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The inclusion of the Digital Sequence Information (DSI) in the scope of the Nagoya Protocol and its consequences**

A inclusão da informação de sequência digital (ISD) no escopo do Protocolo de Nagoya e suas consequências

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Abstract

The Nagoya Protocol, a supplementary agreement to the Convention on Biological Diversity (CBD), was drafted considering the classical model of biopiracy based on the appropriation of physical samples. However, with the development of new technologies of DNA and RNA sequencing, scientists are no longer using just tangible samples on their research. Instead, they are accessing genetic resources in a digital format, the Digital Sequence Information (DSI). Through a deductive approach method and monographic procedure, using bibliographic and documental research techniques, mainly based on the studies requested by the Conference of the Parties to the CBD, in its thirteenth and fourteenth meetings, this article aims at examining the challenges that the ABS system will have to face in case DSI is considered a genetic resource under the Nagoya Protocol. This article concludes that the emergence of new forms of accessing the genetic resources does not undermine the role of the ABS regime, which should walk alongside the advances of technology to guarantee distributive justice.

Keywords: biodiversity; Nagoya Protocol; access and benefit-sharing system; Digital Sequence Information.

Resumo

O Protocolo de Nagoya, um tratado complementar à Convenção sobre Diversidade Biológica (CDB), foi elaborado considerando o modelo clássico de biopirataria baseado em na apropriação de amostras físicas. No entanto, com o desenvolvimento de novas tecnologias de sequenciamento de DNA e RNA, os cientistas não estão mais usando apenas amostras físicas em suas pesquisas. Em vez disso, eles estão acessando recursos genéticos em formato digital, a chamada Digital Sequence Information (DSI). Através de método de abordagem dedutivo e procedimento monográfico, utilizando-se técnicas de pesquisa bibliográfica e documental, com base nos estudos solicitados pela Conferência das Partes da CDB, este artigo examina os desafios que o sistema de acesso e repartição de benefícios (ABS) terá que enfrentar caso a

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DSI seja considerada um recurso genético no âmbito do Protocolo. Este artigo conclui que o surgimento de novas formas de acesso aos recursos genéticos não prejudica o papel do regime de ABS, que deve caminhar de mãos dadas com os avanços da tecnologia para garantir a justiça distributiva.

Palavras-chave: biodiversidade; Protocolo de Nagoya; sistema de acesso e repartição de benefícios; Digital Sequence Information.

1 Introduction

The Nagoya Protocol, a supplementary agreement under the framework of the Convention on Biological Diversity, came into force in 2014, ninety days after the 50th ratification deposit. Currently, the protocol has 132 (one hundred and thirty-two) signatures, including countries as China and Brazil and it aims to further advance the Convention's third objective: the fair and equitable sharing of benefit arising from the utilization of genetic resources¹. Consequently, the Protocol endeavors to avoid the misappropriation of genetic resources, so-called biopiracy, which is defined by Mbigeoji as “the unauthorized commercial use of biological resources and/or associated traditional knowledge, or the patenting of spurious inventions based on such knowledge, without compensation”², usually perpetrated by the countries from the North hemisphere in detriment of the countries from the South hemisphere.

The Protocol and the Convention were drafted considering the classical representation of biopiracy: a tangible sample, such as a seed, that is stolen from a country of the South, usually a developing country, rich in biodiversity. However, with the development of new technologies, the genetic resources have been accessed in a different form. Sophisticated machines “read” DNA or RNA sequences of nucleotides and the scientists work over this material, with no need of a physical sample. Once finalized a specific research, usually the sequence is sent to one of three major international databases, with public open access.

The main issue is that the Access and Benefit-Sharing (ABS) regime, primarily created by the Convention and further developed by the Nagoya Protocol, was not conceived to tackle genetic resources in a digital format. Taking that into consideration, in 2016, the Conference of the Parties (COP) to the CBD and the Parties to the Nagoya Protocol (in their thirteenth and second meeting, respectively) established an Ad Hoc Technical Expert Group on Digital Sequence Information (AHTEG) to clarify the subject. The COP also requested the Executive Secretary to contract a fact-finding and scoping study to better understand DSI terminology and concepts³.

At the COP's fourteenth meeting, in 2018, additional studies were requested, through the Decision 14/20. In March 2020, due to the coronavirus (COVID-19) pandemic, these studies were presented in an AHTEG's virtual meeting. The expressed intention was to take the outcome of the discussions and make recommendations to the Open-ended inter-sessional Working Group (Open-Ended Working Group), established by Decision 14/34. This group is in charge of preparing the post-2020 global biodiversity framework, which will be based on a new set of targets to stem the loss of biodiversity, to be presented at phase 1 (virtual) and 2 (in person) of COP15 in October 2021 and April 2022, in Kunming, China. From August 23rd to September 3rd 2021, during the online discussions of the Open-Ended Working Group, it was defined that DSI is officially an item of the provisional agenda of the Conference⁴. Thus, the matter related to the DSI inclusion in the ABS system is considered one of the key Protocol's issues.

Through a deductive approach method and monographic procedure, using bibliographic and documental research techniques, mainly based on the studies requested by the Conference of the Parties to the CBD, in its thirteenth and fourteenth meetings, this article aims at examining the challenges that the ABS system will have to face in case DSI is considered a genetic resource under the Nagoya Protocol. This paper aims to analyze whether the inclusion of Digital Sequence Informa-

¹ CONVENTION ON BIOLOGICAL DIVERSITY. *About the Nagoya Protocol*. Available at: <https://www.cbd.int/abs/about/>. Access on: 1 oct. 2020.

² MGBEOJI, Ikechi. *Global biopiracy: patents, plants and indigenous knowledge*. UBC Press, 2006. p. 13.

³ CONVENTION ON BIOLOGICAL DIVERSITY. *Decision XIII/16*, paragraph 3(b). Available at: <https://www.cbd.int/decisions/cop/13/16>. Access on: 10 sep. 2020.

⁴ CONVENTION ON BIOLOGICAL DIVERSITY. *CBD/COP/15/1/Rev.1*, 18 August, 2021. Available at: <https://www.cbd.int/doc/c/c678/abc2/2ff4f204cf2d46569a376d6a/cop-15-01-rev1-en.pdf>. Access on: 26 sep. 2021.

tion⁵ (DSI) in the ABS regime is feasible and which are the available tools to make it possible. The importance of this discussion rests in the fact that most of the current scientific research have already been made using DSI⁶ and as it is out of the scope of the considered “genetic resources”, it does not need to comply with the ABS rules. Hence this loophole has the potential of turning the Protocol of little effect.

However, the subject is far from being a consensus. Indeed, it is controversial, complex, and multidisciplinary. For this reason, it has been demanding a lot of studies by the CBD. Many researchers affirm that the obstacles created by the ABS system tend to hinder research. They defend that a public open system database to access DSI is more important to the development of science and preservation of the biodiversity⁷.

The first section of this paper explains some key definitions to better understand the subject; the second section describes the historical background of Nagoya Protocol, focusing on the Convention on Biological Diversity. The third and fourth sections explain the Protocol, giving emphasis to the Access and Benefit-Sharing (ABS) system and its role to achieve distributive justice. Subsequently, section 5 describes the emergence of the Digital Sequence Information, as a result of technological development of bioinformatics and genetic studies and, finally, section 6 analyses the possible ways to enable the inclusion of DSI in the scope of the Nagoya Protocol.

2 An important definition: genetic resources

The Convention on Biological Diversity establishes, in its article 2, that “genetic resource means a genetic material of substantial or potential value”. The expression “genetic material” is defined as “any material

of plant, animal, microbial or other origin, containing functional units of heredity”⁸. However, as the Convention does not clarify what constitutes the term “functional units of heredity”, the definition is rather imprecise.

The disagreement around the term has jeopardized the effectiveness of the ABS system. As Tvedt and Schei point out “[the] lack of consistency creates legal uncertainty in ABS transactions, and this will have to be resolved for an international regime to be functional”⁹. So far, regarding the scope, the COP only decided to exclude from the CBD/Nagoya the biological materials that are exploited as commodities and the human genetic resources.¹⁰

Back in 1992, the expression “functional unit of heredity” was considered the synonymous of gene and the word “functional” was related to the part of it that was deemed as useful. The gene was considered useful if it could produce a blueprint in the form of protein, which controls different processes in the organism¹¹.

With the development of genomics, proteomics and bioinformatics, the understanding of genetic resources has been evolving. New discoveries and uses of these resources indicate that “functional units of heredity must have a more flexible and dynamic interpretation to cope with the novelties of the field. Some authors, such as Deplaze-Zemp, Muller and Tvedt and Schei, defend a more modern definition based on the value of the information within the biological material. Deplaze-Zemp affirms that unlikely the timber or petroleum, the value of the genetic resources depends on the information that they “carry rather than on their material, even if it is material samples that have been collected, exported, exchanged or stolen”¹².

⁵ This term has been used by the Convention, but there is no consensus over the term at international level.

⁶ LAIRD, Sarah; WYNBERG, Rachel. *A fact-finding and scoping study on digital sequence information on genetic resources in the context of the Convention on Biological Diversity and the Nagoya Protocol*. Montreal: Secretariat of the Convention on Biological Diversity, 2018. Available at: <https://www.cbd.int/doc/c/b39f/4faf/7668900e8539215e7c7710fe/dsi-ahteg-2018-01-03-en.pdf>. Access on: 15 set. 2020.

⁷ LAWSON, Charles; ROURKE, Michelle. Digital Sequence Information as a marine genetic resource under the proposed UNCLOS legally binding instrument. *Marine Policy*, v. 122, 2020.

⁸ CONVENTION ON BIOLOGICAL DIVERSITY. Available at: <https://www.cbd.int/doc/legal/cbd-en.pdf>. Access on: 10 dec. 2020.

⁹ TVEDT, Morten Walløe; SCHEI, Peter Johan. The term “genetic resources” flexible and dynamic while providing legal certainty?. In: OBERTHÜR, Sebastian; ROSENDAL, G. Kristin. *Global governance of genetic resources: access and benefit sharing after the Nagoya Protocol*. Routledge, 2013.

¹⁰ CONVENTION ON BIOLOGICAL DIVERSITY. *COP - 2 Decision II/11*. Available at: <https://www.cbd.int/decision/cop/?id=7084>. Access on: 01 oct. 2021.

¹¹ TVEDT, Morten Walløe; SCHEI, Peter Johan. The term “genetic resources” flexible and dynamic while providing legal certainty?. In: OBERTHÜR, Sebastian; ROSENDAL, G. Kristin. *Global governance of genetic resources: access and benefit sharing after the Nagoya Protocol*. Routledge, 2013. p. 23.

¹² DEPLAZES-ZEMP, A. Genetic resources, an analysis of a mul-

In order to better understand how the genetic information of the living organisms has been accessed, it is necessary to know the basic structure of molecular biology. A DNA molecule is made up of two long strands of nucleotides wrapped around each other, constituting a double helix. A deoxyribose sugar, a phosphate group, and a nitrogenous base form a nucleotide. There are four different types of nitrogenous base in DNA: adenine, thymine, guanine and cytosine. The sequence of A, T, G and C on a strand represents the coded information carried by the DNA molecule¹³. With the technology developments, modern computers and software are decoding the DNA sequences of biological materials. Thus, the sequences are stored in large international databases, open to public use.

Muller, Laird and Wynberg explain that in the biotechnology field, the genetic resources are utilized in the form of genetic sequence data, rather than physical samples¹⁴. Facing this new scenario, where the genetic resources have been accessed as information in a digital format, the parties to the CBD have been demanding the inclusion of DSI in the concept of genetic resource. The problem is that, although the Conventions' definition is imprecise, it defines genetic resource as a material resource what makes some members defend that the genetic information should not be included in the scope of the ABS regime.

3 Convention on Biological Diversity

Most biological diversity resources are located in the Southern hemisphere, mainly in Africa, Asia, and South America. There is a natural inequality in the distribution of the genetic resources of the Earth. On one hand, the North is industrialized and economically rich, but its territory is poor in biodiversity. On the other hand,

the South is economically poor, but rich in biodiversity¹⁵. Biodiversity in the words of Ikechi Mgbueji is the “variability among living organisms from all sources including, amongst others, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part, this includes diversity within species, between species and ecosystems”¹⁶. In addition, it comprises the genetic variation between species, based on different breeds, chromosomes, genes, and genetic sequence (DNA)¹⁷. The importance of biological diversity is threefold: providing sources of biological resources, maintaining the balance of the biosphere, and expressing aesthetic value for humankind¹⁸.

The issue of biodiversity gained notoriety because of the controversial relationship between genetic resources and biotechnology. The lack of precise rules related to the access of genetic resources fostered the idea that biodiversity was a Common Heritage of Mankind. Furthermore, pharmaceutical companies, to profit from plants, microbes, and algae, have been misappropriating the traditional knowledge of local communities of the South and imposing intellectual property rights, such as patents, over their findings¹⁹. Therefore, the exploitation of genetic resources without the due compensation to the South and the misappropriation of its traditional knowledge along with the concern of the loss of biological diversity became important questions, which demanded an urgent answer to be addressed by International Law.

The CBD recognizes that biodiversity is a “Common Concern of Mankind”, and it affirms that genetic resources are subjected to the sovereignty of states. In other words, the convention affirms that the states have rights over their resources, and it is their responsibility to preserve and use them in a sustainable manner. It means that the misappropriation of genetic resources of the South, henceforth, is considered illegitimate²⁰.

tifaceted concept. *Biological Conservation*, n. 222, p. 86-94, 2018. p. 89.

¹³ GRIFFITHS, A. J. F.; WESSLER, S. R.; CARROL, S. B. *Doebley: introduction to genetic analysis*. 8. ed. New York: W. H. Freeman and Company, 2004.

¹⁴ MULLER, Manuel Ruiz. *Genetic resources as natural information*. Routledge Studies in Law and Sustainable Development, Taylor and Francis, 2015.; LAIRD, Sarah; WYNBERG, Rachel. *A fact-finding and scoping study on digital sequence information on genetic resources in the context of the Convention on Biological Diversity and the Nagoya Protocol*. Montreal: Secretariat of the Convention on Biological Diversity, 2018. Available at: <https://www.cbd.int/doc/c/b39f/4faf/7668900e8539215e7c7710fe/dsi-ahteg-2018-01-03-en.pdf>. Access on: 15 set. 2020.

¹⁵ HASSEMER, M. Genetic resources. In: VON LEWINSKI, Silke (ed.). *Indigenous heritage and intellectual property: genetic resources, traditional knowledge and folklore*. London: Kluwer Law International, 2004. p. 215-216.

¹⁶ MGBUEJI, Ikechi. *Global biopiracy: patents, plants and indigenous knowledge*. UBC Press, 2006. p. 50.

¹⁷ CHASEK, P.; DOWNIE, D.; BROWN, J. W. *Global environmental politics*. 7. ed. Routledge Press, 2018. p. 189.

¹⁸ SANDS, P. *Principles of international environmental law*. 3. ed. New York: Cambridge University Press, 2012. p. 450.

¹⁹ MILLER, Marian. *The third world in global environmental politics*. Buckingham: Open University Press, 1995. p. 109.

²⁰ HASSEMER, M. Genetic resources. In: VON LEWINSKI, Silke

The concept of Common Concern of Mankind (CCM) is intimately related to the North-South equity discussion. The Stockholm Declaration considers the environmental as a Common Heritage of Mankind (CHM) and until the advent of the CBD, some countries of the North have insisted on considering the genetic resources as CHM²¹. However, the concept is applied to very specific situations in International Law. According to Alexandre Kiss, the first elements of the concept started to be developed under the Antarctic Treaty (1959), followed by the Treaty Governing the Activities of States on Moon and other Celestial Body (1979) and the United Nation Convention on the Law of the Sea (Montego Bay Convention, 1982)²². The last one expressly stated the application of the principle of CHM. Kiss asserts that the main characteristics of the principle of the CHM are: peaceful uses, rational management and conservation of the resources²³. Ikechi Mgbeoji points out that, additionally for the peaceful purposes and rational common management, other requirements should be considered, such as area free from appropriation and economic benefits reverted to the global community²⁴.

Cançado Trindade points out that, apparently, there has been an evolution in the Environmental Law from the notion of Common Heritage of Mankind to the Common Concern of Mankind²⁵. Trindade e Jutta Bruneé explains that CHM is related to the sharing of benefits arising from the economical exploration of natural resources and the CCM is related to the sharing

of burdens related to the protection of the resources²⁶. It means that since biodiversity is relevant to all human beings indistinctly, it shall be considered a common concern that involves cooperation between North and South. Moreover, the CCM also expresses the concept of Common but Differentiated Responsibilities, since developed countries also have responsibility for solving the problem of the loss of biodiversity. This responsibility exists because the countries of the North have technology and resources to address the problem²⁷.

As a result of the recognition of the sovereign right of states over their genetic resources, the CBD stipulates in Article 15, conditions regarding the access and sharing of benefits arising from the commercialization or utilization of genetic resources that should be adopted through the national legislation of the parties. After the authorization through a Prior Informed Consent (PIC), the user of the genetic resource shall establish a private contract, called Mutually Agreed Terms (MAT), with the provider, to enable an equitable sharing of benefits. In other words, there is an obligation to compensate holders of genetic resources. The compensation may come in different forms, depending on each case, and can take the form of access fees, royalty payment, participation in improvement of products or transfer of technology, training of local people or even institutional relationships, usually between universities to foster the development of research in the provider country²⁸. The equitable sharing of benefits can be perceived in two ways: first, as protection for the holders of traditional knowledge and second as retribution to genetic resources holders for hosting and preserving biodiversity²⁹.

(ed.). *Indigenous heritage and intellectual property: genetic resources, traditional knowledge and folklore*. London: Kluwer Law International, 2004. p. 215-216.

²¹ OLIVEIRA, Liziane Paixão Silva; BARROS, Ana Flávia; CRAVO, Jorge Gomes. Mitigating the principle of sovereignty over biological resources?. *Nomos*, v. 38, n. 2, p. 244-256, jul./dez. 2018.

²² KISS, Alexandre. The common heritage of mankind: utopia or reality?. *International Journal: Law in the International Community*, v. 40, n. 3, p. 423-441, 1985.

²³ KISS, Alexandre. The common heritage of mankind: utopia or reality?. *International Journal: Law in the International Community*, v. 40, n. 3, p. 423-441, 1985.

²⁴ MGBEOJI, Ikechi. Beyond rhetoric: state sovereignty, common concern, and the inapplicability of the common heritage concept to plant genetic resources. *Leiden Journal of International Law*, v. 16, n. 4, p. 821-837, 2003.

²⁵ TRINDADE, Antônio Augusto Cançado. The parallel evolutions of international human rights protection and of environmental Protection and the absence of restrictions upon the exercise of recognized human rights. In: TRINDADE, Antônio Augusto Cançado; LEAL, César Barros (coord.). *Human rights and environment*. Expressão Gráfica e Editora, 2017.

²⁶ See TRINDADE, Antônio Augusto Cançado. The parallel evolutions of international human rights protection and of environmental Protection and the absence of restrictions upon the exercise of recognized human rights. In: TRINDADE, Antônio Augusto Cançado; LEAL, César Barros (coord.). *Human rights and environment*. Expressão Gráfica e Editora, 2017. and BRUNNÉE, J. Common areas, common heritage and common concern. In: BODANSKY, Daniel; BRUNNÉE, Jutta; HEY, Ellen (ed.). *The Oxford handbook of international environmental law*. Oxford: Oxford University Press, 2007. p. 566-567.

²⁷ BRUNNÉE, J. Common areas, common heritage and common concern. In: BODANSKY, Daniel; BRUNNÉE, Jutta; HEY, Ellen (ed.). *The Oxford handbook of international environmental law*. Oxford: Oxford University Press, 2007. p. 566-567.

²⁸ CULLET, P. Environmental justice in the use, knowledge and exploitation of genetic resources. In: EBBESSON, Jonas; OKOWA, Phoebe (ed.). *Environmental law and justice in context*. Cambridge: Cambridge University Press, 2009. p. 376.

²⁹ BRUNNÉE, J. Common areas, common heritage and common concern. In: BODANSKY, Daniel; BRUNNÉE, Jutta; HEY, Ellen

The vagueness of some provisions of the CBD was a hurdle to the implementation and compliance by states. It is true that the Access and Benefit sharing regime was a great achievement and a change of paradigm, addressing the old pleas of the South of focusing more on the economic dimension of biodiversity. However, in attempting to please both sides in the negotiations, the CBD, in some provisions, such access and benefit sharing in Article 15, remains in an empty space. In this context, the COP adopted respectively, in its sixth and tenth meeting, the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization³⁰ and the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol). These instruments are supplementary to the Convention and enhance its provisions in more detail to promote the compliance of the states.

4 Nagoya Protocol

The low level of implementation of the CBD due an ambiguity in the most important provisions related to access and benefit-sharing, especially Article 15, raised the awareness of the Developing countries to the necessity for an international instrument that could enhance the implementation of the Convention. In this context, the Nagoya Protocol was adopted in 2010, as a supplementary agreement to the CBD, coming into force in 2014.³¹ In August 2021, the Protocol counted with 130 (one hundred thirty) ratifications, including countries as Brazil and China³².

(ed.). *The Oxford handbook of international environmental law*. Oxford: Oxford University Press, 2007.

³⁰ CONVENTION ON BIOLOGICAL DIVERSITY. *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization*. Available at: <https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf>. Access on: 20 sep. 2020.

³¹ BASTOS, R. Z.; CANTO, Otávio do; VESTRIS, I.; GALY, K. Le régime international de l'accès aux ressources génétiques au prisme de l'entrée en vigueur du Protocole de Nagoya. *Revista de Direito Internacional*, v. 13, p. 130-144, 2016.; FRUGONI, Alina Celi. Análisis jurídico del ordenamiento jurídico internacional sobre protección de los recursos genéticos: desafíos y perspectivas en Uruguay a partir de la implementación del protocolo de Nagoya. *Revista de Direito Internacional*, v. 13, p. 117-131, 2016.

³² CONVENTION ON BIOLOGICAL DIVERSITY. *Parties to the Nagoya Protocol*. Available at: <https://www.cbd.int/abs/nagoya->

The Protocol's objective is to further advance 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 the establishment of the procedural aspects of Articles 8 (j) and 15 of the CBD, to render viable, the implementation of these provisions by the Contracting Parties as an instrument of distributive justice. Nollkaemper understands that the distributive justice is one of the conceptions of environmental justice and it is related to the fair allocation of resources and burdens across people or states, respectively, in the domestic and international sphere³³. Furthermore, Article 1 also states that the ABS regime shall be instrumental "to [the] conservation of biological diversity and the sustainable use of its components". Therefore, the primary objective of the Protocol is linked to the two objectives of the CBD³⁴.

Article 4(1) states the relationship of the Protocol with other international instruments. The provision basically repeats the content of the Article 22 (1) of the CBD. It also emphasizes that it does not intend to create a hierarchy between the Protocol and other international instruments. Paragraph 3 declares that the Protocol "shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol"³⁵.

4.1 Access and Benefit-Sharing

The Protocol reiterates the sovereignty of states over their genetic resources and the obligation of the PIC and MAT to access them. Paragraph 3 imposes some obligations over the provider countries that aim to require PIC, such as providing information about the national procedures on how to apply for PIC, ensuring legal certainty, clarity and transparency of their national ABS legislation and establishing "fair and non-arbitrary

protocol/signatories/. Access on: 05 mar. 2021.

³³ NOLLKAEMPER, A. Sovereignty and environmental justice in international law. In: EBBESSON, Jonas; OKOWA, Phoebe (ed.). *Environmental law and justice in context*. Cambridge: Cambridge University Press, 2009.

³⁴ KAMAU, E. C.; FEDDER, B.; WINTER, G. The Nagoya Protocol on access to genetic resources and benefit sharing: what is new and what are the implications for provider and user countries and the scientific community?. *Law, Environment and Development Journal*, 2010.

³⁵ Available at: <https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>. Access on: 20 sep. 2020.

rules and procedures” on access to genetic resources³⁶. Moreover, paragraph 3 also emphasizes the obligation on providing countries, to issue a permit or equivalent, which would be the evidence of the decision to grant PIC and of establishing MAT, and also to notify the Access and Benefit-sharing Clearing House (ABS Clearing House). This latter mechanism was established in Article 14 of the Protocol and works as a means for sharing information related to access and benefit sharing between the Parties of the Protocol.

Paragraphs 6. (2) and 6. (3) (f) are also related to having access to genetic resources and establishing an innovative provision related to indigenous and local communities. As claimed by these provisions, each Party, subject to domestic legislation, shall take measures to ensure that PIC or approval and involvement of indigenous and local communities is obtained for access to genetic resources held by them. It was a great achievement compared to the vague Article 8 (j) of the CBD. However, Harrop criticizes the “subject to domestic legislation” provisions. He argues that as many countries do not recognize indigenous rights in domestic legislation, these provisions would be ineffective to them³⁷.

Article 5 of the Protocol is related to the fair and equitable benefit sharing through MAT. Paragraph 1 requires that benefits arising from the utilization and subsequent applications and commercialization of genetic resources shall be shared in a fair and equitable means with the providing Party, through the MAT. The benefits enumerated under the Protocol include monetary and non-monetary benefits. Still, the emphasis of the Protocol is on encouraging benefits to Developing countries through technology transfer, collaboration and cooperation in technical and scientific research and development programs, as stated in Article 23³⁸.

Article 5 in its paragraphs 2 and 5 also states that the Parties shall enact administrative, legislative or policy measures in order to ensure that benefits arising from the utilization of traditional knowledge and genetic re-

sources held by indigenous people and local communities are shared in a fair and equitable way. Access to traditional knowledge associated to genetic resources is also addressed in Article 7, which states that, subject to domestic law, the Parties shall ensure that the utilization of traditional knowledge held by indigenous and local communities takes in consideration the PIC or any form of approval by them in addition to their participation.

4.2 Compliance

The core issue of the Protocol to the Developing Countries was related to the mechanisms of compliance. They believed that without provisions to enhance the monitoring access and benefit sharing of genetic resources through PIC and MAT, the problem of bio-piracy would never be redressed. Article 15 (1) and 16 (1) emphasize that the Parties shall take appropriate legislative measures to ensure that genetic resources and traditional knowledge associated with them are accessed with due attention to the PIC and the establishment of the MAT within their jurisdiction, as required by the provider country’s ABS legislation³⁹. Moreover, the user country shall take appropriate and effective measures to address the situations of non-compliance, according to Article 15 (2) and 16 (2). However, Josep argues that “the Protocol has been very lenient on non-compliance by expressing its sympathy to violators in saying “as far as possible and as appropriate”⁴⁰. Indeed, Articles 15 (3) and 16 (3) state that “Parties shall as far as possible and appropriate, cooperate in cases of alleged violation” and do not state any mechanism to deal with the situation of non-compliance.

During the negotiations there were some issues that divided the Developed and Developing countries, especially in relation to the monitoring mechanisms of the Protocol. The most controversial topic was the implementation of checkpoints within the jurisdiction of the Parties. The checkpoints would be a type of national authority for which the users of genetic resources should submit information about the PIC, MAT, the

³⁶ SANDS, P. *Principles of international environmental law*. 3. ed. New York: Cambridge University Press, 2012. p. 465.

³⁷ HARROP, S. R. Living in harmony with nature? outcomes of the 2010 Nagoya Conference of the Convention on Biological Diversity. *Journal of Environmental Law*, 2011. p. 127.

³⁸ KAMAU, E. C.; FEDDER, B.; WINTER, G. The Nagoya Protocol on access to genetic resources and benefit sharing: what is new and what are the implications for provider and user countries and the scientific community?. *Law, Environment and Development Journal*, 2010. p. 251.

³⁹ BUCK, Mathias; HAMILTON, Claire. *The Nagoya Protocol on Access to Genetic Resources and the fair and equitable sharing benefits arising from their utilization to the Convention on Biological Diversity: review of European Community & international environmental law*. 2011. p. 52.

⁴⁰ JOSPEH, R. K. International regime on access and benefit sharing: where are we now?. *Asian Biotechnology and Development Review*, 2010. p. 90.

source, and utilization of genetic resources accessed within its jurisdiction. Developing countries defended that the intellectual property offices or research institutions should be explicitly designated as the mandatory checkpoint in the Protocol⁴¹. However, these alternatives were refused by the North. Therefore, Article 17 of the Protocol just states that each Party shall designate one or more checkpoints, without further details about what entity should be appointed as the national authority that will supervise and guarantee the compliance with the ABS regime.

Another issue related to the checkpoints is the disclosure of information. Since the negotiations of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), the Developing countries have requested the disclosure of origin as a requirement for granting patents related to genetic resources. This measure would be useful to combat biopiracy because they argued that this prerequisite would avoid patents based on their traditional knowledge. Developed countries, especially USA, did not accept this position because they understood that it would impose new burdens on patent applications. Again, Developed countries did not agree on this point for the Protocol and because of that, the duty of disclosure is vaguely incorporated in Article 17 (1) (iv). In other words, it means that the requirement to disclose information is not mandatory⁴². However, Margo Bagley asserts that disclosure of origin is already a requirement in the patent domestic legislation of many countries, such as China, Brazil, India and Switzerland, and that “with the entry into force of the Nagoya Protocol, additional countries are likely to include a DOO [disclosure of origin] obligation in their implementing legislation [ABS]”⁴³.

⁴¹ LING, Chee Yoke. *Access obligations increased: the road to an anti-piracy agreement: the negotiations under the United Nations Convention on Biological Diversity*. 2. ed. Penang: Third World Network, 2011.

⁴² KAMAU, E. C.; FEDDER, B.; WINTER, G. The Nagoya Protocol on access to genetic resources and benefit sharing: what is new and what are the implications for provider and user countries and the scientific community?. *Law, Environment and Development Journal*, 2010. p. 257.

⁴³ BAGLEY, Margo. Of disclosure “Straws” and IP System “Camels”: patents, innovation, and the disclosure of origin requirement. In: ROBINSON, Daniel; ABDEL-LATIF, Ahmed; ROFFE, Pedro (ed.). *Protecting traditional knowledge: the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*. Routledge Press, 2017.

Article 17 (3) confirms that an international certificate of compliance shall serve as verification that the genetic resources were accessed taking into consideration the PIC, the establishment of the MAT and eventual benefit-sharing thereof. It is important to highlight that the Protocol aims at applying the countries’ ABS domestic legislation to the access of genetic resources. The objective is to guarantee that a genetic resource originally from Brazil could be used in China upon the conditions of the Brazilian ABS legislation. The national authorities should be able to monitor and issue an international certificate of compliance that must be submitted to the ABS Clearing House.

Finally, the Protocol also addresses other issues of relevance to Developing countries, such as access and benefit sharing related to genetic pathogen resources, in Article 8 (b), and the situations when it is difficult or impossible to obtain the PIC from the provider party, in Article 10. In the latter case, the “Parties shall consider the need and modalities of a global multilateral benefit-sharing mechanism”. Such mechanism would be very important to address the situation of the genetic resources placed at “ex situ collections”, where it is not possible to obtain the PIC⁴⁴.

Despite all the challenges the Protocol still faces, the relevance of the initiative of the instrument to address the problem of biopiracy is irrefutable. At long last, an international ABS regime has been created, emphasizing not just the access and sharing benefits of genetic resources, but also of the traditional knowledge associated with them. The Protocol is a striking recognition of the environmental injustices suffered by the South and emerged in the international sphere as a form of corrective justice.

5 Digital Sequence Information

The ABS regime was arranged taking into consideration tangible biological resources. The classical idea of biopiracy that comes into our mind is a seed, plant or animal that is exported illegally by a Party, usually situated in the North, and taken to laboratories to develop

⁴⁴ BUCK, Mathias; HAMILTON, Claire. *The Nagoya Protocol on Access to Genetic Resources and the fair and equitable sharing benefits arising from their utilization to the Convention on Biological Diversity: review of European Community & international environmental law*. 2011. p. 59.

products to industry. However, with the recent developments of Biology and Computer Science, the genetic information has been acquired and shared in an intangible format. As Hammond⁴⁵ points out “while yesterday’s biopirate hid seeds in his luggage, tomorrow’s gene thief may smuggle her loot on a thumb drive or upload it to the cloud”.

This change is also due to the discovery of new methods used to sequence DNA. The first-generation sequencing used the technique of DNA amplification and electrophoresis⁴⁶. It relied greatly upon physical samples and the ABS regime was drafted based on this process. However, with the advances in molecular biology and computational algorithms, a new generation of DNA sequencing came to light. The so-called Next-Generation Sequencing still uses physical resources to decode the sequence, however once the code is available in a digital format, the research material becomes autonomous, no longer depending on tangible resources. According to the Submission of information on the use of digital sequence information on genetic resources for food and agriculture:

These next-generation sequencing (NGS) technologies are able to generate DNA sequence data at low cost and at a rate much faster than that of traditional technologies. With NGS technologies it is possible to resequence entire genomes or sample entire transcriptomes more efficiently and economically than in past, and in greater depth than ever before⁴⁷.

In this context, a new concern came up to the provider countries: the digital biopiracy. As Margo Bagley⁴⁸ explains, they are worried that once the PIC is given to a physical sample, the DNA sequence information is obtained and uploaded to publicly databases, and then used to get ABS-free products. Put plainly, they are afraid that the new technology and the fluidity of information could hamper the compliance with the ABS rules.

The emergence of technological changes in research methods and in the way of sharing genetic information raised the debate over whether Digital Sequence Information (the terminology used by the CBD to the genetic resources in a digital format) should be considered a genetic resource under the scope of the Nagoya Protocol. As the Convention establishes that “genetic resources” means a genetic material of substantial or potential value, some members interpret that the treaty encompasses just biological physical samples⁴⁹ (See section 2 – An Important Definition).

As previously mentioned, the Nagoya Protocol was primarily designed to further advance the implementation of the third objective of the CBD: the fair and equitable sharing of benefits arising from the utilization of genetic resources. If due to the new technologies the genetic resources are being accessed without the PIC/MAT and/or being economically explored without due compensation, the Protocol becomes just a piece of paper.

Aiming to understand this cross-cutting issue, in December 2016, the thirteenth meeting of the Conference of the Parties to the CBD and the second meeting of the Parties to the Nagoya Protocol established an Ad Hoc Technical Expert Group on Digital Sequence Information (AHTEG). Additionally, the Executive Secretariat of the CBD requested a fact-finding and scoping study to clarify the terminology and evaluate the use of Digital Sequence Information (“DSI”) on genetic resources. The COP also invited Parties, indigenous people, local communities, relevant NGOs, and stakeholders to submit their comments over the matter⁵⁰.

The Fact Finding and Scoping Study on Digital Sequence Information on Genetic Resource was released in 2018. It is a long and complex study that explores the current situation of the use of DSI. It demonstrated that DSI has already been widely used in laboratories; however, some researchers stated that it is still necessary to have physical material in most cases. Nowadays the minor part of the commercial research is based on tangible samples, but academic groups are still interested

⁴⁵ HAMMOND, E. *Gene sequences and biopiracy: protecting benefit-sharing as synthetic biology changes access to genetic resources*. Third World Network, aug. 2017. p. 1.

⁴⁶ Report of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources, Act February, 2018.

⁴⁷ Submission of information on the use of “digital sequence information on genetic resources for food and agriculture. Available at: <https://www.cbd.int/abs/DSI-views/CGRFA-DSI-3.pdf>. Access on: 15 set. 2020.

⁴⁸ BAGLEY, Margo. Digital DNA: the Nagoya Protocol, intellectual property treaties, and synthetic biology. *Virginia Public Law and Legal Theory Research Paper*, n. 11, Emory Legal Studies Research Paper, feb. 2016. p. 11.

⁴⁹ LAIRD, Sarah; WYNBERG, Rachel. Locating responsible research and innovation within access and benefit sharing spaces of the Convention on Biological Diversity: the challenge of emerging technologies. *Nanoethics*, v. 10, 2016.

⁵⁰ LAIRD, Sarah; WYNBERG, Rachel. Locating responsible research and innovation within access and benefit sharing spaces of the Convention on Biological Diversity: the challenge of emerging technologies. *Nanoethics*, v. 10, 2016. p. 8.

in field and “ex situ” collections⁵¹. The use of digital sequence has also revealed a new genetic manipulation technique, considered the next stage of Genetic Engineering, based on DSI: the synthetic biology.

The report of the AHTEG was released in February 2018, but the most important point remained without conclusion: the definition of the term genetic resources. Some experts expressed that the definition includes DSI⁵²; and the study also presented arguments in the sense that genetics resources refer just to tangible material⁵³. For some countries of the South, not including DSI compromise sovereign control over genetic resources. Other countries, especially where the major sequence database is situated, consider that the publication of sequence information in open-access databases can be seen as a form of benefit-sharing⁵⁴.

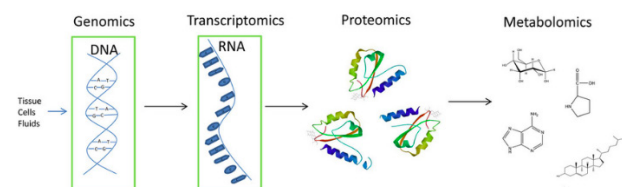
The complexity of the issue, the ongoing advances on technology and the lack of a precise definition of DSI influenced the COP, at its 14th meeting, in November 2018, to adopt the Decision 14/20. The resolution requested four peer reviewed studies on DSI and established an extended Ad Hoc Technical Expert Group (AHTEG).

One of the studies requested by the CBD provided a science-based analysis on the concept and scope of DSI. The study explains the technical ground to develop some discussion around the scope and correct terminology to replace the term DSI. It systematizes in different groups the various types of biological information that could compose the DSI. The explanation is based on the “central dogma of molecular biology” in which DNA is converted to RNA, which is trans-

lated into proteins that finally turn into metabolites (See Figure 1 below). The first group includes just the DNA and RNA (narrow scope); the second comprises the DNA, RNA and proteins (intermediary scope); the third includes DNA, RNA, proteins and the metabolites (intermediary scope) and the fourth, is the broadest concept, which includes traditional knowledge, environment influences, etc.⁵⁵

These groups were organized to facilitate a future decision at the COP over the scope of DSI. Moreover, the method is important to identify the source from which the information was derived. The authors affirm “the proximity of data/information has significant implications for traceability to a genetic resource and also in identifying the source of information [...]”⁵⁶. In other words, they explain that it is easier to track back the original resource derived from DNA, RNA or protein sequence than biosynthetic information (metabolites), because of their proximity in the flow of information of the Central Dogma of molecular biology (See Figure 1 below).

Figure 1: Central dogma of molecular biology



Source: https://www.researchgate.net/figure/Biological-central-dogma_fig1_284729558

Based on studies and the outcomes of the AHTEG, an Open-ended inter-sectional Working Group on The Post-2020 Global Biodiversity Framework will make recommendations to COP 15 to be held in China⁵⁷.

⁵¹ Fact Finding and Scoping Study on DSI. Available at: <https://www.cbd.int/doc/c/e95a/4ddd/4baea2ec772be28edcd10358/dsi-ahteg-2018-01-03-en.pdf>.

⁵² MULLER, Manuel Ruiz. *Genetic resources as natural information*. Routledge Studies in Law and Sustainable Development, Taylor and Francis, 2015. p. 85.

⁵³ Ad Hoc Technical Expert Group (‘AHTEG’) on Digital Sequence Information on Genetic Resources, ‘Synthesis of Views and Information on the Potential Implications of the Use of Digital Sequence Information on Genetic Resources for the Three Objectives of the Convention and the Objective of the Nagoya Protocol’ (2018) CBD/SBSTTA/22/INF/2, p. 36, 2018.

⁵⁴ Ad Hoc Technical Expert Group (‘AHTEG’) on Digital Sequence Information on Genetic Resources, ‘Synthesis of Views and Information on the Potential Implications of the Use of Digital Sequence Information on Genetic Resources for the Three Objectives of the Convention and the Objective of the Nagoya Protocol’ (2018) CBD/SBSTTA/22/INF/2, 2018.

⁵⁵ CONVENTION ON BIOLOGICAL DIVERSITY. *CBD/DSI/AHTEG/2020/1/7*. Report of the ad hoc technical expert group on digital sequence information on genetic resources. Available at: <https://www.cbd.int/doc/c/ba60/7272/3260b5e396821d42bc21035a/dsi-ahteg-2020-01-07-en.pdf>. Access on: 02 feb. 2021.

⁵⁶ CONVENTION ON BIOLOGICAL DIVERSITY. *CBD/DSI/AHTEG/2020/1/3*. Digital sequence information on genetic resources: concept, scope and current use. Available at: <https://www.cbd.int/doc/c/fe9/2f90/70f037ccc5da885dfb293e88/dsi-ahteg-2020-01-03-en.pdf>. Access on: 05 feb. 2021.

⁵⁷ CONVENTION ON BIOLOGICAL DIVERSITY. Available at: <https://www.cbd.int/dsi-gr/2019-2020/>. Access on: 15 sep. 2020.

6 DSI and ABS regime: a possible marriage?

As previously explained, there is no certainty whether the DSI will be considered a genetic resource for ABS purposes. Considering that just physical samples are considered genetic material, maintaining the classical understanding of biopiracy, the ABS regime is fated to be out-of-date and with little effect. Being considered a genetic resource, new instruments to guarantee the compliance with the ABS regime shall be established by the Parties.

The study on DSI in Public and Private Databases and DSI Traceability (hereinafter “Study on DSI”), requested by the 14th meeting of the COP, elucidates and proposes many possible ways to enable an ABS regime focused on DSI.

One of the main problems of an ABS regime focused on DSI is the fluidity of the information that makes difficult traceability. The information about the place of origin, its users and usages are very important for establishing a PIC/MAT and benefit sharing commitments. The Study on DSI brought to light the importance of the INSDC⁵⁸ as a tool to track the NSD. It explains that the submission of a NSD into the INSDC creates an Accession Number (AN), which can enable anyone to localize the NSD. Moreover, once the research is published, it also receives a Digital Object Identifier (DOI) to trace publications. Usually, the researcher reports to the INSDC and informs the NSD register with the DOI from the publication. Thus, the AN and DOI could be very useful to enable the genetic resources traceability. However, the authors also emphasize that currently there is no dedicated PIC/MAT field in the INSDC submission forms⁵⁹.

⁵⁸ The International Nucleotide Sequence Database Collaboration (INSDC) is a long-standing cooperation for the storage of genetic material data. The database holds the vast majority of DSI used in the public databases and imposes no use restrictions, licensing requirements or fees on the use of database by any party. The INSDC includes the three largest international databases for genetic data: the Genbank (based in Maryland, USA), the European Nucleotide Archive (Cambridge, UK) and DNA Data Bank of Japan. DRÖGE, Gabriele; HUANG, Sixing; ROHDEN, Fabian; SCHOLZ, Amber Hartman. *Combined Study on DSI in Public and private databases and DSI traceability*. 2019. Available at: <https://www.cbd.int/abs/DSI-peer/Study-Traceability-databases.pdf>. Access on: 15 sep. 2020. p. 12.

⁵⁹ DRÖGE, Gabriele; HUANG, Sixing; ROHDEN, Fabian; SCHOLZ, Amber Hartman. *Combined Study on DSI in Public and private databases and DSI traceability*. 2019. Available at: <https://www.cbd.int/abs/DSI-peer/Study-Traceability-databases.pdf>. Access on: 15 sep. 2020.

Biodiversity is considered a common concern of humanity and the solutions for its conservation demands the participation of all players of the international sphere. Furthermore, the commercial interconnections between the states will require a single solution for the DSI problem. For instance, companies situated in the United States, a non-signatory party of the Protocol, are likely to have to comply with Brazilian ABS legislation if they intend to commercialize their products in Brazil (Brazilian ABS legislation comprises DSI). As Dinah Shelton asserts “a common concern requires international action and necessitates new forms of law making, compliance techniques and enforcement”⁶⁰. It is also important to bear in mind that the Nagoya Protocol foresees, in its article 10, the possibility of the creation of a multilateral system for transboundary situations or when is impossible to obtain the PIC. In some sense this system could undermine states sovereignty over their resources and bring biodiversity closer to the concept of the Common Heritage of Mankind for some specific situations. The urgency of creating a multilateral mechanism for sharing benefits make believe that the mega biodiverse countries did not comprehend the concept of CHM at the time of the CBD’s negotiation. Their fear of appropriation of their resources without sharing benefits made them to insist on the concept of the Common Concern of Mankind, based on the sovereignty principle. However, the CHM also applies the sharing of benefit and the classical notion of sovereignty of states seems to be outdated to deal with some environmental issues, which are international and transboundary by essence⁶¹.

6.1 Possible solutions for traceability

The study suggests some possible solutions for traceability. One of them is the improvement of the INSDC, applying the country of origin requirements on new NSD/DSI submissions. Although since 2011 there is a specific field to insert the country, there are many sequences without a place of origin associated

[cbd.int/abs/DSI-peer/Study-Traceability-databases.pdf](https://www.cbd.int/abs/DSI-peer/Study-Traceability-databases.pdf). Access on: 15 sep. 2020.

⁶⁰ SHELTON, Dinah. *Common concern of humanity*. Iustum Aequum Salutare V. 2009/1. Available at: <http://ias.jak.ppke.hu/hir/ias/20091sz/05.pdf>. Access on: 11 oct. 2021. p. 40.

⁶¹ OLIVEIRA, Liziane Paixão Silva. *A Convenção sobre Diversidade Biológica e o princípio da soberania nacional*. 2006. Dissertação (Mestrado) – Universidade de Brasília, 2006.

with them. Thus, the study indicates that the researchers should be better trained in order to submit NSD/DSI, filling all blanks required⁶².

Another possible solution is the use of the blockchain technology. This system became known for its application with cryptocurrencies, such as Bitcoin, but it can be used for many different applications. According to Tama et al., “blockchain has drawn a lot of attention to the decentralized transaction ledger functionality which could be used to register, confirm, and send the payment or contracts⁶³”. Simply put, the blockchain is a decentralized database, shared and audited by its participants, with no need of a central authority for examining the information.

In this context, as the blockchain registers and validates all inputs of the database, the DSI could take the advantage of the storage, traceability, and trust. In addition to that, it also permits to store the terms of use for the data, using a mechanism called smart contracts. Thus, a MTA related to a genetic resource could also be stored and “everyone that access the NSD [DSI] via blockchain system would automatically be required to accept the conditions of the MTA [...]”⁶⁴ Dröge et al. suggest the use of blockchain based on the success of its application on individual human genomes. Moreover, they were influenced by the Earth Biogenome Project, which was launched in 2018, aiming to sequence the plants and animals of the planet and store their NSD in a blockchain.

It is important to highlight that the study indicates that the traceability will just be technically feasible if the concept of DSI solely includes DNA, RNA and proteins. Otherwise, the compliance mechanisms will be ineffective⁶⁵. It means that if the states decide that the

DSI concept encompasses metabolites and other environment interactions (See section 4), the blockchain technology cannot track back these elements to the origin country. Conversely, it is possible to track the information of a protein, RNA or a DNA to the country of origin of the genetic resource.

6.2 Benefit-sharing issues

Due to the challenges of implementation of the ABS system regarding the DSI, it has been alleged that the cost of maintenance of the database should be considered a compensation for the use of genetic resources. Some experts also argue that ABS rules do not stimulate the research because imposes unnecessary red-tapes⁶⁶.

Some researchers also say that the bureaucracy created by the ABS rules hinder the preservation of biological diversity and that “digital sequence data in the public domain provides a key resource for the conservation of biological diversity and the sustainable use of its component”⁶⁷. Bond and Scott comment that scientific publications raised concern that, if ABS regime includes DSI, this would encumber, rather than discouraging biopiracy⁶⁸. The Ecological Society of America also expressed concern if the inclusion could delay important health measures, especially related to the development of vaccines and monitoring the pathogens evolution in a scenario of Covid-19 pandemic⁶⁹. On the other hand, the Third World Network, a civil society group, alleges that companies are using the DSI to bypass the established mechanisms for fair and equitable sharing of benefits. The NGO calls this practice of digital biopiracy

private databases and DSI traceability. 2019. Available at: <https://www.cbd.int/abs/DSI-peer/Study-Traceability-databases.pdf>. Access on: 15 sep. 2020.

⁶² DRÖGE, Gabriele; HUANG, Sixing; ROHDEN, Fabian; SCHOLZ, Amber Hartman. *Combined Study on DSI in Public and private databases and DSI traceability*. 2019. Available at: <https://www.cbd.int/abs/DSI-peer/Study-Traceability-databases.pdf>. Access on: 15 sep. 2020.

⁶³ TAMA, A.; KWEKA, B. J.; RHEE, K. *A critical review of blockchain and its current applications*. International Conference on Electrical Engineering and Computer Science (ICECOS), Palembang, Indonesia, 2017. p. 109.

⁶⁴ DRÖGE, Gabriele; HUANG, Sixing; ROHDEN, Fabian; SCHOLZ, Amber Hartman. *Combined Study on DSI in Public and private databases and DSI traceability*. 2019. Available at: <https://www.cbd.int/abs/DSI-peer/Study-Traceability-databases.pdf>. Access on: 15 sep. 2020.

⁶⁵ DRÖGE, Gabriele; HUANG, Sixing; ROHDEN, Fabian; SCHOLZ, Amber Hartman. *Combined Study on DSI in Public and*

⁶⁶ LAWSON, Charles; ROURKE, Michelle. Digital Sequence Information as a marine genetic resource under the proposed UNCLOS legally binding instrument. *Marine Policy*, v. 122, 2020. p. 7.; Also HIEMSTRA, S. J.; BRINK, M.; VAN HINTUM, T. Digital Sequence Information (DSI): options and impact of regulating access and benefit sharing: stakeholder perspectives. Centre for Genetic Resources, the Netherlands (CmGN), Wageningen University & Research. *CGN Report*, n. 42, 2019.

⁶⁷ WATANABE, Myrna. The Nagoya Protocol: the conundrum of defining digital sequence information. *BioScience*, v. 69, n. 6, jun. 2019. p. 480.

⁶⁸ SCOTT, D.; BOND, M. Digital biopiracy and the (dis)assembling of the Nagoya Protocol. *Geoforum*, n. 117, p. 24-32, 2020.

⁶⁹ PARSONS, Jill. *Benefit-Sharing, Nagoya, and DSI: oh my!* Ecological Society of America. Available at: <https://www.esa.org/esa-blog/2020/05/11/benefit-sharing-nagoya-and-dsi-oh-my/>. Access on: 05 mar. 2021.

and demands some compensation to the countries of origin of these genetic resources⁷⁰.

Manuel Ruiz Muller proposes a radical change in the ABS system. Pursuant to the author, who regrets defending the current definition of genetic resources in the CBD's negotiation, a multilateral benefit sharing mechanism would be more effective for the DSI. He suggests that the benefit-sharing should come from royalties derived from genetic resources discoveries. As these findings would be protected under intellectual property law, the national intellectual property institutes could charge royalties depending on the economical results. These royalties would be "transferred to a benefit-sharing fund for proportional distribution among countries of origin of species"⁷¹, with no need of PIC and MAT. His idea resembles the multilateral mechanism used sharing the benefits under the International Treaty on Plant Genetic Resources for Food and Agriculture, which came into force in 2004 and currently counts with 148 (one hundred forty-eight) contracting parties⁷². The treaty establishes a simplified access mechanism for specific agricultural genetic resources, with no need to indicate the origin of it. The monetary benefit-sharing mechanism is based on a fee payment directly to an international fund. However, the ITPGRFA's application is limited to (i) species listed on its Annex I; (ii) genetic resources present in "ex situ" collections and public domain and (iii) purposes of conservation, research and improvement for food and agriculture⁷³. The treaty coexists with Nagoya and its multilateral mechanism is considered a source of inspiration to the implementation of the Nagoya multilateral mechanism.

In the third meeting (online) of the Open-Ended Working Group on the Post-2020 Global Biodiversity Framework, which occurred from August 23 to September 3, 2021, it was proposed a draft recommendation to the COP-15 related to Digital Sequence information on genetic resources. Although the document may suffer

many alterations, it provides a hint of the direction of the future discussions. The item 16, for instance, suggests a multilateral benefit-sharing mechanism, operated by the Global Environmental Facility, to ensure that

[at least] 1 per cent of the retail price of all commercial income resulting from all utilization of genetic resources, traditional knowledge associated with genetic resources or digital sequence information on genetic resources is shared through the multilateral benefit-sharing mechanism [...] unless such benefits are otherwise being shared on mutually agreed terms established under the bilateral system [...]⁷⁴

At this point we have a fork in the road: considering an open access system to maximize research efficiency, ignoring the ABS rules for DSI, or accepting a new challenge and make some adaptation to guarantee the compliance with Nagoya Protocol. In this sense, governments of many countries are trying to find ways to regulate cryptocurrency and fake news. These issues appeared and took the advantage of the regulatory limbo, working in the blind spot of the legal systems. Although Law is always a step behind considering the speed of technological development, it is undeniable that it should be used as an instrument to guarantee the fair application of technology.

7 Conclusion

The Nagoya Protocol developed, in more detail, Articles 15 of the Convention on Biological Diversity related to the access to and benefit-sharing arising from genetic resources. As a framework convention, the CBD was extremely vague in relation to these two provisions. Therefore, the Nagoya protocol, as a legally binding instrument, came to guarantee the operationalization of the ABS regime. More importantly, the Protocol is an instrument of distributive justice, and the equitable sharing of benefits approach is a tool to achieve sustainable development.

However, with the emergence of new technologies, the scientists have been changing the forms of accessing genetic resources. Many times, the physical samples are no longer necessary; and instead, researchers

⁷⁰ TWN. Available at: https://www.twon.my/title2/briefing_papers/No93.pdf. Access on: 05 mar. 2021.

⁷¹ MULLER, Manuel Ruiz. *Genetic resources as natural information*. Routledge Studies in Law and Sustainable Development, Taylor and Francis, 2015. p. 85.

⁷² FOOD AND AGRICULTURE ORGANIZATION. Membership. Available at: <http://www.fao.org/plant-treaty/countries/membership/en/>. Access on: sep. 2021.

⁷³ FOOD AND AGRICULTURE ORGANIZATION. *International Treaty on Plant Genetic Resources for Food and Agriculture*. Available at: <http://www.fao.org/3/i0510e/i0510e.pdf>. Access on: 6 sep. 2021.

⁷⁴ CONVENTION ON BIOLOGICAL DIVERSITY. *Item 5 of the provisional agenda: digital sequence information on genetic resources*. Available at: <https://www.cbd.int/doc/c/4dff/3b82/916f7588c96fd1d499bea130/wg2020-03-crp-01-en.pdf>. Access on: oct. 2021.

are using digital sequences of DNA/RNA, which are usually stored in public international databases. Before this new scenario, the COP to the CBD and the Parties of the Nagoya Protocol have been requesting many studies and establishing many working groups to clarify whether the DSI should be included in the scope ABS system and how it could be operationalized.

Based on the principles of distributive and corrective justice, which supported and conceived the ABS system, the rationale of the system remains untouched. The fact that the biological resources that were primarily appropriated in a tangible form are being accessed in a digital format does not change the need of the PIC and the equitable sharing of benefit. The logic of the system is still the same: equalizing the inequality between the technological rich countries of the North and the biodiverse rich countries of the South to guarantee the biodiversity conservation and distributive justice.

Therefore, the technology should be used to support a new regulatory framework for the ABS system. New technologies, such as blockchain, could enhance the available mechanisms for DSI access and traceability, providing simple solutions well suited to the speed of scientific progress. In addition, Parties may propose a multilateral mechanism that would be better suited for sharing DSI's research economical results. The ABS system does not need to be a nightmare to researchers. However, the conservation of biodiversity demands the creation of innovative solutions and the use of collective compliance mechanisms. The objective is not to create hurdles to scientific research but guarantee that they are conducted respecting ABS principles.

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