use of genetic resources, including through the adequate access to genetic resources and the appropriate transfer of relevant technologies, considering all rights over such resources and technologies, and through adequate financing, thus contributing to the conservation of biological diversity and

¹ Extracted from: <https://www.cbd.int/abs/infokit/revised/print/factsheet-nagoya-pt.pdf>. Accessed on: 05 abr. 2020.

the sustainable use of its components. " There is also a concern in this document to protect the least developed countries and encourage the transfer of technology. This protocol determines access to traditional knowledge from indigenous communities and other local communities. As stated by Andrade (2013), excessive bureaucracy and lack of legislation or respect for laws are equally harmful. International laws have points in common and must above all respect the commands of the Convention on Biological Diversity, but from the above, glimpse the amateurism that surrounds the theme and the difficulty in reconciling state interests with those of traditional communities. Not that such a discussion serves as an excuse, but the excess of bureaucratization and different legislation undoubtedly serves, at least, as a facilitator, Biopiracy. The term Biopiracy came up in 1993, by the NGO RAFI (International Foundation for Rural Progress, today ETC-Group) which aimed to draw attention to the fact that multinational companies and scientific institutions are subtracting and patenting biological resources and indigenous knowledge without government authorization . Andrade (2013) explains that, since then, biopirates have been called those who, sometimes with governmental endorsement, remove from other countries, usually underdeveloped, with loose, ineffective legislation with little or no supervision, genetic resources with economic potential. Historically, according to Milanezi and

Barbosa (2013), the use of genetic resources and knowledge and associated traditional knowledge has been unfair. The countries of origin of the genetic resources and the indigenous and local communities, holders of associated traditional knowledge, have not even been consulted by those who use these resources to obtain economic gains with commercial products, the more any kind of benefit is received. This unfair appropriation, often aggravated by the use of patents, corresponds to biopiracy, and has occurred throughout the history of Brazil. A classic example is the açaí that attracted the interest of foreign companies that registered brands such as "Açaí" and "Açaí Power" to guarantee the exclusive use of the word. The Brazilian government has taken several actions to prevent this absurdity. Another example, quite current, that is worth discussing is that of quinine or quinine substance extracted from the plant *Cinchona officinalis* (Rubiaceae) and which is the basis for a medicine that is widely cited today, which is chloroquine and hydroxycloquine (FIOCRUZ, 2020) a promising drug to combat COVID19. This substance has already been used extensively to combat malaria in Brazil and its inputs are imported from India for production and possibly this substance would be difficult to discover by ethnobotanical surveys considering SisGen protection standards that protect the biodiversity of Brazilian researchers and having little efficacy against international research. that is worth discussing is that of quinine or

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protect the biodiversity of Brazilian researchers and having little efficacy against international research. 2020) a promising drug to combat COVID19. This substance has already been used extensively to combat malaria in Brazil and its inputs are imported from India for production and possibly this substance would be difficult to discover by ethnobotanical surveys considering SisGen protection standards that protect the biodiversity of Brazilian researchers and having little efficacy against international research. According to the Pro-Rector of the Federal University of ABC (2020), with the intention of avoiding biopiracy and ensuring the fair distribution, among companies, researchers and traditional communities, of the economic benefits generated from the exploitation of biodiversity, Brazil regulated the use of Genetic Heritage (PG) and Associated Traditional Knowledge (CTA) as early as 2001 (MP 2186-16). Recently, the Biodiversity Law (Law No. 13,123 / 2015) revoked MP 2186-16, establishing, among other things, the National Fund for the Sharing of Benefits (FNRB), determining the transfer of 1% (or up to 0.1 % via sector agreement) of the net income obtained from the sale of the finished product or reproductive material from the national PG. In the case of finished product or reproductive material originating from CTA of identifiable origin, the deposit in the FNRB will be 0, 5% of annual net revenue. This action by the Brazilian government is in accordance with the Nagoya Protocol, generated at the tenth meeting of the Conference of the

Parties to the Convention on Biological Diversity (COP10). The Nagoya Protocol came into force on 10/12/2014, aiming at biological conservation, sustainable use and fair and equitable sharing of the benefits generated from the use of genetic resources.

However, the Dean of the Federal University of ABC (2020) understands that, in practice, the Brazilian Biodiversity Law created barriers for Research & Development (R&D) by including studies in the areas of phylogeny, taxonomy in the concept of PG, systematics, ecology, biogeography and epidemiology. According to the new definitions of access to PG and research, the Law now includes some activities not covered in Resolution 21, such as molecular taxonomy, phylogeny, molecular epidemiology, molecular ecology, as well as the simple use of strings available in public banks.

LAW N. 13,123, MAY 20, 2015: NEW REGULATORY FRAMEWORK FOR THE USE OF BIODIVERSITY

In a published article, Távora et al (2015) makes expressive comments about law 13123 of 2015. Bill 7.735, 2014, presented in the Chamber of Deputies by the Executive Branch, which “regulates item II of § 1 and § 4 of art. 225 of the Federal Constitution, Article 1, Article 8 (j), Article 10 (c), Article 15 and Paragraphs 3 and 4 of Article 16 of the Convention on Biological Diversity, promulgated by Decree No. 2,519, of 16 March 1998; provides for access to genetic heritage, protection and access to associated traditional knowledge and the sharing

of benefits for conservation and sustainable use of biodiversity, repeals Provisional Measure No. 2,186-16, of August 23, 2001; and take other measures” represented an attempt to improve legislation, to seek legal certainty,

Távora et al (2015) explain that the project that generated the new Law had as characteristics greater adherence to reality, incentive to bioprospecting, non-taxation of research and technological development; support for the commercialization of the products generated, encouragement of traceability of the entire process, establishment of an appropriate and feasible benefit sharing regime, reduction of transaction costs, issuance of possible problems to legal standards, Thus, the heavy restrictions on access to biodiversity by national researchers themselves, barriers to research and bioprospecting activities and strict contractual criticism demanded new legislation, not only to avoid biopiracy, but also to encourage R&D projects and national research. , as well as to guarantee the rights of all actors who can benefit from access to genetic heritage and associated traditional knowledge. In addition, the new legislation sought to ensure the equitable sharing of benefits in order to promote the conservation and sustainable use of biodiversity in the country. (TÁVORA et al., 2015, p. 13). With regard to the environment, the law conferred legal certainty, as it defined genetic heritage as being "information of genetic origin of plant,

animal, microbial or other species, including substances from the metabolism of these living beings". (BRAZIL, LAW 13123/2015).

The financial resources obtained from the commercialization of new products based on genetic heritage, according to Távora et al (2015), will be allocated to the National Benefit Sharing Program (PNRB), which, among other purposes, will foster research and technological development associated with heritage genetics and associated traditional knowledge.

LAW No. 13,123 / 2015 AND THE BACKWARD IN THE PROTECTION OF TRADITIONAL KNOWLEDGE

The traditional knowledge associated with the genetic heritage of biodiversity (CTA) is part of the Brazilian cultural heritage and is collective rights specially protected by the 1988 Federal Constitution, as set out in articles 215 and 216, which provide for the fundamental right to culture. Thus, traditional knowledge, as Moreira and Conde (2017) they form a categorization of cultural human rights necessary for the free development of traditional peoples and communities, with a view to a dignified life and intrinsically linked to the right to cultural identity. Depending on the activity that the user intends to develop, the new law imposes the need for one or more declaratory acts to be fulfilled. In general, for the access activity, it is only necessary for the user to register at SisGen, declaring access. If the access intended by the user is to an area indispensable to national security or in

Brazilian jurisdictional waters, on the continental shelf and in the exclusive economic zone, it is also necessary to demonstrate, in addition to the registration, the Union authorization; and, if the activity is economic exploration, it is necessary that the user still perform, after registration,

Before, Article 11 of MP 2186/01 attributed competence to the Genetic Heritage Management Council (CGEN) to decide on the authorization of access and remittance activities, with the prior consent of the CTA or genetic heritage holder, as well as to give consent to the Contracts for the Use of the Genetic Heritage and Benefit Sharing.

In current law, the CGEN is only competent to regularize access to the CTA, by automatically issuing proof of registration, after completing the electronic form available in the National System for the Management of Genetic Heritage and Associated Traditional Knowledge (SisGen), an electronic system that is being implemented and operated by CGEN's Executive Secretariat. This shows, according to Moreira and Conde (2017), that the management structure of genetic heritage and associated traditional knowledge, created by Law no. 13,123 / 15, represents a setback to the protection rights of CTAs, since, in the previous legislation, there was broader State control over access, use and economic exploitation of these goods and, consequently, less vulnerable, for example, biopiracy and irregular use of patents, since state control occurred before access. An

important issue that must be mentioned is that the new law establishes rights to traditional peoples and communities aimed at protecting CTAs against the illegal use and exploitation of traditional knowledge; however, these rights do not reveal advances in the legal protection of traditional peoples and communities. As stated by Moreira and Conde (2017), in addition to the new Biodiversity Law not binding the activity of access to registration, the right established in § 2 of art. 8 of Law No. 13,123 / 15 has no practical effect for the purpose of protecting CTAs and protecting the cultural rights of traditional peoples and communities in relation, for example, to the right to grant invention patents. There is also an omission in the law regarding the right of traditional peoples and communities to decide in relation to the use of their CTAs, which violates rights that would need to be clearly disposed; see, for example, with regard to the right to prevent unauthorized third parties from using, carrying out tests, research, exploration, related to CTAs, as well as to disclose, transmit or relay data or information that integrate or constitute CTA, formerly provided for in item II of art. 9 of the MP and not reproduced in Law no. 13,123 / 15. In this context, it is evident that the new legislation has regressed in the defense of socioenvironmental rights, harming the development of the social groups that hold CTA, affecting their dignity and, reflexively, removing the freedom of traditional peoples and communities. (MOREIRA; CONDE, 2017, p. 191).

These are some of the aspects mentioned by the authors who still deal with SisGen registration. This does not guarantee that the user has obtained the prior consent of the owner community (required in the case of CTA of identifiable origin) or that the user has shared the benefits, in any of the modalities provided for in the law itself. Thus, in the aspect related to intellectual property, according to Moreira and Conde (2017) the legislator, maintained the incoherent Brazilian stance towards the international community of not ratifying the Nagoya Protocol, despite the fact that Brazil led the bloc of the countries called “megadiverse” in the negotiation process for this protocol - an agreement that establishes instruments that provide greater legal security for both providers and users of CTAs.

Therefore, Law no. 13.123 / 15 brought, in its text, several provisions that mitigated and suppressed rights that were already guaranteed by the CTA providers in MP n. 2.186-16 / 01, violating the principles of environmental non-setback, progressive human rights and, consequently, the principle of human dignity.

CONCLUSION

As seen in this article, biological diversity provides many important resources for medical research and brings innovations to the market of different types. It represents an invaluable value for the Brazilian and world economy. The Convention on

Biological Diversity was signed in 1992 to guarantee the conservation of this biological diversity, sustainable use and also its components, in addition to the equitable sharing of the benefits resulting from the use of genetic resources and traditional knowledge associated with all of this. To guarantee this issue, Brazil published Law 13123 of 2015, after many discussions. This law provides for access to genetic heritage, also for the protection and access to traditional knowledge and the sharing of benefits for the conservation and sustainable use of biodiversity. This new law was intended to remove bureaucracy of the process related to the aforementioned issues and to make it faster than previously regulated by Provisional Measure 2186-16, of 08/23/2001.

However, it was also seen in this article, that this law was also criticized, because it is inadequate in the face of the American Convention on Human Rights, other international norms, in addition to the principles of our Federal Constitution that provides for our basic foundations. Our Democratic State imposes a constant progression of measures that requires strengthening human rights. The new law hurts with regard to the fact of having prior informed consent for access to traditional knowledge and sharing of benefits for the exploitation of CTAs in an unconditional way. In this case, these two pillars of sustainable development, which are so important, are vulnerable, they cease to be for those entitled to, as they should be. In this case, it is a law restricting rights.

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