

THE NAGOYA PROTOCOL, BENEFITS FROM GENETIC RESOURCES AND BRAZILIAN LEGISLATION

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ABSTRACT

This work seeks to analyze the regulation of the Access and Benefit Sharing (ABS) regime arising from terrestrial genetic resources in Brazil. To this end, a study was carried out on the history of the regulation of the matter, from international treaties to national legislation, with an emphasis on the Nagoya Protocol. Internally, Provisional Decree No. 2.186-16/01 and Law No. 13.123/15 (Biodiversity Law), which revoked the former, were analyzed. This work was developed from a bibliographic and documentary survey. It is concluded that Law No. 13.123/15 does not violate the text of the Nagoya Protocol, but it is congenitally defective as it breaches the provisions of Convention 169 of the International Labor Organization (ILO) on indigenous peoples and traditional communities. It is thus expected that the recent ratification of the Protocol will encourage the amendment of Law No. 13,123/15, so that the rights of indigenous peoples and traditional communities are adequately addressed and that a specific criminal type is created for the practice of biopiracy.

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Keywords: Access and benefit sharing; biodiversity; biopiracy; biodiversity law; Nagoya Protocol.

O PROTOCOLO DE NAGOYA, OS BENEFÍCIOS ORIUNDOS DOS RECURSOS GENÉTICOS E A LEGISLAÇÃO BRASILEIRA

RESUMO

Este trabalho busca analisar a regulamentação do regime de Acesso e Repartição de Benefícios (ARB) oriundos dos recursos genéticos terrestres no Brasil. Para tanto, foi realizado um estudo sobre o histórico da regulamentação da matéria, começando pelos tratados internacionais até chegar à legislação nacional, com ênfase no Protocolo de Nagoya. No âmbito interno, analisou-se a Medida Provisória n. 2.186-16/01 e a Lei n. 13.123/15 (Lei da Biodiversidade), que revogou aquela. Este trabalho foi desenvolvido a partir de pesquisa bibliográfica e documental. Conclui-se que a Lei n. 13.123/15 não viola o texto do Protocolo de Nagoya, entretanto sofre de vício congênito, de acordo com a Convenção 169 da Organização Internacional do Trabalho (OIT), no que diz respeito aos povos indígenas e comunidades tradicionais. Assim, espera-se que a recente ratificação do Protocolo sirva de estímulo para a alteração da Lei n. 13.123/15 a fim de que os direitos dos povos indígenas e comunidades tradicionais sejam adequadamente contemplados e de que seja criado um tipo penal específico para a prática de biopirataria.

Palavras-chave: *Acesso e Repartição de Benefícios; biodiversidade; biopirataria; Lei da Biodiversidade; Protocolo de Nagoya.*

INTRODUCTION

Most of the terrestrial biodiversity is present in the countries of the southern hemisphere, especially in Africa, Asia and South America. Brazil is home to one of the greatest biodiversity on the planet, comprising six different biomes and the largest expanse of tropical forest cover in the world, including nearly two-thirds of the Amazon rainforest. However, although the countries of the South are rich in biological resources, they are, for the most part, developing or less developed countries, with few investments in the technological area and with fragile economies. On the other hand, the countries of the Northern Hemisphere are economically and technologically developed, but poorer in biodiversity. This relationship of inequality served as a driving force for the interest in the exploitation of the biological resources of the South.

The search for economic development on the part of the North has historically led to a broad demand for the natural resources of the South. If during colonial times in Brazil there was the exploitation of brazilwood, sugarcane and gold, the 20th century presented us with a new way of using biodiversity: the use of genetic resources in scientific research. Free access to the natural resources of the South, based on the idea of biodiversity as a common heritage of all humanity, capable of being exploited and commercialized, gave legitimacy to the activities of bioprospecting of the North.

Associated with the problem of access to genetic resources without proper authorization and compensation, the rate of biodiversity loss began to increase substantially, especially because of new patterns of consumption, urbanization, biotechnology, overpopulation and global cultural homogeneity. Due to the serious consequences of the loss of biodiversity for the subsistence of all living beings, the topic has become predominant in international environmental forums.

In this context, the Convention on Biological Diversity (CBD, 1992) emerged in 1992, which established that terrestrial biodiversity is considered a common concern of humanity. This means that natural resources in the territories of the countries of the South cannot be exploited without prior authorization and compensation. Thus, the so-called biopiracy has become a reprehensible practice at the international level. Prior authorization serves to recognize the jurisdiction of the countries of the South over their biological resources and the compensation aims to repay these countries for their expenditures and investments to preserve and conserve

biodiversity. It is the application of the Principle of Common but Differentiated Responsibility.

The CBD and, later, the Nagoya Protocol emerged as a response to the Southern claim. The Protocol regulates in detail the regime for sharing benefits arising from the exploitation of genetic resources and associated traditional knowledge, guaranteeing means of recording access and consideration for use. The CBD was included in Brazilian legislation and regulated in 2001 with Provisional Measure No. 2186-16. As an improvement to the MP, Law No. 13.123/15, known as the Biodiversity Law, which came to regulate the forms of access to genetic heritage in Brazil and the exploitation of associated traditional knowledge, regulating the respective benefit sharing.

In March 2021, more than ten years after its signature, Brazil finally ratified the Nagoya Protocol. Ratification means an important advance in the benefit-sharing issue and in the search for distributive justice. However, Legislative Decree no. 136/2020, which ratifies Brazil's participation in the Protocol, provides that the Biodiversity Law must be considered as the domestic law for the purposes of implementing the treaty. It happens that some authors defend the impossibility of coexistence of the two normative diplomas, since the law contradicts certain provisions of the Protocol.

It is unnecessary to highlight the extreme relevance for the country, since benefit-sharing has the potential to contribute to environmental conservation and socioeconomic development, which is especially relevant for countries with such greater biodiversity as Brazil. It is expected that, with the increasing economic value of natural resources, Brazil can apply the available legal mechanisms in order to explore its "hyperdiversity" in a sustainable way.

In view of this, this work intends to analyze the regulation of the Access and Benefit-Sharing (ABS) regime arising from terrestrial genetic resources in Brazil, from the verification of the compatibility of the aforementioned law with the Protocol, according to the limits provided for in the international agreement, to find out if the former violates the latter. For this, a study will be carried out on the history of the regulation of the matter, starting with international treaties until reaching the current national legislation, with greater emphasis on the Nagoya Protocol and its regulation, always seeking to make a critical reading of the subject.

In order to achieve the objective pursued by this study, we also adopted as a basis the taxonomy that qualifies the research in two aspects: as

for the purposes and as for the means. As for the purposes, the survey will be explanatory because it will seek to clarify the regulation of the ABS regime arising from terrestrial genetic resources in Brazil, by verifying the compatibility of Law No. 13.123/15 with the Nagoya Protocol. As for the means, the survey can be classified as bibliographic and documentary, as has been the rule in Law. The article is divided into four main parts: the first explains the problem of biopiracy; the second analyzes the way in which the solution was constructed within the scope of International Environmental Law, with the advent of the Convention on Biological Diversity, in 1992; in the third, the main points of the Nagoya Protocol were examined and, finally, in the fourth part, the Brazilian legislation on biodiversity and its relationship with the aforementioned protocol were analyzed.

1 BIOPIRACY

According to Mgbeoji (2006), biopiracy can be conceptualized as the unauthorized commercial use of biological resources and/or traditional knowledge associated⁴ with genetic heritage, as well as the registration of patents relating to the results of this exploitation, without proceeding with the due recognition and compensation to the origin. In this context, we have that the countries of the northern hemisphere, especially the United States and Japan, access the genetic resources of the countries of the southern hemisphere, rich in biodiversity, to use them as raw material for inventions that will later be patented, however, without any recognition or retribution to the originating countries (MILLER, 1995). Brazil nut, carapa and cupuaçu are examples of Amazonian plants that were used in research for patent application by the United States and Japan (HOMMA, 2005).

This way of using genetic resources is considered a misappropriation of the biodiversity of southern countries, as it is done without consent and due compensation. Moreover, the so-called “bioprospectors” take advantage of the traditional knowledge of indigenous peoples or traditional communities in the South, making use of their millenary knowledge, in the development of scientific research for commercial purposes. The products obtained are registered as authored by the research laboratories, from the perspective of the intellectual property system (MGBEOJI, 2006).

⁴ According to the Instituto do Patrimônio Histórico Nacional (IPHAN), associated traditional knowledge can be defined as “the individual or collective information or practice of an indigenous people or traditional community, with real or potential value, associated with the genetic heritage. Traditional knowledge associated with the genetic heritage is related to nature, living beings and the environment, and is part of the daily practice of peoples and communities” (IPHAN, 2021).

However, it is not possible to understand biopiracy without an adequate definition of what traditional knowledge is. The problem is that there is no single accepted definition and even the holders of traditional knowledge are quite different from each other.

Most scholars associate traditional knowledge directly with indigenous or tribal peoples. However, traditional knowledge can be maintained by such other population groups as local farmers and other minority groups. Some characteristics of this knowledge are useful for understanding the term. Traditional knowledge is developed over time and passed on from generation to generation orally. Furthermore, such knowledge is collectively owned and embedded in customs, language, local practices and cultural heritage (ROBINSON, 2010). It is worth noting that this form of knowledge is not protected by the Trade-Related Aspects of Intellectual Property Rights (TRIPs) of the World Trade Organization (WTO), as it does not meet the requirements of the agreement.

The free use of the genetic resources of the South was not considered illegal under international law until the emergence of the Convention on Biological Diversity. As biodiversity was considered a “common heritage of humanity”, all states could exploit genetic resources located outside their jurisdictions, because there was no sovereignty over them. Hassemer (2004) states that the idea that genetic resources located in the South were in the public domain resulted in the development of large “ex situ” collections. In other words, collections of genetic resources stored outside their natural place, such as collections from botanical gardens, private company collections, microbial resource centers and gene banks. These germplasm stocks, in particular gene banks, are very useful for research, as they store the genetic information necessary for developing new biotechnologies (HASSEMER, 2004).

Understanding gene banks is very important to understand the subtle process of biopiracy hidden under the veil of legality. International agricultural research centers were responsible for much of the transfer of plant germplasm from the South to the North. As biodiversity was considered a common heritage of humanity, Northern countries established research centers in many regions of the South, such as the International Rice Research Institute, located in the Philippines, and the International Potato Center, located in Peru, to store local genetic resources of those regions to be used in their research (MGBEOJI, 2006).

The global concern about the loss of biodiversity and the claims of the South against the conception of biodiversity as the “common heritage of

humanity”, forced the United Nations to look at the demands of the South in a different light. The South claimed the right to guarantee its economic development through the application of the principle of sustainable development. As a result of several negotiations at the international level, a new instrument emerges: The Convention on Biological Diversity.

2 CONVENTION ON BIOLOGICAL DIVERSITY (CBD)

The problem of biodiversity loss was addressed in several international instruments before the Convention on Biological Diversity. The Convention on International Trade in Endangered Species, in 1973, and the World Charter for Nature, in 1982, are examples that demonstrate the concern with the conservation of biological diversity. However, as these instruments were fragmented and dealt only with limited aspects of biodiversity, there was a need to develop a global instrument, such as the Convention on Biological Diversity (BOWMAN, 1996; MGBEOJI, 2006).

The CBD’s objectives are threefold: the conservation of biodiversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising from the use of genetic resources. Boyle (1996) argues that despite the recognition in the preamble of the convention of the “intrinsic value” of biodiversity, the convention is not a preservationist instrument (GODINHO; MOTA, 2013). In fact, the convention emphasizes the role of biodiversity linked to human needs, considering economic development as one of the priorities of developing countries.

The CBD recognizes that biodiversity is a “common concern of humanity” and states that genetic resources are subject to the sovereignty of States. In other words, the convention states that States have rights over the resources situated within them and it is their responsibility to preserve and use them sustainably. This change of understanding is important because it rejects the concept of common heritage of biological resources. This idea is central to understanding the achievements of the South, as the appropriation of genetic resources from the South begins to be considered illegal and illegitimate by international law (HASSEMER, 2004).

The concept of “common concern of mankind” is closely related to the discussion of North-South equity: in which “common heritage of mankind” is related to the sharing of advantages and “common concern of mankind” is related to the division of the burden related to the preservation of the environment. As biodiversity is considered a common concern, as

established by the CBD, the North and the South must make efforts to, in a cooperative process, find solutions to the problem of the loss of global biodiversity. Furthermore, the “*common concern of mankind*” also expresses the principle of Common but Differentiated Responsibility, since developed countries have a greater share of responsibility in solving the problem of biodiversity loss. This responsibility exists because the countries of the North have the technology and resources to face the problem (BRUNNÉE, 2007).

As a result of the recognition of the sovereignty of States over their genetic resources, the CBD establishes, in its art. 15, that States are entitled to authorize access, in accordance with their national legislation. After authorization of access by Prior Informed Consent (PIC), the user of the resource must establish by mutual agreement, called *mutually agreed terms* (MAT), with the provider, in order to enable equitable benefit sharing. In other words, there is an obligation to reward holders of genetic resources. Compensation can occur in different ways, and can take the form of: access fees, payment of royalties, participation in product development or technology transfer, training of local people or even institutional relationships, usually between universities to foster research development in the provider country (CULLET, 2003). Equitable benefit-sharing can be perceived in two ways: first, as protection for holders of traditional knowledge, especially after the strengthening of life patents in TRIPs, and second, as retribution to holders of genetic resources for hosting and preserving biodiversity (CULLET, 2003).

The Convention also emphasizes the importance of financial assistance and technology transfer to developing countries as a means of preserving biological diversity. This favorable treatment of developing countries is a materialization of the principle of Common but Differentiated Responsibilities, since these countries are not able to bear the environmental burden. However, technology transfer is a very complex issue, mainly because of the protection of the intellectual rights of some technologies.

Art. 8, *j*, establishes that the contracting parties must respect and preserve the traditional knowledge of indigenous peoples and local communities. This provision emphasizes the importance of their participation in sharing the benefits arising from the use of their knowledge. However, as intellectual property rights are based on the western model of invention, the protection of traditional knowledge becomes very difficult (CULLET, 2009).

The imprecision of some provisions of the CBD has become an obstacle to implementation and compliance by states. It is undeniable that the ABS regime was a great achievement and a paradigm shift, responding to the old calls of the South. However, in an attempt to please both sides in the negotiations (North and South), the convention, in some of its provisions (such as traditional knowledge in article 8, *j*, and the ABS, in article 15), presents itself as a merely rhetorical instrument. As evidence of the low level of implementation at the national level, in 2007 only 39 Contracting Parties out of 189 established any national legislation or committed to do so (BUCK; HAMILTON, 2011). In this context, the COP adopted, respectively, at its sixth and tenth meetings, the Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Deriving from Their Use and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of benefits arising from its utilization (Nagoya Protocol). These instruments are complementary to the Convention and deepen its provisions in order to enable the effective implementation of the rules, at the domestic level, by the States.

3 NAGOYA PROTOCOL

The low level of CBD implementation due to the imprecision of most provisions and the absence of monitoring mechanisms, especially with regard to arts. 15 and 8, *j*, made developing countries pay attention to the need for an international instrument that could guarantee the effectiveness of the terms of the Convention. Therefore, in 2000, COP-5 established an Ad Hoc Working Group on Access and Benefit-Sharing (ABS) to develop guidelines on how to incorporate ABS provisions into their national legislation (related to Article 15 of the CBD). The result was the development of the Bonn Guidelines, which were adopted during COP-6, in 2002. That same year, the city of Johannesburg, South Africa, hosted the World Summit on Sustainable Development, which established an Implementation Plan. This plan provided for a negotiation within the CBD to establish an international regime for the equitable sharing of benefits (UN, 2020).

In 2004, COP-7, in its decision VII/19, determined that the Ad Hoc working group on Access and Benefit-Sharing, with the assistance of the Ad Hoc working group on art. 8, *j*, and the participation of non-governmental organizations, indigenous peoples, local communities, the private sector and academic institutions to develop an international regime of access

and benefit-sharing. The negotiations lasted six years and were concluded in October 2010, at the tenth meeting of the COP. Decision X/1 finally approved the Nagoya Protocol, which was opened for signature in 2011 and entered into force in 2014. Currently, the protocol has 133 members (UN, 2022a).

The Protocol negotiations revealed, once again, the marked division between North and South. In the debates, the Group of Like-Minded Mega-diverse Countries (LMMC), supported by the G-77, played an important role in defining the priorities of the South in measures to combat biopiracy. The Group is made up of 17 countries with biological biodiversity, mainly suppliers of genetic resources: Bolivia, Brazil, China, Colombia, Costa Rica, Congo, Ecuador, India, Indonesia, Kenya, Madagascar, Mexico, Peru, Philippines, South Africa and Venezuela (LING, 2011). One of the group's claims was that the adoption of the Nagoya Protocol was a prerequisite for the approval of the COP-10 "Nagoya Package", which included, in addition to the protocol, a Strategic Plan for the post-2010 period and a new strategy for resource mobilization (WARREN, 2010).

The objective of the Protocol is to advance even further in the implementation of the third objective of the CBD: the fair and equitable sharing of benefits arising from the utilization of genetic resources. Therefore, the Protocol focuses on establishing the procedural aspects of arts. 8, *j*, and 15 of the CBD, in order to facilitate the implementation of these provisions by the Contracting Parties. Art. 1 also states that the ABS regime should be instrumental "for the conservation of biological diversity and the sustainable use of its components". Therefore, the main objective of the Protocol is to guarantee the effectiveness of the two objectives of the CBD (KAMAU; FEDDER; WINTER, 2010).

3.1 Access and Benefit-Sharing

The Protocol reiterates the sovereignty of States over their genetic resources and the need to obtain Prior Informed Consent (PIC) and Mutual Agreement (MA) to access them. Paragraph 3 imposes some obligations on supplier countries that intend to require the PIC, such as providing information on national procedures for access authorization, ensuring legal certainty and clarity of their legislation (SANDS *et al.*, 2012). In addition, § 3 emphasizes the obligation of countries to provide a license or equivalent, which would be proof of the decision to grant the PIC and

establishment of the MA. Member states are also required to notify the ABS Clearing House. This last mechanism was established in art. 14 of the Protocol and serves as a means to share information related to access and benefit-sharing between the Parties to the Protocol.

Paragraphs 6.(2) and 6.(3). (F) are also related to access to genetic resources and establish an innovative provision related to indigenous and local communities. In accordance with these provisions, each Party, subject to national legislation, shall take measures to ensure that the PIC of indigenous and local communities is obtained for access to genetic resources in the territories in their possession. This was a great achievement as compared to the vague art. 8, *j*, of the Convention. However, Harrop (2011) criticizes the expression “subject to domestic legislation”. The author argues that, as many countries do not recognize the rights of indigenous peoples in domestic law, these provisions would be ineffective for them (HARROP, 2011).

Art. 5 of the Protocol is related to the fair and equitable sharing of benefits through the MA. Paragraph 1 requires that the benefits arising from the utilization and subsequent application and commercialization of genetic resources be shared fairly and equitably with the Party that provides them, through the MAT. The benefits listed in the Protocol include both monetary and non-monetary benefits, which are also listed in the Bonn Guidelines. However, the Protocol’s emphasis is on encouraging benefits for developing countries through technology transfer, collaboration and cooperation in technical-scientific research and development programs, as established in art. 23 (KAMAU; FEDDER; WINTER, 2010).

Art. 5, §§ 2 and 5, also establishes that the Parties shall adopt administrative, legislative or policy measures in order to ensure that the benefits arising from the use of traditional knowledge and genetic resources held by local indigenous peoples, people and communities are shared fairly and equitably. Access to traditional knowledge associated with genetic resources is also dealt with in art. 7, which establishes that, in compliance with national legislation, the Parties must ensure that the use of traditional knowledge held by indigenous and local communities takes into account the PIC or any form of approval by them, in addition to their participation.

3.2 Compliance

One of the central issues of the Protocol for developing countries is related to compliance mechanisms. They believed that without provisions

to improve monitoring of access and benefit-sharing of genetic resources through the PIC and MA, the problem of biopiracy would never be corrected. Arts. 15, 1, and 16, 1, emphasize that Parties should develop adequate legislation to ensure that genetic resources and associated traditional knowledge are accessed with due regard to the PIC and the establishment of the MA within their jurisdiction (BUCK; HAMILTON, 2011). In addition, the user country must take adequate and effective measures to deal with situations of non-compliance, in accordance with art. 15.2. However, Jospeh (2010, p. 90) argues that “the Protocol has been very tolerant of non-compliance, expressing its sympathy to violators by using the expression “as far as possible and as appropriate”, such as arts. 15.3 and 16.3, which make cooperation in cases of alleged violations more flexible and do not establish any mechanism to deal with the situation of non-compliance.

Art. 17.3, confirms that an international certificate of compliance should serve as verification that genetic resources have been accessed taking into account the PIC and the establishment of the MA. After acquiring a license or equivalent from the national authority, the “ABS Clearing House” issues the certificate of compliance. However, it is important to note that art. 17 is restricted to the use of genetic resources. This means that it does not apply to traditional knowledge (TK) associated with genetic resources. According to Nijar (2011, p 11), this represents “serious flaw as most cases of biopiracy relate to the unlawful use of such TK”. At this point, the Protocol ends up harming its purpose of valuing Traditional Knowledge.

According to art. 25, § 2 of the Protocol, the same financial mechanism of the CBD, the Global Environment Facility, was responsible for funding activities of the Parties to the Protocol, especially in relation to developing and less developed countries. Financial support focuses on ratifying the protocol and funding projects that will promote technology transfer and private sector engagement (UN, 2022b).

Despite all the challenges that the Protocol still faces, the relevance of the instrument’s initiative to tackle the problem of biopiracy is undeniable. Finally, an international ABS regime was created, emphasizing not only genetic resources but also the traditional knowledge associated with them. According to Lima (2016, p. 58), “the Convention already indicated the importance of countries encouraging sharing in this case [for indigenous and local communities that hold traditional knowledge], but the Protocol recognized this right in a more direct and definitive way [...]”. In this

context, the Protocol is a notable acknowledgment of the environmental injustices suffered by the South and appears, at the international level, as a means of corrective justice.

4 BRAZIL: THE COUNTRY OF “HYPERDIVERSITY”

Brazil holds one of the greatest biodiversity on the planet, covering the largest extent of tropical forest cover in the world, including almost two-thirds of the Amazon (BUTLER, 2020). In addition, the Caatinga is the only uniquely Brazilian biome, housing 900 species of animals and plants (BUTLER, 2020). Approximately a quarter of all freshwater fish in the world (about 23%) are in Brazilian rivers, as well as 16% of the planet’s birds, 12% of mammals and 15% of all animal and plant species (BARLOW *et al.* ., 2018).

Due to its mega-diverse nature, Brazil is at the center of discussions and agendas about global biodiversity. In the CBD context, Brazil was part of the G77, advocating sovereignty over its resources, with an emphasis on sustainable development, while seeking to alleviate the problem of social inequality and income distribution in the country.

The affirmation of the concept of sustainable development, made Brazil and other developing countries start to perceive the environmental issue in a more positive way (HURREL, 1992), since the recognition of the importance for the developing countries of the eradication of poverty and reduction of social inequality allied to economic development began to appear in several international instruments, such as the CBD and Nagoya.

As a megadiverse country, Brazil has always been the target of exploitation of its natural resources. The first natural product to be exploited was pau-brasil, which almost resulted in the extinction of this species in the country (GONÇALVES, 2009). Even after independence, in 1822, Brazil continued to be the target of the appropriation of its resources by the North, insofar as biodiversity was considered “the common heritage of humanity” and access to Brazilian genetic resources occurred free of any burden. As biotechnology developed, access to resources became more sophisticated. Instead of exploring jaborandi’s raw material, for example, companies in the North began to extract the plant’s properties, studying its genetic resources. In the case of jaborandi, in 1991, the German company Merck patented the active that gave rise to the glaucoma drug called Pilocarpine (BRUNO, 2018).

A famous case of biopiracy in Brazil is the “frog vaccine”. The Amazon region is home to a species of frog known by the scientific name of *Phyllomedusa bicolor*. Indigenous and local communities have a tradition of using a secretion expelled by the animal to cure hookworm and relieve pain in general. In the early 1980s, scientists from the North began to research the effects of secretion in international laboratories. Research has revealed that the secretion contains two substances, dermorphin and deltorphin, which are effective as analgesics, antibiotics and in strengthening the immune system (VARGAS, 2014; CUNHA, 2020). The substance ended up being patented in the United States, European Union and Japan, under more than ten patents. None of them took into account the traditional knowledge of Brazilian indigenous healers or the origin of the genetic resource (HOMMA, 2008).

The CBD came to start the process of modifying this scenario, introducing the recognition of the sovereignty of states over their natural resources, in an attempt to prevent or at least create a path for the regulation of their appropriation by other states.

4.1 Brazilian Legislation on Access and Benefit Sharing

In Brazil, the consolidation of the environmental theme in the legislation took place with the Law of the National Environmental Policy (Law No. 6.938/81) and, later, with the Federal Constitution of 1988. The Magna Carta innovated in the country’s environmental order, starting to consider the environment as a diffuse legal asset and a fundamental right, being the duty of the Government and the whole community to preserve it for present and future generations (BRASIL, 1988).

Nonetheless, the legal system remained silent on the issue of biopiracy and its destructive effects on the country, with no advances in terms of inspection and combat. Addressing the issue of biopiracy in Brazil began only after the signing of the CBD. The Convention was enacted in Brazilian jurisdiction through Decree No. 2,519/1998. However, it was only in 2000 that the Convention was effectively regulated, through Provisional Decree No. 2052-1/2000, which underwent several reissues and was eventually replaced by PD No. 2.186-16/2001 (MACHADO; GODINHO, 2011). At the time, the controversial case of a contract between the Organização Social Bioamazônia and the Novartis pharmaceutical company prompted the issue of a legal regulation that dealt with access and benefit-sharing of

genetic resources (SACCARO JR, 2011).

This contract provided that Novartis would have the right to any discovery related to future products and processes developed from the genetic resources of the Amazon. In return, Bioamazônia would receive 1% *royalties* on new discoveries, for ten years. However, the contract suffered several criticisms, among them, the lack of participation and knowledge of the Ministry of the Environment about the terms of the negotiation and the inadequacy of the form of benefit sharing (MACHADO; GODINHO, 2011). In this context, the Brazilian government, which had recently ratified the CBD, realized the urgent need to have a legal instrument that would regulate access to and benefit-sharing of genetic resources in Brazil (AMARANTE; RUIVO, 2017).

Provisional Decree No. 2,186-16/2001 brought important provisions on access to genetic heritage, associated traditional knowledge and benefit sharing. However, it was considered too rigid and restrictive, mainly in relation to the Contract for the Utilization of Genetic Heritage and Benefit Sharing (CURB). This contract was always required when an institution (university or company) wanted to carry out research in which there was a sample of genetic material or associated traditional knowledge. Another problem was the average time to obtain authorization for access to genetic heritage from the Genetic Heritage Management Council (CGEN), which was approximately 550 days (TÁVORA *et al.*, 2015). During the term of PD No. 2,186-16, of 2001, only 110 benefit-sharing contracts were signed, only one of them providing for benefit-sharing for indigenous populations (TÁVORA *et al.*, 2015). It was noticed, therefore, that excessive bureaucracy caused a disincentive to research and innovation, in addition to a low number of benefit-sharing agreements. In response to the limitations of PD No. 2,186/16, of 2001, Law no. 13.123/2015 arises.

4.2 The Brazilian Biodiversity Law

Law No. 13.123/2015, the new legal framework for biodiversity in Brazil, regulates item II of § 1 and § 4 of art. 225 of the Federal Constitution and art. 1, subitem j of art. 8, subitem c of art. 10, art. 15 and §§ 3 and 4 of art. 16 of the Convention on Biological Diversity. The law regulates the form of access to genetic heritage and associated traditional knowledge, in addition to benefit sharing for the conservation and sustainable use of biodiversity. The aforementioned law establishes new rules for the

regularization of these practices, in particular, through the establishment of a mandatory system of self-declaratory registration of activities that use resources from Brazilian biodiversity, the National System for the Management of Genetic Heritage and Traditional Knowledge Associate (SisGen).

Thus, through the new system, an attempt was made to facilitate the registration of access to genetic resources and traditional Brazilian knowledge, as a means of establishing a type of control and traceability of the utilization of biodiversity. According to Boff (2015, p. 118), “it is perceived that the standardization has reduced bureaucracy and facilitated the procedures for access to genetic heritage and associated traditional knowledge, leaving the Federation’s role to guide the entire process, as it will authorize access to genetic heritage”.

SisGen is managed by the Genetic Heritage Management Council (CGen), a body linked to the Ministry of the Environment, with deliberative and normative competence, formed by representatives of federal agencies and entities and civil society from areas ranging from the business and academic sector to groups of traditional communities, family farmers and indigenous populations (TORRES, 2015).

Under the law, the Associated Traditional knowledge (ATK) is classified as identifiable and unidentifiable in origin. In the case of access to ATK of identifiable origin, in addition to the fixed amount of 0.5% of the net revenue of the finished product or reproductive material, to be paid to the National Fund for Benefit Sharing, the law provides for a variable amount to be fixed by free negotiation, between the users and communities involved to be paid on the basis of benefit sharing. In theory, they can demand any amount. The law provides for the participation of indigenous populations and traditional communities through the Sectorial Chamber, through meetings, with the possibility of proposing criticisms and suggestions to the CGEN plenary. This was considered a positive point in the legislation, as it allows the effective participation of interested parties, generating the gradual improvement of the standard.

However, despite some significant advances, the new law has been the target of severe criticism. One of them is that, even though they are the addressees of the norm, traditional communities were not previously consulted and did not participate in the process of drafting the law (MOREIRA; CONDE, 2017). Brazil, as a signatory to Convention No. 169 of the International Labor Organization (ILO) on Indigenous and Tribal Peoples (Decree No. 5051, of April 19, 2004), has a duty to ensure

that indigenous people are consulted in advance about any laws that are being discussed and that may impact their rights (TÁVORA *et al.*, 2015; MOREIRA; CONDE, 2017). According to Távora *et al.* (2015, p. 45) “this failure can expose the Federation to national and international responsibility for imposing a law on the Indians without first hearing them properly, an affront to the provisions of this Convention”.

Likewise, civil society had no participation in the construction of legislation (SANTILLI, 2015). Social movements only achieved some visibility when the law had already been enacted, at the stage of its regulation, clearly a pro forma gesture only on the part of the government. Consequently, there was an emptying of popular participation in the construction of a dialogue on the regulation (TORRES, 2015). At this point, as Torres (2015) asserts, despite the presence of civil society in the composition of the CGen, it does not present itself as effectively equal, insofar as the government’s participation is greater than that of civil society, with the representation of traditional communities and of the academy being only 1/3 each, which ends up generating a clear advantage for the representation of economic interests.

According to its defenders, the idea of sanctions provided for in the laws relating to mandatory registration would prevent resources from being taken out of the country and patented without the proper distribution of resources to Brazil, as is the case with biopiracy.

It so happens that another part of the criticism points out that the effect generated with the new legislation was precisely the opposite, due to the strong deregulation that can be extracted from the law, triggering a backlash that would make access to resources too easy, generating less protection for resources, intensified, it should be noted, by the reduction of the Federation’s supervisory power compared to the previous regulation (SBMT, 2018). Still with regard to inspection, it is important to note that art. 93 of Decree No. 8,772/16 established the common competence of Ibama, the Navy Command and the Ministry of Agriculture and Livestock for monitoring access and sharing. However, this shared competence ends up increasing the chances of omission, as practice shows that one ends up waiting for the other to act, generating a paralysis of the monitoring bodies. In environmental matters, the simultaneous indistinct administrative competence does not seem to be the best way, so much so that the Complementary Law No. 140/2011 sought to establish as a primarily responsible body the one that grants the authorization or license.

Another significant change was the alteration in the Cgen's decision regarding the authorization of access and remittance activities. Previously, the body deliberated on authorization in agreement with the holder of traditional knowledge. Now, it has competence only to attest to the regularity of the access itself (CUCO; FERES; MOREIRA, 2018). That is, the control of the body is done after access, increasing the chance of biopiracy. It is worth noting that to date there is no criminal classification for the crime of biopiracy, which is absolutely regrettable⁵. In effect, Law No. 9,605/1998, the so-called Environmental Crimes Law, and the Biodiversity Law did not stipulate criminal sanctions for the practice (MENDES; POZZETTI, 2014), although several ecologically less serious conducts are typified as a crime. Therefore, the conduct consists of a mere administrative infraction, provided for in Decree No. 8,772/2016, punished with a fine.

The classification of traditional knowledge started to be done as of identifiable and unidentifiable origin, only requiring the prior consent of the first group. In other words, this means that when there is no possibility of establishing a link of origin with at least one indigenous population, community or traditional farmer, consent is waived. Furthermore, the law considers genetic heritage of a traditional local or Creole variety or locally adapted or Creole breed for agricultural activities to be of unidentifiable origin (BRASIL, 2015).

Regarding benefit-sharing, art. 17 of the legal framework limits its application only to finished products and reproductive materials, not considering all stages of production and not providing for distribution to intermediate products in the production chain. In addition, art. 20 establishes fixed criteria for sharing (1% of annual net revenue from economic exploitation), which, combined with the forecast of exemptions, open the way to stifle benefit sharing (TORRES, 2015).

The academy received the new legal diploma with optimism, as it won three seats in the CGEN (SBPC, ABC and Associação Brasileira de Antropologia) and an exclusive sectoral chamber to propose suggestions and improvements for the sector (BUSTAMANTE *et al.*, 2018). The most adversely affected were the holders of traditional knowledge, since the classification of their knowledge in identifiable origin or not limits the obligation to obtain prior consent and benefit-sharing (MOREIRA; CONDE, 2017). Furthermore, the lack of mention of benefit-sharing from

5 Bills No. 4225/04 and No. 6794/06, authored by deputies Carlos Rodrigues (PL-RJ) and João Campos (PSDB-GO), respectively, seek to typify biopiracy as an environmental crime.

intermediary products also harmed the interests of holders of traditional knowledge.

Recently, the Nagoya Protocol was ratified by Brazil, which means a positive nod to the resumption of discussions on environmental issues in the country, a gesture considered relevant, above all, to lessen the negative effects on the international scene of the deleterious posture taken in recent years with regard to environmental protection.

4.3 Is the Biodiversity Law compatible with the Nagoya Protocol?

Legislative Decree No. 136 of 2020 that approved the Nagoya Protocol provides for some conditions for the final approval of the text. Among them, that Law No. 13.123/2015, should be considered as the domestic law for the implementation of the Nagoya Protocol. It so happens that, according to some authors, there are provisions of the Protocol that conflict with the aforementioned law (BARBA, 2017; DOURADO, 2017; SILVEIRA, 2017). According to them, the absence of the obligation of prior consent for traditional knowledge of unidentifiable origin and the establishment of a percentage for benefit-sharing violates arts . 5 and 7 of the Protocol.

It is well known that international agreements tend to be quite generic, precisely to encompass the largest number of signatory states and avoid controversies arising from the peculiarities of each legal system. As a means of facilitating implementation, the text of the Protocol grants wide discretion to member states to regulate the matter. In this sense, Possenti and Colombo (2020) understand that, in general, Law No. 13.123/2015 is compatible with the text of the Nagoya Protocol, as Brazil acted in accordance with the freedom that the Protocol itself granted it.

However, freedom of regulation cannot contradict the objective of the international agreement: the fair and equitable distribution of the benefits arising from the utilization of genetic resources in order to contribute to the conservation of biodiversity. Therefore, it is necessary to assess whether the absence of mandatory prior consent for access to traditional knowledge of unidentifiable origin and the establishment of a percentage for the sharing of monetary benefits are compatible with the spirit of the treaty in question.

Souza Filho (2017) criticizes the division made by the law between identifiable and unidentifiable knowledge. According to him, the “unidentifiable” is actually just a difficulty in identification. Also according to the author, such an obstacle should not be a reason to waive the need for

consent, since a more elaborate research could discover indigenous peoples and communities of origin. Silveira (2017) states that the percentages set for benefit sharing remove the decision-making power of traditional communities in negotiations, since the percentages have already been fixed by law. On this point, we dare to disagree with Silveira, because in addition to the fixed percentage of 0.5% to be paid as monetary distribution to the National Benefit Sharing Fund, the law provides for a variable amount to be negotiated between the user and traditional communities. Regarding the criticism made by Souza Filho, the difficulty in identifying the holder of the CTA is real, since it is about a knowledge that by its essence does not have a single (collective) owner and is extremely dispersed.

Since its inception, Law No. 13.123/15 has been criticized for the lack of participation of indigenous peoples. Compared to PD 2,186-16/2001, the aforementioned law was, in general, more harmful to these communities. However, it cannot be said that the Biodiversity Law contradicts the text of the Protocol, as the use of open clauses with expressions such as “each party shall take legislative, administrative and policy measures, as appropriate” provide a wide degree of discretion for the States Parties.

CONCLUSION

By establishing that terrestrial biodiversity is a common concern of humanity, abandoning the concept of common heritage, defended by the North, the CBD represented an enormous achievement for the countries of the South. The Nagoya Protocol was an offshoot of this movement, which was led by the Group of 77 countries, and which seeks distributive justice within the scope of international environmental law.

In Brazil, CBD was internalized in the Brazilian legal system through Decree No. 2,519/1998. However, only in 2001, as a consequence of the repercussion of the controversial case of the contract between the Organização Social Bioamazônia and the pharmaceutical company Novartis, was the Convention effectively regulated. Provisional Decree 2,186-16/2001 was the legislative instrument chosen to address the issue of access and benefit-sharing of genetic resources.

However, this MP was heavily criticized, mainly by researchers, for establishing many bureaucratic procedures to authorize access to genetic resources. The main focus of criticism was related to the Contract for the Utilization of Genetic Heritage and Benefit Sharing (CURB) and, in the

long term, to obtain authorization for access to genetic heritage from the CGEN. It was noticed that the excessive bureaucracy that, in principle, aimed to curb the practice of biopiracy, ended up discouraging research and innovation in the area, including at the national level (TÁVORA *et al.* , 2015).

In response to the limitations of the PD arose Law No. 13.123/2015, known as the Biodiversity Law. This rule brought greater flexibility to the rules of access to biological resources. However, the legal diploma has been severely criticized, starting with its undemocratic legislative process. As the law directly addresses a matter of interest to the indigenous community, a broad participation of their representatives in the discussions of the bill should have been guaranteed, which occurred in a very incipient way in practice (MOREIRA; CONDE, 2017). Also with regard to the indigenous community, the law establishes that there is no need to authorize access to resources derived from traditional knowledge of unidentifiable origin. The LDB established an unfavorable rule for Brazil regarding benefit-sharing, as it limited such sharing only to finished products in the production chain and reproductive material. This means that the so-called intermediate products (inputs used for the making of the final product) were excluded, causing the country to no longer benefit from the economic exploitation of intermediate products that use genetic resources from its territory.

Brazil actively acted as a defender and promoter of agreements in defense of biodiversity-rich countries in the negotiations of the Nagoya Protocol. Ironically, though, it took ten years to ratify it. One of the reasons for this delay was the distrust of the agribusiness sector. It turns out that, as there was wide adherence to the Protocol at the international level, Brazil, fearing isolation, ended up being forced to consider the ABS rules.

Against this backdrop, in 2021, the Protocol was finally ratified. The celebrations, however, did not last long, as Legislative Decree No. 136 of 2020 brought several conditions for the final approval of the text. Such conditions aim to ensure the coexistence of the Protocol and the Biodiversity Law in the Brazilian legal system. It so happens that some authors have stated that certain provisions of the Protocol conflict with the aforementioned law. However, no violations of the text of the treaty were found, since, due to the presence of generic clauses, the member States are authorized to regulate the matter in the way that is most convenient for them, as long as they respect the objectives of the agreement.

Law No. 13.123/15 removed many bureaucratic obstacles to scientific

research and greatly facilitated access to genetic resources by industry. However, it suffers from a congenital defect, as it emerged without the proper participation of indigenous peoples and traditional communities, violating arts. 6 and 7 of ILO Convention 169, incorporated into national law through Decree No. 5.051/2004. This tendency was perpetuated in the text of the law, which again ended up harming some of these populations' rights. Given this scenario, it is expected that the ratification of the Protocol will serve as a stimulus for the drafting of a new law that can maintain the improvements achieved by Law No. 13.123/15, as well as rectify the injustices committed by it. Furthermore, as the misuse of genetic resources ends up being an activity that is harmful to the environment, it is suggested that the National Congress enact a specific criminal type for the crime of biopiracy, in order to guarantee triple environmental responsibility in this matter, given the existing gap.

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