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ECOSYSTEMS

New Law of Brazilian Biodiversity: Legal Aspects and Impact in the Field of Biotechnology

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Abstract: Access to genetic resources (GR) and/or traditional knowledge associated with genetic resources (ATK) has been regulated in Brazil since 2001. The law 13,123 / 2015 determined a significant change in the theme, mainly on the rules of distribution of benefits obtained for conservation and sustainable use of biodiversity, the access to technology and technology transfer, the exploitation of products or reproductive material from the GR or ATK and consignment to the outside of part or all the living or dead organism shipped for GR. The implementation of international treaties on GR and ATK for research, biotechnological development and bioprospecting have been causing difficulties for Brazilian researchers, mainly due to the lack of information and dissemination available for compliance with the legislation. In this work, the members of the Committee for Access to Genetic Resources and Associated Traditional Knowledge of the Federal Fluminense University (UFFGEN) - Brazil, and collaborators performed a critical reflection on the new law, helping Brazilian researchers with information necessary to understand the changes made by the new legislation, especially in the field of Biotechnology associated with Brazilian Biodiversity.

Key words: Genetic resources, associated traditional knowledge, benefit sharing, biotechnology.

INTRODUCTION

Initially, law 13,123 / 2015 defines GR as information on the genetic origin of plant, animal, microbial or other species, including substances from the metabolism of these living beings and ATK as information or practice of the indigenous population, traditional community, or traditional farmer about the properties on direct or indirect uses associated with the GR. Established at the United Nations Conference on Environment and Development held in Rio de Janeiro in 1992 (popularly termed ECO 92), and enforced on December 29, 1993, the Convention on Biological Diversity (CBD) (UNO 1992, Brazil 1998) set-forth a legal framework that was established for the formation of national and international standards. These standards centered on five main objectives:

1 - "The conservation of biological diversity"

2 - "The sustainable use of its components"

3 - "The fair and equitable sharing of benefits arising from the use of GR and the adequate transfer of relevant technologies, taking into account all rights over such resources and technologies; and through adequate funding. "

4 - "National Sovereignty over GR"

5 - "Protection of ATK"

The ratification and thereby enforcement of the CBD aligned a State's right to protect its natural resources and common law of peoples on ATK with that of sovereign rights. According to Berger (2009), negotiations involving the juxtaposition of political issues and norms of biological diversity creates a fierce opposition between large companies and peoples with ATK of GR. History has evidenced these large companies' long-term interests in gaining access to GR for the purpose of research, technological development, bioprospecting, and biotechnology (with respect to research and technological development for economic pursuits). These histories also implicate a long stance in the pursuance of legislation advocating for minimal restrictions and legal requirements seeking to forgo protected sovereign rights for States wherein the biodiversity resides; and thus, undermining the intended purpose of the CBD (Taubman & Leistener 2008). The higher developed countries support the current system of intellectual property protection, the Trade-Related Aspects of Intellectual Property Rights System (TRIPS), an international treaty created by the World Trade Organization (WTO) in 1994. TRIPS (WTO 2005) seeks to protect and monopolize the ownership and development of new technologies and products, including those from biodiversity accessed through traditional knowledge. On the other hand, local and indigenous communities, most of them inhabitants of developing countries, rely on the 1992 CBD, which guarantees the sovereignty of States that have GR, establishing principles of fair sharing of benefits, GR and, consequently, the recognition of their cultural and collective rights, in addition to expanding their participation in the management of biological diversity and biotechnological products (Baylao & Bensusan 2000).

The geopolitical and socioeconomic implications associated with the branding of a country as being" highly developed" are espoused in the international model established by TRIPS. By design the treaty does not encompass the aspects of sovereignty protective, and managerial rights over one's GR of their biodiversity and the future technology derived from such as originally prescribed in the intent of the CBD.

An example of this is the concept of ATK, as it does not fit the requirements for patents, i.e.: novelty, inventive activity, application, and descriptive sufficiency, therefore ATK as industrial property does not meet the formal requirements of modern scientific and technological knowledge, and, thus, forfeits any sovereign rights for being considered as protected knowledge (Braithwaite & Drahos 2000). Such is the case for Brazil, which in 1988, that is, before the appearance of the CBD, the Constitution of the Federative Republic of Brazil (CF/88) (Brazil 1988) already recognized the importance of the genetic patrimony, so much so that it dedicated specific foresight to the chapter on the environment. Article no. 225, paragraph 1, item II, establishes that it is the Government's responsibility to "preserve the diversity and integrity of the country's general resources and oversee entities dedicated to the research and manipulation of genetic material" (Brazil 1988). However, it was only through Provisional Act (PA) no. 2.186-16 / 2001 (Brazil 2001a), later regulated by Decrees no. 3,945 / 2001 (Brazil 2001b) and 4,946 / 2003 (Brazil 2003a), that Brazil began regulating access to the GR of Brazilian biodiversity and its ATK. The protective measure was regulated through the granting of authorizations by the presiding government agency after the following conditions had been met: a detailed description of the research project and the proof of a prior consent granted

by the community in question. In fact, PA No. 2,186-16 / 2001 was abruptly ended after a leonine agreement signed between the Social Organization of the Brazilian Association for the Sustainable Use of Amazonian Biodiversity (Bioamazonia) and the Swiss pharmaceutical company Novartis, in which Novartis was given exclusive access to the biodiversity of germplasm in the form of strains of microorganisms and plants. In this agreement, the Swiss company was allowed to export live genetic material from the Amazon to the outside, on a large scale, for the manufacture of medicines, thus damaging the public interest. Furthermore, we should not forget that PA 2,186-16/2001 was criticized because it did not encourage companies to invest in Research and Development (R & D) due to the rigid and time-consuming bureaucracy that demanded high transaction costs with economic exploitation. The provisions set-forth by the PA made it difficult for researchers to follow, thus provoking many into illegal activities resulting in heavy fines and the abandonment of research (Gilbert 2010). Due to the regular desertion of research projects, Brazil is at risk to lose its ability to generate knowledge, new technologies and new products based on biodiversity, ultimately harming all the actors involved (Melo 2015). Since 2001, literature points to growing international interest in biodiversity and in the ATK to it, based on the increased economic potential and biotechnological outcomes associated with the intrinsic value of GR (Capobianco et al. 2001). Bioprospecting activity and the collection of biological material and access to its GR are directly involved in the search for new compounds for the development of new pharmaceutical, chemical and food products; moreover, the underlying motive of these activities can result in commercial exploitation (Bensusan 2005, Oberthür & Rosendal 2013). In the advent of the law 13,123, dated May 20, 2015, effective November 20, 2015 (Brazil 2015a) and repealing PA 2,186-16 / 2001 (Brazil 2001a), other significant changes were determined, as the regulation of paragraph 2 of paragraph 10 and article 225, paragraph 4, of the CF/88 (Brazil 1988), article 1, article 8 (j), article 10 (c), article 15 and article 16 (3) and (4), all of the CBD, promulgated by Decree no. 2,519, dated March 16, 1998 (Brazil 1998); and, further, it disposes on:

1 - Access to GR of the country (including domesticated species, varieties and locally adapted breeds or creatures and introduced species that form spontaneous populations, besides microorganisms that have been isolated in national territory, territorial sea, continental shelf or exclusive economic zone).

2 - ATK to GR, of identifiable origin or not.

3 - Access to technology and technology transfer.

4 - Exploration of the finished product or reproductive material from GR or ATK.

5 - The consignment to the exterior of part or all of organisms, alive or dead, destined to the GR.

6 - Implementation of International treaties on GRs and ATK.

7 - Benefit sharing for the conservation and sustainable use of biodiversity. According to the new law, the Genetic Heritage Management Council (CGEN) has the normative, deliberative, advisory and appeal functions, being constituted in 60% by representatives of public bodies and entities of the public administration and 40% by representatives of the partnerships among business, academic, indigenous populations, traditional communities, and traditional farmers. Law 13,123/15 brought new advances in bureaucracy in research, thus reducing the long waiting time that led to the processing of applications, which in some instances persisted for more than two years, to obtain authorization

for research. The request for authorization, a requirement of revoked PA 2.186-16 / 2001 was replaced by a compulsory registration with the National Genetic Heritage and Associated Traditional Knowledge Management System (SISGEN), in the effort of preventing scientists from being accused of biopiracy (da Silva 2017, da Silva & Oliveira 2018). The new law represents a revolt against the revoked PA by adopting modern and simplified procedures to foster research and leverage technological innovation; ultimately generating benefits for society as a whole. This new law has faced harsh criticism from various segments of society from the academic and legal sector (da Silva & Oliveira 2018). Apart from the severe budgetary constraints that have been affecting science in Brazil, the new legal framework regarding access to GR and ATK still generates a great deal of distrust and legal insecurity for the various actors involved. In retrospect, many statements and concerns cited in recent articles largely denote a dearth knowledge of law 13,123 / 2015 (da Silva 2017). The new legislation created mechanisms for guaranteeing social and environmental rights including the recognition of the right to intellectual and immaterial property of traditional peoples and communities. The aforementioned conditions are most favorable for access to GR for scientific and technological development to have full prosperity in a mega-diverse country like Brazil (Smith & Plagnol 2016). Furthermore, redressing the previous errors which led researchers to engaging in illegal activities, the assessing of hefty fines, and the eventual abandonment of research projects was the creation of Regulatory Decree 8.772 / 2016 (Brazil 2016), which provides better vehicles of intervention for scientists and researchers. In this context to this, GR and ATK Management Committees were set up within public institutions of education and research, such as the Commission of the Federal Rural University of Rio de Janeiro (UFRRJ), the Genetic Patrimony Commission of the State University of Campinas (PATGen) and the Committee of FIOCRUZ.

MATERIALS AND METHODS

Among others, UFFGEN (http://www.uffgen.uff.br) acts as an interdisciplinary collegiate of an advisory nature, exercising public functions and was created to contribute to the development of activities related to access to GR and ATK and to guide towards compliance with pre-established rules and laws by regulatory units. The Committee's activities are guided by the relevant rules and procedures, especially those issued by the CGEN of the Ministry of the Environment and include a set of guidelines for researchers, teachers, managers and the scientific community, playing a consultative and disseminating role, clarifying doubts and taking information about the subject in question to the scientific community in order to make it knowledgeable about the matter, which involves other actors, such as teachers, lawyers, as well as researchers of the health area, in a multidisciplinary way facilitating the exchange of dialogue and knowledge. In this work, the members of UFFGEN, and collaborators performed a critical reflection on the new law, helping Brazilian researchers with information necessary to understand the changes made by the new legislation, especially in the field of Biotechnology associated with Brazilian Biodiversity.

RESULTS AND DISCUSSION

About the biodiversity law nº 13,123/2015

Subject to criticism and negative positions by the scientific community and other sectors of interest, Brazilian biodiversity law still raises doubts about its efficiency, especially with regard to the clarifications necessary for its interpretation and its repercussions into the academic world. There are so many questions, especially, in the academic area such as: "Who is interested in this law?", "What benefit can this law generate?", "What its essential purpose is?" For some the law leads to completely loss of biodiversity control by the country and also the loss of competitiveness in the area of Biotechnology. Buckup (2018) considered that the protection of Brazilian biodiversity should encourage research on genetic patrimony so that Brazil can act with sovereignty over its biodiversity: "Imposing limitations on national research is to subject the country to subservience to other nations that do not adopt these types of restrictions at all. The idea that there is a need to control access to establish a market reserve for biodiversity is as misleading as the reservation of the computer market created in Brazil in the last century ". On the other hand, proponents of the law argue that it interests Brazil as a megadiverse country and because of the use of the biodiversity of other countries. Brazil, along with another 104 countries plus the European Union signatory, is signatory to the Nagoya Protocol, which is the international agreement that regulates "Access to GR and the fair and equitable sharing of benefits arising from their use" (*Access and Benefit Sharing)* - (ABS), i.e., "establishes standards and guidelines for the regulation of research and relations between the country provider of GR and ATK and who will use them, covering points such as the sharing of benefits, payment of royalties, establishment of *joint ventures* , right to technology transfer and training (da Silva 2019). Thus, with the new law, Brazil has left behind old customs and concepts about the exploitation and distribution of benefits over traditional products and knowledge derived from cultural and environmental heritage (see the section: reflections on the provisions of the law on the protection of ATK to GR). Therefore, as previously stated by Andrade (2013) about a law that could guarantee a fair protection to those who hold traditional knowledge as well as more effectively and legally facing biopiracy, current legislation has brought advances as compared to the previous however, adjustments are still needed, especially in the case for research without commercial purposes. The new law also emphasizes the importance of peer review amongst researchers for the purpose of critiquing and providing suggestions using the CGEN Sectorial Chamber of the Academy, such an adequate and legitimate space for these discussions and proposals (da Silva & Oliveira 2018). The Chamber is made up of members representing the academy including the Brazilian Botanic Society (SBB), Brazilian Society of Microbiology (SBM), Brazilian Society of Zoology (SBZ), Brazilian Anthropology Association (ABA), specialists in biotechnology and metagenomics as well as CGEN advisers including the Brazilian Society for the Advancement of Science (SBPC), Ministry of Science, Technology, Innovation and Communications (MCTIC) and Ministry of Environment (MMA).

The access to SISGEN

Created by Decree no. 8772/2016 that regulates the Law of Biodiversity no. 13.123 / 2015, the SISGEN is an electronic system maintained and provided by CGEN's Executive Secretariat, serving to assist the user in registering access to the GR or ATK as well as sending or submitting

samples containing GR, notifying finished product or reproductive material, applying for the authorization to access GR or ATK, requesting accreditation from institutions that maintain *ex situ* collections that contain samples of GR, and to obtain certificates and documents attesting the regularity of access. According to the Ordinance SECEX / CGEN # 1 of 3 October 2017 (Brazil 2017), the SISGEN was implemented and made available from the day November 6, 2017, at the website: <htpp: //sisgen.gov. br/ pages / login .asp>, and the regularization of all projects should be carried out until November 5, 2018. However, this registration procedure has been subject to harsh criticism since it did not respond and still does not meet the user's satisfaction as to its operability, nor did it properly consider some areas of research such as molecular phylogeny, which involves many different species; collections, that demands great problem of exchange with foreign institutions and farming covered by the law, which led to the extension of deadlines for the regularization of the projects to access GR and/or ATK.

Legal aspects of law 13,123/ 2015

In accordance with the Nucleus of Studies and Research of Brazilian Senate (Brazil 2015b) which disposes and comments on the provisions of the new law that may be questioned as to its legality and constitutionality, we can highlight some embarrassing points from the legal point of view.

From the use of the term "indigenous population"

According to the Constitution of the Federative Republic of Brazil (Brazil 1988), the expressions "populations", "communities" and "groups" are those established in the infra-constitutional text. However, after more than twenty years of discussion regarding the condition of the indigenous people of Brazil, there was a technical and academic understanding that the correct term was to designate these groups as "peoples" thus recognizing the ethnic and cultural identity of these groups beyond that which is autonomous regarding the subject of collective rights, and with the rejection of attributing said group's wealth of knowledge and understanding to a universal principle and/or idea. The problem in designating these groups as "nations" is the strong political connotation that this term reinforces a homogeneous identity among said peoples and therefore contradicts the already accepted anthropological understanding affirming Brazil as a multi-ethnic and plurinational State. (Schiel & Smith 2002)

As a signatory to Convention no. 169 of the International Labor Organization (ILO), the Convention on Indigenous and Tribal Peoples promulgated by Decree no. 5,051 (Brazil 2004), ratified the understanding that standardizes the treatment of indigenous peoples as "peoples" and that this nomenclature is adopted by Brazilian legal system. In addition to the Convention no. 169 of the ILO, there is the United Nations Declaration on the Rights of Indigenous Peoples, adopted by General Assembly on 13 September 2007 (ILO 1989, UNO 2007), which confirms and uses the term "indigenous peoples" in respect for the rights of those living under their own ways of social organization, customs, and traditions, strengthening the recognition of their autonomy and not independence.

The legal nature of the benefit allocation to the National Fund for the Benefit Division (FNRB).

Law 13,123 of 2015 (Brazil 2015a) provides for two types of benefit sharing: monetary or non-monetary (art.19). The monetary allocation may be: a) optional (art.19, §1), when there is

economic exploration resulting from access to the GR; and b) mandatory (article 23 and § 2 of article 24), when there is economic exploration originated through access to the identifiable and non-identifiable ATK. In such cases, the proceeds from the sale of the finished reproductive material from national GR and/or ATK that garner a return of 0.1% to 1% (one percent) of net income shall be deposited in a public fund, FRNB. Microenterprises, small businesses, individual microentrepreneurs, traditional farmers and their cooperatives with annual revenues equal to or less than those established in relevant legislation will be excluded from the obligation to distribute benefits. In addition, the intermediate product used in the production chain is also exempt from the obligation to share benefits. In the present case, it is important to note that, according to the legal understanding of the country, the question of revenues earned on behalf of the public authority, in this case, the amounts received as benefits-sharing, can generate controversies in view of the need to define which legal category benefit sharing fits. It is understood that public revenue can be classified into two species according to the doctrine of financial law: originating revenues and derived revenues, both based on law no. 4.320, dated March 17, 1964 (Brazil 1964a). According to this doctrine, the originating revenues are those that originate in the State's assets (assets revenues) or in the profitable exploitation of these assets by the State (business revenues). That is, the revenues indicated above come from the *jus gestionis*, when the State acts in the same way as individuals. In turn, derived revenues are derived from the manifestation of *jus imperii*, from the tax authority of the State. Here the collections are the result of coercive acts by means of legal constraint of the patrimony or the income of the private individuals, as is the case of taxes and fines. By making a brief interpretation of the bill that was forwarded to Congress by the Executive Branch and which culminated in the law 13,123/2015 (Brazil 2015a), one can state that what was intended was the creation of a model of collection of resources in the modality of original revenue, however, without specifying in the project, expressly, the definition of the taxable species, the generating fact, the calculation basis for taxpayers, guidelines for requirements and legal support for the creation of a tax.

From the point of view of financial law no. 4,320, of 1964 (Brazil 1964a) in its article 9, defines tax as:

Tax is derived revenue created by public law entities, including taxes, fees, and contributions in accordance with the constitution and laws in force in financial matters, and its product is allocated to the cost of general or specific activities carried out by these entities.

From the point of view of tax law, the concept of tax is provided in the National Tax Code in the following terms:

Tax is any compulsory pecuniary benefit, in money or whose value can be expressed in it, which does not constitute sanction of an unlawful act, established by law, and charged by administrative activity and fully bound.

In order to be able to identify, in particular, the legal nature of the tax imposed by the Federal law 13.123 / 2015, when it is part, on the receipt of amounts due to access to the GR and/or ATK, it is necessary to stick to the model in the old PA nº 2.186-16 of August 23, 2001 in its Contract of Utilization of GR and Benefit Sharing (CURB), where such revenues would be classified as originating. In that PA, the two types of monetary benefits, by way of benefit sharing, derived from the profit sharing and the payment of *royalties* (items I and II of the PA article).

Law No. 4,506, dated November 30, 1964 (Brazil 1964b), classifies as *royalties* the following revenues:

Art.22. The income of any kind arising from the use, enjoyment, exploitation of rights, will be classified as "*royalties*", such as:

a) the right to harvest or extract plant resources, including forestry.
b) the right to research and extract mineral resources.
c) use or exploitation of inventions, manufacturing processes and formulas, and trademarks of industry and commerce.
d) exploitation of copyright, except when perceived by the author or creator of the property or work.
e) Single paragraph: Interest on late payment and any other compensation for late payment of the royalties shall accompany the latter's classification.

What was intended by the new legal framework with law 13,123 / 2015 (Brazil 2015a) regarding the receipt of amounts as benefit-sharing was similar to the model adopted in the former PA, where the payment of a percentage of the annual net revenue earned due to the exploitation of finished product or of reproductive material resulting from access to GR and / or ATK.

In this case, it is possible to assume from the point of view of financial law that the GR is well publicly owned, thus recognizing its legal adequacy of the benefit sharing provided for in law 13,123 / 2015. Therefore, it is concluded that the identification of the original revenue will always depend on whether the public revenue is derived from the state equity or from the exploitation of that equity. On the other hand, they will be classified as derived revenue, in this case, taxing those that are not derived from the access to the state patrimony. As stated in the CF/88 and law 13,123 / 2015 (Brazil 2015a), authorize the controversial belief that GR is a public good. In the environmental part of its article 225 of CF / 88, states that the environment is for the common use of the people, while item I of article 1 of law 13,123 / 2015 establishes that the GR has the same nature legal basis. The new legal framework states the following:

- Art.1º. This law provides for assets, rights and obligations relating to:
- I - the access to the GR of the country and of common use found in *situ,* including domesticated species and spontaneous populations, or kept in *ex situ* conditions, provided that found in *situ* within the national territory, the platform the territorial sea and the exclusive economic zone.

As for the classical subdivision of goods in public or private, the basis of article 99 of the Civil Code of 2002 follows, which reads as follows:

- Art. 99. They are public goods:
- I - those of common use of the people, such as rivers, seas, roads, streets, and squares.
- II - those of special use, such as buildings or land intended for the service or establishment of the federal, state, territorial or municipal administration, including those of its local authorities.
- III - the proprietary, which constitute the patrimony of legal entities under public law, as an object of personal or real right of each of these entities.

In this way it can be deduced that the GR is a public good (in the subspecies, well of common use of the town) and the State, therefore, is authorized to demand by means of legal prediction, the payment of value due to the economic exploitation of product derived from access to genetic information through royalties which is a form of original

revenue. In disagreement with law 13,123 / 2015 (Brazil 2015a) and also with CF / 88 (Brazil 1988) that defines GR as a public good, the doctrine of environmental law supports a different concept for this definition, arguing that GR would be classified in a third genus of goods, distinct from public goods and private goods, that is, GR would be called an environmental good. This trend is defended by some jurists, such as Celso Pacheco Fiorillo: "In verifying civil law, we note that the basic powers of traditional property law of the nineteenth century are understood by the right to use, enjoy and dispose of the good. In turn, the Brazilian Federal Constitution of 1988 (Brazil 1988) innovates the ordering, highlighting of the environmental good some of these rights and protecting assets that are not susceptible of appropriation, either by the individual or by the legal entity. In fact, the Constitution formulated revolutionary innovation in the sense of creating a third kind of good, which, due to its legal nature, is not confused with public goods, much less with private ones (Fiorillo 2019). The aforementioned jurist even maintains the unconstitutionality of item I of article 99 of the Civil Code, (Brazil 2002), removing the characterization of environmental goods as public goods, in the following terms: " Thus, as already stated in previous editions of our course on Brazilian environmental law, we reiterate the statement that not only is article 66, I of the Civil Code of 1916 (Brazil 1916), not fully accepted by the Federal Constitution, and article 99.1 of the Civil Code of 2002 is clearly unconstitutional. The examples of common use goods mentioned in the civil subsystem have their legal definition specifically set out in constitutional (Arts. 182, 183 and 225) and infra constitutional environmental standards (rivers and seas as environmental resources in the natural environment as defined in the law as well as roads, squares and streets as environmental resources of the artificial environment defined in laws 9,503 / 97 (Brazil 1997b) and 10,257 / 2001, (Brazil 2001c). If this is the understanding, in which the conclusion of the environmental law doctrine prevails, even in the light of the literality of item I of article 1 of law 13,123 / 2015, the legal nature of the revenue from the distribution of benefits to FNRB may be interpreted as other way. In other words, by excluding public ownership of the GR, the tax character of these revenues would then be set, and, lastly, derived in nature. Surely, it would be necessary to define which kind of tax would have been created by law 13,123 of 2015 and whether it would have a constitutional basis for the creation of a new tax. However, before mentioning the possible tax nature of the benefit-sharing, the legal possibility of qualifying the GR as a Union good can be gauged by detailing the reading of article 20 of CF / 88, which describes what is owned of the federative body.

- Art.20. They are Federal Union goods:
- I - the ones that currently belong to the Union and those that are to be attributed to it.
- II - the vacant lands indispensable for the defense of borders, fortifications and military constructions, the federal means of communication and environmental preservation, as defined by law.
- III - lakes, rivers, and any watercourses on land in its domain, or which cover more than one State, serve as boundaries with other countries, or extend to or from foreign territory, as well as marginal lands and beaches fluvial.
- IV - the river and lake islands in the border areas with other countries; the sea beaches; the oceanic and coastal islands, excluded from these, those that contain the headquarters of municipalities, except those areas affected to the public

service and the federal environmental unit, and those referred to in art. 26, II.
- V - the natural resources of the continental shelf and the exclusive economic zone.
- VI - the territorial sea.
- VII - the lands of the navy and its additions.
- VIII - hydraulic power potentials.
- IX - the mineral resources, including subsoil.
- X- the underground natural cavities and the archaeological and prehistoric sites.
- XI - lands traditionally occupied by Indians.

In analyzing item I of the provision, evidences other assets belonging to the Union, while other assets not found in the law may be attributed to it. Therefore, when considering GR as a public good, ownership would be exclusive to the Union. The tributary species are divided into taxes, rates, improvement contributions, special contributions and compulsory loans. Considering the characteristics presented in the law one can conclude that tax revenues as a bioproduct of GR are a contribution before the linkage of the product collected identified with or a specific purpose. Linking is one of the most characteristic traits of the contributions. In the case of the Biodiversity Law, the correlated tax contribution appears to conform with those prescribed and authorized by CF / 88 in its article 149 and considered by the Brazilian Federal Supreme Court as constitutional by means of an ordinary law, the Contribution of Intervention in the Economic Domain (CIDE - *royalties*), by way that the Union has the exclusive competence to levy this form of taxation. However, although there is no problem in recognizing that the new legal framework created a CIDE, from the legal perspective, the tax legislation is ill-conceived by its lack of necessary elements, more specifically related to the legal text for this purpose, since the tax elements are not explicitly stated in the legal text, namely: aspects (active and passive subject) and quantitative (basis of calculation and percentual). This paper presents the results of the study while providing basic requirements for the creation of a tax in line with CF / 88 that presupposes all aspects mentioned in the text, although not expressly stated. Thus, for all the above reasons, it is felt that the rule to be followed is from the point of view of financial law while recognizes that GR is owned by the Union. Consequently, it can be seen that the classification of GR that generated revenues should be treated as values originating from the deposits by the economic agents as a result of the economic exploitation derived from access to GR. Thus, the assertion of GR as a Union owned good would remove the tax character of the revenue and alleviate problems with respect to constitutionality and the jurisdiction of the adopted model.

The legal nature of the allocation of benefits intended as a result of the economic exploitation of the ATK.

The controversy generated by the economic exploitation of ATK, arises from the benefits and amounts received as a result of said activities. Law No. 13,123, of 2015 (Brazil 2015), in article 2, item II, provides that the ATK is an information or practice of indigenous population, traditional community or traditional farmer on the direct or indirect properties or uses associated with the GR (Smith & Fausto 2016). Therefore, it is possible to verify with this understanding that the property in question belongs to the communities and people and not to the State. This discussion would lead to the same rules as the prevailing hypothesis of this understanding that ownership of the ATK belongs to communities and individuals, and therefore, derived revenue, would not be exempt from the aforementioned

tax rules and analysis. no escape from the tax rules that would be analyzed under the terms described above. According to CF/88 and the National Tax Code, GR is the identification code for all elements in the tax incidence matrix rule, while having this uniform code the law allows for adequate capture of the unique derivatives from each element (Brazil 1966). However, what is best concluded here is the understanding from the financial point of view, also with the positioning of the doctrine that the ATK is in the public domain even though the State recognizes the rights of the ATK providers and derives benefits as a result the economic exploitation, by third parties of finished product or of reproductive material. The other orientation - to which we are affiliated - intends to create a *sui generis* legal regime, that is, totally different from the patent system, both from a conceptual and an evaluative point of view. This guidance is based on the fact that the entire patent system, which protects intellectual property rights, protects the so-called "new knowledge" as being individually produced and not the product of ATK knowledge generated collectively and informally and transmitted orally from one generation to another. These are considered, within the current system, as belonging to the public domain, and without any patent protection (Santilli 2005a, b).

Reflections on the provisions of the law on the protection of ATK to GR

Article 8:

As its core, the article 8 clearly defines that the scope for understanding that the GR in question belongs to indigenous peoples, traditional communities and traditional farmers is clear the suggestion proposed by the Nucleus of Studies and Research of Brazilian Senate (Brazil 2015b) makes the wording clearer by stating: "The rights of indigenous peoples, traditional communities and traditional and family farmers over ATK to GR are protected by this law."

Art. 9: Prior Informed Consent

The paragraph 1 of the article 9 guarantees indigenous peoples, traditional communities, and farmers' autonomy consenting to access to ATK associated with GR, however, establishes that the procedural manner of access is not only authorized by CGEN, but must also be heard by the designated indigenous governing body. The important thing here is to clearly establish the mandatory listening of the indigenous agency to prevent the asymmetry of information between the many indigenous peoples and the parties interested in the indigenous ATK as an effort to decrease the possibilities of leonine contracts. article 9, paragraph 3, provides that the ATK is a non-identifiable origin whose access to the traditional local or creole variety or the locally adapted or creole breed has taken place, thereby removing the legitimate rights of the holders of such knowledge. It is of the utmost importance to deepen the discussion with the participation of all concerned about possible distortions that this device may cause. By the wording of the device, it is enough clear to say that any interested party who has access to copies of these components of GR can avoid the obligation to respect and compensate the ATK holders.

Regarding the ATK of non-identifiable origin defined in article 2, item III, there is the possibility that the knowledge may be linked to a specific source in the future due to better studies, technical review or dispute resolution on origin or authorship. In this way, there was a lack of mechanisms in the law to compensate the holder of this knowledge or any contingency reserve for this case in the FNRB.

Article 10, item V - On the Law of Cultivars (Law No. 9,456, of 1997, (Brazil 1997a) and the Law of Seeds (Law No. 10.711, of 2003), Brazil 2003b)

The normative content of the new law regarding the rights that indigenous peoples, traditional communities, and traditional farmers have to use and freely sell their products that contain ATK is already born fragile. According to the provisions of law 13,123, of 2015, the rights of these peoples over plant GR are limited since they are bound by the definition established by the Ministry of Agriculture, Livestock and Supply (MAPA) - which establish the Law of Cultivars and Seeds - without recognizing CGEN's competence on the issue of ATK.

The current criticism is that the identification of creole seeds by MAPA has been carried out with discretionary and not very precise criteria from the point of view of scientific point of view. Going in the opposite direction, where new scientific criteria based on the use of molecular markers for the definition and identification of locally adapted creole seeds and races is what accompanies modern genetics today. Since native seeds provide intrinsic ATK, this assumption directly affects the rights of holders to benefit from the benefits generated from the GR of agro-biodiversity. It is important to point out that law no. 10,711 of August 5, 2003 (Seed Law) (Brazil 2003b) in its article 2, item XVI, defines a variety of creole different from law 13,123 / 2015, providing that this definition is at the discretion of MAPA. This discretion has the potential to generate ambiguity in the interpretation of what it means to be creole, and thus affecting the benefits derived from this classification.

Article 24: Benefit Sharing Among Other Holders of ATK

As provided by law, the distribution of benefits may be mandatory and not mandatory, however, article 24 provides that in addition to sharing benefits with the ATK provider, sharing with other holders of such knowledge will also be mandatory through the FNRB. However, there may be inequality and unbalanced with the FNRB if transfer of technology, technical assistance, human resources training, and product distribution are established as a form of benefit sharing.

Absence of Prior Consultation of Indigenous Peoples

According to the Convention no 169 - ILO promulgated in Brazil by Decree No. 5,051, of April 19, 2004, indigenous peoples must be consulted in advance to express their views on any laws or regulations that may affect their rights. Regarding the procedures that resulted in law 13,123 / 2015, it did not count on the participation of the indigenous peoples or the federal indigenous body satisfactorily (Smith et al. 2006). Therefore, the law is in direct affront to the provision of this Convention and may hold the federal government accountable nationally and internationally. In short, with the advent of the new law, the benefit-sharing model was defined in monetary and non-monetary modality, which simplified and established clearer rules for its effectiveness. The previous rules established in PA nº 2.186-16 of 2001 inhibited the access and made it almost impossible to materialize the distribution of benefits due to the difficulties of identifying the beneficiaries and, consequently, of reaching an agreement on values to be distributed. In addition, each stage of the innovation process was subject to allocation. The extinction of the Contract of Utilization of GR and Benefit Sharing (CURB), which was the procedure adopted by PA nº 2.186-16 (Brazil 2001a), and that, frustrated in advance any initiative of access instead of generating a high cost of transaction for the

authorization of CURB, has been replaced. In its place was created the ABS whose requirement is derived only for the exploration of finished product or reproductive material and at a time after all innovation activity has ceased. In this way, it facilitated the emergence of innovations and exempted the process of licensing and transfer of technology involving university patents. The discussion here arises at a time when, even with the advancement and simplification of procedures to be adopted for an ABS that excluded the manufacturers of intermediary products. According to article 17, paragraph 5, I, allowed for the cascading effect in the avoidance and exemption from benefit payments and the distribution of benefits to intermediate links of the production chain, including large company producing inputs from the originating GR and ATK and its main buyer's microenterprises, small business and individual microentrepreneurs.

Another important concern that has been discussed by jurists is the requirement embedded in article 17 that the GR or ATK component is one of the key elements of value adding of the finished product for benefit-sharing. Subsection XVIII of article 2 states that such elements are those "whose presence in the finished product is decisive for the existence of the functional characteristics or for the formation of the marketing appeal". Such a definition is not consistent with the reality of the facts since it is subjective and may motivate numerous litigations because of the difficult verification of these determinants. A clear example of this contention lies in the fact that only the manufacturer has a real idea of the weight of each component in the definition of the value of its product and does not disclose that information for reasons of secrecy or intellectual property rights. The most vulnerable will bear the legal burden of proving that the element in a possible judicial dispute is decisive for the existence of functional characteristics or for the formation of the marketing appeal of the finished product. From this it can be seen that there is a non-negligible risk that many companies will not comply with the obligation to distribute benefits on the basis of the argument of the GR component or the ATK present in the finished product is not among the main elements of value added. Under the new legal framework, the Union will establish by decree the List of Classification of Benefit Sharing, based on the Mercosul Common Nomenclature (MCN). In the original draft submitted to the House of Representatives, a "positive list" was proposed in which the distribution of benefits of finished products would only occur exclusively on the products provided for the list. This list was jointly defined by the Ministries of Environment, Ministry of Development, Industry and Foreign Trade and Ministries of Science and Technology and Innovation. However, although it was drafted together, it did not make it clear what kind of list it would be. It should be emphasized here that, if it is a positive list, until it is edited, no product will be eligible for benefit-sharing. The ones that would be disadvantaged would be the right holders of benefit-sharing rights, for example, on cosmetic products that, as it happens, have a short life cycle? On the other hand, innovative products might not be on such a list. Actually, what is really intended is a "negative list" i.e., exemption from benefit sharing, for example with products considered essential and strategic by the Union for public health innovative products might not be on such a list.

For all of the above, the new legal framework establishes that the ATK can be classified as having an identifiable or unidentifiable origin, making the rules simpler and clearer on the distribution of benefits. Thus, the problem created in the previous rule, PA No. 2186-16

(Brazil 2001a), which was the need to identify all ATK holders before concluding a benefit-sharing contract, was overcome.

On the provisions dealing with matter regulated by the CBD and the environmental legislation

Law 13,123 (Brazil 2015a) regulates certain articles of the CBD, promulgated by Decree No. 2,519 (Brazil 1998), as part of Brazil's commitment to internalize CBD objectives, principles, and guidelines through of its own legislation. According to doctrinal and jurisprudential understanding, the new regulatory framework is the specific law that will have its preponderant application to the CBD. Such a situation may cause legal uncertainty regarding article 2 that, in spite of establishing new concepts, it proposes to consider the definitions contained in the CBD. In the case of item I of article 2 of the law, for example, defines GR as "information of genetic origin of plant species, animals, microbial or other species, including substances derived from the metabolism of these living beings ". The term "or species of a different nature" may generate legal uncertainty and allow for different interpretations to the detriment of legislative technique and the second part to include "substances" differs from the concept of GR as "genetic information" since in the CBD text, definitions of genetic and biological resources, conceptualize genetic material as "material of plant, animal, microbial or other origin that contains functional units of heredity". Due to the ability of biotechnology to synthesize assets from information available in a database, regardless of the genetic material to complete its process of technological development may conclude that the concept of GR adopted in the law is the most appropriate. More importantly is the fact that with the current technological development it is possible to obtain all the necessary information from other types of molecules, other than the hereditary ones, like proteins and other metabolites. In addition, information from genetic material should be protected, since once accessed it could be freely distributed, especially those associated with the reading and sharing of genetic data. Consequently, the genetic material would lose importance to the user, causing harm to the provider (Brazil 2015b, Santos et al. 2018).

Regarding the sample collection of GRs as a triggering factor for the obligation to obtain authorization or registration, this is not provided for in the new law, since item VIII of article 2° provides that access to the GR is considered the research or technological development carried out on a sample of GR and will be required to register, authorize, or notify the competent authority. In clause X of the same article, the research is defined as the:

"Experimental or theoretical activity carried out on genetic patrimony or ATK, as the objective of producing new knowledge, through a systematic process of knowledge construction that generates and tests hypotheses and theories, describes and interprets the fundamentals of phenomena and facts observed."

In this sense, article 3, when deciding on the purposes of access such as research or technological development, repeats the very definition of access, which is precisely research or technological development. When conceptualizing access as research or technological development, it may be assumed that collection, an activity not regulated in the law, is an inherent act of research. When analyzing article 14 of the Law of Fauna (Brazil 1967) it establishes the possibility of granting to scientist's special license for the collection of material destined for scientific purposes, at any time. By not referring to the Law of Fauna, any collection of material presupposes,

today, the technical possibility of accessing the GR. Therefore, it is recommended to insert a new paragraph to article 14 of the Wildlife Law, whose purpose would be to clarify that "the collection referred to in *caput* does not authorize access to GR, which will observe specific legislation". "It is important, for now, to mention that paragraph 1 of article 14 of the Wildlife Law authorizes foreign scientists to obtain a license to collect material, through an official scientific institution. However, the new regulatory framework is closed in paragraph 1 of article 11, access to GR by natural person foreign. Therefore, when it appears that the collection of material, when considered as part of the research activity, can make the access to the GR possible, though it is suggested by lawyers and parties involved that the first paragraph of article 14 of the Wildlife Law, since the prohibitive or authorizing regime for the foreign natural person should be symmetrical between the laws. Another point worth mentioning is the forecast, in article 13, items I and II, of the requirement of prior consent of federal agencies in situations involving access to the GR or ATK in an area indispensable to national security or in Brazilian jurisdictional waters, the continental shelf and the exclusive economic zone. In this case, there was an omission of the law regarding the activities of GR and ATK in conservation units that are regulated by law no. 9,985 (Brazil 2000). It should be specified in its own device and for legal certainty, according to the understanding of the Nucleus of Studies and Research of the Legislative Consulting (Brazil 2015b) that the activities of access to the GR or the ATK in conservation units will depend on the prior authorization of the body responsible for the administration of the unit and will be subject to the conditions and restrictions established by it, as well as those established by regulation.

Further analysis of the articles 8 and 44 of the law

Regarding the final content of the provisions of paragraph 2 of art. 8 of law 13,123 (Brazil 2015a):

paragraph 2: The ATK associated with to GR referred to in this law is part of the Brazilian cultural heritage and may be deposited in a database, as provided by the CGEN or specific legislation.

Here there is a conflict of jurisdiction, since an act of the CGEN could not be equated with specific legislation, nor could it deal with matter reserved to the law or modify understanding present in the current legislation. An act of the CGEN is considered secondary normative act of whose foundation is taken away of the laws to which it would be subordinated and, indirectly from the own Federal Constitution. On the basis of that provision, acts of the CGEN could deal with matters outside its jurisdiction and, until the judiciary decided on possible abuses, those acts would be presumed to be valid and therefore infringing rights. Thus, a correct registration on SISGEN seems to be nowadays the best way to prevent legal troubles to Brazilian researchers once they send any GR or ATK material to foreign.

Analysis of Art. 44

The criticism here is about the remission of civil damages related to GR or ATK to rights of the Union. There is loss of rights of the Brazilian State when economic agents who failed to comply with the current legislation have benefited from the amnesty. There are estimates that the Union would be assuming a loss of revenue of nearly R$ 220 million. On the other hand, it is argued as to the legality of the fines imposed and that these would be ineffective in the face of the low capacity of the State in its collection and also because such collection processes are uneconomical, above all, and mainly, that a large portion of these fines were

imposed on researchers of public institutions and not biopirates. Thus, these important actors would not benefit economically from the difficult and long research work, provoking a negative effect by discouraging the research process.

Biodiversity law X Biosafety law

In article 4, the law provides for non-application to human genetic patrimony but does not make any reference to the application of the Biosafety Law (Brazil 2005) that regulates items II, IV and V of paragraph 1 of article. 225 of the Federal Constitution and establishes safety standards and mechanisms to supervise activities involving genetically modified organisms (GMOs) and their derivatives. In addition, it creates the National Biosafety Council (CNBS), restructures the National Technical Biosafety Commission (CTNBio), provides for the National Biosafety Policy (GNP) and repeals the former Law of Biosafety (Brazil 1995). It is understood that the revoked PA no 2.186-16 (Brazil 2001a) in its article 36 expressed clearly that its provisions would not apply to the matter governed by the former Biosafety Law. This same understanding was adopted by the new framework excluding the possibility of discussion on the application of aspects related to biosafety and biotechnology. With regard to legal certainty, the Nucleus of Studies and Research of the Legislative Consultancy speaks with assertive precision on the theme: legal certainty derives from the fact that the forecasts on access and research, for example, are not uniform in both legislations. As an example, an argument about tacit abrogation of the future law with respect to the Biosafety Law would be possible, with the aggravating fact that the law on biodiversity is later. In addition, the new legislation could prevail, even with the understanding that the new legislation does not intend to regulate that matter, generating problems in the application of the new legislation. On the issue of GMOs, which should also be regulated by the new legal framework, there is a discussion on whether the Biodiversity Law will overlap on the Biosafety Law.

Impacts of the new legal framework on the field of biotechnology

The new legal framework (article 8 to 10) had great impact in the areas of biotechnology related to the environment, traditional knowledge, and agriculture. As an example of this is the regulamentation found in article 225 of CF/88 which was especially important in the preservation of national biodiversity as it regulated the access to GR and ATK. According to article 9, the law guarantees that only the results will be subject to laws which include taxes and benefits sharing, not processes involved in the research itself. In this compass, the discussion about the biodiversity problem in relation to the transition from an intensive techno-economic paradigm in fossil energy from natural resources to another based on information and the growing use of science and technology in the productive process, reveals, in this context, the importance of advanced biotechnologies as a mean to add value to biodiversity in the globalized market, valuing not the living organisms themselves, but the genetic information contained therein. Information, as said before, occupies an increasingly prominent place in contemporary societies. The so-called new technologies comprise a series of applications of scientific discoveries, whose main objective is the development of an increasing capacity of information refinement, as well as its direct application in the productive process, both in symbolic information through intelligent communication and in microelectronics and computer science, or through living matter through genetic engineering, the basis of advanced biotechnologies. In the case of

biotechnologies, biological and genetic diversity become a basic raw material for the advances that have occurred in this area, transforming it from mere natural resource into an information resource. On the other hand, there is an asymmetric spatial distribution of biogenetic resources and scientific-technological resources (Albagli 1998). While most of the biodiversity is found in developing countries, the knowledge that underlies modern biotechnologies is located in advanced economies (Da Silva 2017, Oliveira et al. 2017)

In this context, the control of strategic information, as well as the techno-sciences that add value to this information, becomes one of the centers of dispute and conflict in the international economic and political scenario. Such control can be exercised both in the domain of access to biodiversity resources and in the protection of intellectual property rights, in modern biotechnologies and in the ATK of local peoples. Therefore, the discussion on biodiversity is no longer an ecological or scientific-technological issue to assume a geopolitical dimension, but also that "the privatization of life are two facets of this process. However, it can be verified that biodiversity is invested with a double meaning: as an essential element supporting life and as a reservoir of future value. In general, the concept of biotechnology may include any technique which uses living organisms (or parts of organisms) with the aim of producing or modifying products; improvement of plants or animals and discovery of microorganisms for specific uses (Dahms 2004). It was in the early 1970s, from the recombinant DNA technique, that it became possible to transfer genetic material between living organisms by biochemical means that biotechnology came to be denominated by two concepts: traditional biotechnology and modern biotechnology. The latter associated with the possibility of obtaining products and substances through new genetic techniques and not only coming from the crossing of species found in nature. Today, scientific advancements in biotechnology fields motivate high hopes for disease prevention since most of them come from genetic component as well to increase the food supply in general, besides to promising high economic gains with the new products generated. From the linkage of molecular, chemical, and genetic biology, the possibility of not only unraveling the mysteries of the genetic code but also of being able to manipulate it has opened up, which makes the twenty-first century a harbinger of new age, the gene, or the scientific paradigm.

Impacts of the law on biotechnology with regard to patents

The positive impacts in the framework of the law on patents in Brazil, can be attributed to the participation of the industrial sector in the CGEN. Through their active participation, much has been elaborated regarding the weighting issue of inputs in the production process. This contribution is imperative, especially regarding the cosmetics sector among others that have contributed to the positive effects resulting from the new law. Consultants and experts were hired to ensure that companies and their researchers were duly monitored to join SISGEN in a timely manner. These measures were taken as way to better gauge the use of exemptions and fines that were applied to those institutions and some researchers, during the validation process (Brazil 2001a), This newly adapted process provided flexibility in the issuing of exemption and fines to account for previous allowances of activities that were no longer permitted in the adaptation of the new law. These exemptions from fines included prior acts committed by companies and researchers that were done without the authorization of the competent

bodies to search GR and/or ATK. However, these penalties that occur imposed to institutions and researchers are, until now, *sub judice*, since due to legal inconsistencies of the law itself, and thus, the decisions still have not been possible to be proclaimed. There are still many doubts about the legality of collections and questions of legal interpretations. The negative aspects of the law can be attributed that even today researchers and companies still feel insecure on how the new law can be interpreted. Many academics have defended and still defend the thesis that the law did not benefit research and that this would leave researchers in a vulnerable state due to legal uncertainty and uncertainties regarding the registration deadlines in SISGEN. This sentiment has led many researchers to abandon their studies with Brazilian products including research using what can be considered as cutting-edge Brazilian technology and consequently damaging the national economy and the country's biodiversity. There is an outcry that the flaws in the registration system are sometimes incorrigible and in fifteen years of drafting the law no specialized technical assistance was hired to aid in the operation of the new system that would effectively enable the registration in SISGEN. In short, what is clear today is that there is a more proactive attitude on the part of companies to inform themselves and to conform to the new law than the academic sector that is still resistant to some aspects of the law.

The Brazilian patent law no 9,279 (Brazil 1996), had been made early at a non-favorable moment, and is considered by some specialists to be very restrictive, because it did not anticipate advances in biotechnology, because of an industrial backwardness of the country itself and, therefore, for not obtaining patent possibilities. At the same time, Brazil has the greatest biodiversity on the planet, 24% according to the UN, and it is already known, economists predict, that more than 70% of the drugs that will serve humanity in the future will come from this biodiversity. A primary example of this is a drug currently being produced and patented by the Swiss company NOVARTIS for the cure of a degenerative disease, such as family hypertrophy, will cost around R$ 4 million. The question is: who can pay for this treatment? The answer that biodiversity and biotechnology can counter this onerous demand is that its biotechnological products have a particularly important bias in terms of the equality of treatments and their availability to the public. In the case of Brazil, due to a delay in the technological industry, we do not have the power to deposit patents on natural products, technology, molecules, extracts, etc., since the promotion and public policies focused on the issue of innovation and technology are basically in public health and education. Who will put the biotech products on the market is not the Brazilian industry, but the companies from the most technologically advanced countries that have the resources to invest in technology and take the risks that the results can bring. In Brazil, the money invested in technology is public, which makes research even more difficult, since in the developing countries public funds are directed to other essential purposes such as education and health as stated before and cannot take risks. This time, it is easy to see that such propositions and investments in science and biotechnology, as well as the filing of patents on products of Brazilian biodiversity, will be carried out by companies located in technologically developed countries (Angeli 2017). Here, it is worth mentioning that living matter may be subject to corporeal, public, or private property, (e.g., through ownership over the outcome of a harvest), and intellectual property, which is exercised for a fixed term in accordance with

the legislation established in each territory, according to general principles defined internationally. Thus, patents have been granted for technological innovations related to all or part of living beings, be they microorganisms, plants, or animals (processed by genetic engineering or not), as well as for gens or part thereof, covering products, their uses, and processes of obtaining them. However, intellectual property rights over living things or biological material derived from these metabolic processes are related to the information contained therein in the genes of the organism and not in the organism itself, other than the physical or bodily property of a given species of animal or plant. In the case of a pseudo-inventor granting intellectual property rights over a living being or biological material may affect access to it or some part of it, as well as the use made of it, enabling the exercise of monopoly rights, even if temporary, on reproduction and commercialization of the product, or the assignment of this right in exchange for the receipt of *royalties* (Rabitz 2017, Williams et al. 2020). The first patent grant for a living organism occurred in 1871 to Louis Pasteur, France, for perfecting the brewing process through a yeast free of pathogenic germs. However, there are some who still consider that the international legal framework for granting patents for living organisms, excluding man, comes from the US Supreme Court decision in 1980, where the patentability of microorganisms engineered to *per se* to manufacture or composition of matter. Since this initial milestone, there has been a great growth in patent applications in the area of genetic engineering worldwide, promoting, in a certain way, the toughening and standardization of mechanisms for the protection of intellectual property rights. The current TRIPS agreement, signed by the World Trade Organization (WTO), of which Brazil is a signatory (Brazil 1994), is highly comprehensive as regards the recognition of intellectual property rights in the biological and biotechnological areas.

Today different forms of legal protection of intellectual property are used, such as patents for DNA sequences, patents of microorganisms, patents of cultivars and transgenic animals and protection of cultivars and rights of breeders (breeders who dedicate themselves to breeding of a breed or herd). However, strong controversies have been generated due to the current tendency to establish mechanisms to protect intellectual property on living beings or their components (Rabitz 2017, Simmonds et al. 2020). The first concerns the differentiation between a natural living being and a biotechnological product, or between a *discovery* and an *invention* new gene product. There is a dominant current that argues that biological and genetic engineering research actually produces discoveries rather than inventions because they only recombine preexisting genetic materials or isolate substances found in nature. Another major difficulty in the application of intellectual property laws in the biological and biotechnological areas lies in the fulfillment of the requirement of full description of the object of the patent, in particular when describing all or part of a living being, in relation to biotechnological processes and products), thus compromising the possibility of reproduction of the invention. Another problematic aspect, associated with the previous problem, refers to the frequent disrespect to the requirement of industrial application before a patent application in biotechnology, which can lead to a monopoly on genetic material essential to the advancement of research and scientific knowledge. This problem has been most recurrent in patent applications for gene sequences. The scope and delimitation of the patent object is also a controversial point regarding the definition of which parts

of the physical structure of the gene must be patented and about the scope of the granted patent, since the same biotechnological process can generate different products that can be incorporated to many other products. Parallel to these technical issues, the granting of patents in the biological and biotechnological areas involves other aspects of moral, political, and economic order, which allows the mobilization of different interest groups with different points of view. In the face of the increasingly strategic nature of new biotechnologies, the international flow of information and knowledge in this area tends to be under the political control of the most advanced countries, scientifically and technologically, to the detriment of developing countries.

CONCLUSION

This review presented the antecedents and innovations of law 13,123, of 2015, and its Regulatory Decree no. 8772, of 2016, raising issues that, in contrast to the various positive aspects of previous legislation, such as the attempt to protect the rights of traditional communities and the regulation of benefit sharing resulting in GR and ATK in order to put an end to biopiracy, have endowed research and innovation in biotechnology in Brazil for fifteen years. With the advent of the new legal framework, many doubts still linger among the actors involved, especially concerning procedures for registration with SISGEN, which is still precarious, as well as on the viability of encouraging R & D projects and national research, In general terms, the manipulation and exploitation of nature and its resources, which initially served as a simple raw material used in the construction of a material structure for industrialized societies, now plays a new role as a source for science experiments and advanced technologies, leading to the manufacture of sophisticated and high value-added products in the world market. As enlightened by Becker (1997): The new mode of production redefines nature and society-nature relations. On the one hand, it tends to become independent of the natural resource base by using less raw materials and energy, but, on the other hand, it values the elements of nature on another level through the use of new technologies, especially biodiversity crucial information for biotechnology - and water, as a possible energy matrix. In other words, its values nature as present or future realization capital. With reference to the current globalized scenario, it is known that the tendency towards the private appropriation of information and knowledge through increasingly restrictive legal instruments in relation to the protection of intellectual and industrial property becomes the rule, since life itself and nature can be virtualized into patentable microscopic fragments and will certainly be the objects of privatization by large economic conglomerates. Thus, what we have to reflect in the present moment is not the diversity of nature, or the life itself that has been valued. What is at the heart of matters related to matter, are the genetic particles, or the information contained therein, which has strategic value for advanced biotechnologies. It is impossible to deny the importance and contribution that the development of modern biotechnologies brings to humanity. However, according to Cruz (2018), the private appropriation of GR, even if indirectly, protected by patent protection, may restrict access to biogenetic resources and, consequently, the benefits derived from their use. In this course, the motto shall be the responsibility of all actors involved with the new regulatory framework of biodiversity as a whole and the precise knowledge of the law and its interpretation.

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