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Article

The challenges in the utilization of marine genetic resources in national and international jurisdictions from a legal perspective

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Abstract: This article examines the legal challenges associated with the utilization of marine genetic resources (MGR) at both the national level and beyond national jurisdiction (BBNJ). The legal challenges addressed are as follows: 1) MGR are located across various jurisdictions, encompassing both national and international domains. The analysis starts with an overview of the international regulations that govern the utilization of genetic resources (GR) and their influence on national legislation. It emphasizes the principle of state sovereignty over natural resources while defining MGR and determining ownership; 2) It further highlights the intersection of national and international laws, particularly in transboundary contexts and within Indigenous and Afro-descendant peoples (IADP) territories, analyzing how these regulations are interpreted and applied in such scenarios; 3) The legal challenges related to the use of MGR in international waters are examined. Special emphasis is placed on the recent United Nations (UN) Agreement concerning this issue. This includes an analysis of its impact and specific provisions related to the utilization of MGR, such as the quantity to be collected, the methodology employed, collection sites, among others. The article concludes by asserting that the equitable distribution of benefits from the use of GR should begin at the earliest stages of access to these resources, including project planning and sample collection, rather than being delayed until the patenting and commercialization phases. Early benefit-sharing is essential for promoting fairness and equity in the use of MGR.

Keywords: marine zones; natural protected areas; sample collection; indigenous people; BBNJ; biotechnology

1. Introduction

A significant portion of the legal challenges associated with the utilization of marine genetic resources (MGR) arise from the diverse jurisdictions where biodiversity is found globally. This complexity makes it a human activity that demands precise and efficient regulation. This regulation should be implemented globally through both hard law and soft law mechanisms. Hard law refers to binding, mandatory rules, while soft law consists of non-binding, recommended guidelines. As well as at the national level, regardless of the legal systems in the countries involved. In this context, international environmental law establishes minimum international standards and adapts regulatory mechanisms to foster harmonious interactions between humans and nature (Bilder, 1980). This process shapes an environmental normative framework aimed at addressing planetary needs effectively (Nunes Chaib, 2022). Consequently, domestic courts and tribunals are compelled to apply international environmental law (Angstadt, 2023). However, regarding the utilization of MGR, coherence and articulation are challenging both internationally and nationally. Particularly in the sector of MGR, there remain legal issues around definitions and

intellectual property. It is widely recognized that patents associated with MGR are held by a small number of influential private and national entities (Mendenhall et al., 2022).

As an international process begins to regulate biodiversity beyond national authority, including MGR, technical and practical obstacles persist. Despite this ongoing process, it is imperative not to disregard the enduring legal challenges associated with the bioprospecting of MGR at the national level. Notably, not all countries have clearly defined legislation in this realm, and there are instances where these resources fall under national areas, necessitating the application of international environmental law. Unfortunately, there are legal gaps that require attention to ensure the proper and sustainable management of MGR and to protect the interests of all stakeholders involved. This article conducts a legal dogmatic analysis to articulate crucial international treaties for conducting the utilization of MGR in national and international jurisdictions.

It is essential to understand that the utilization of MGR in national jurisdictions and its implementation at the international level are complementary. This is because biodiversity does not acknowledge the political and legal divisions established by humanity. This article begins with an explanation of what the utilization of MGR entails as a human activity that possesses unique, distinctive, inherently complex, and highly significant characteristics, warranting specific regulation due to its internal and external effects at various levels, such as economic, social, political, environmental, health, nutrition, human rights, cultural, and others. Moreover, a legal study is conducted to articulate and highlight relevant aspects for the utilization of MGR from the following six (6) major treaties:

1) Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) (United Nations, 1973).
2) United Nations Convention on the Law of the Sea (UNCLOS) (United Nations, 1982).
3) Convention No. 169 concerning Indigenous and Tribal Peoples (Convention 169) (International Labour Organization, 1989).
4) Convention on Biological Diversity (CBD) (United Nations, 1992a).
5) Nagoya Protocol (NP) (United Nations, 2010).
6) Agreement Under the United Nations Convention on the Law of the Sea on the Conservation and Sustainable Use of Marine Biological Diversity of Areas Beyond National Jurisdiction (BBNJ Agreement) (United Nations, 2023).

These treaties have specific objectives and subject matters that are interrelated and crucial for the utilization of MGR, and each of these treaties are part of hard law. To ensure legal certainty from the beginning of the utilization of MGR, the opening sections of this article delve into the six primary treaties, with a focus on the legal challenge such as defining MGR, determining ownership, understanding their utilization and significance, and analyzing the regulatory framework governing GR rights. This serves as a fundamental prerequisite for starting the utilization of MGR, as identifying GR owners facilitate determining from whom to seek permission for sample collection. Subsequently, the international legal framework is examined to address the technical requirements for sample collection on an individual basis, encompassing aspects such as the quantity to be collected, the methodology employed,

collection sites, among others, culminating in the legal prerequisites for conducting studies on collected samples in either a laboratory or another ex-situ location.

2. Methodology

To develop the article using a legal dogmatic methodology, it was necessary to examine and analyze international law as it relates to the bioprospecting of MGR. This approach systematically studies treaties and legal principles to comprehend the legal framework and address issues of interpretation and practical application in the field of the utilization of MGR. The methodology consists of the following key steps:

1) Systematic Analysis: This step involves a thorough examination of legal norms, considering their structure, hierarchy, and interrelation with other norms.
2) Value Neutrality: The methodology maintains neutrality concerning moral or political values, concentrating on the objective interpretation of legal norms without external biases.
3) Deductive Method: This approach employs deductive reasoning, applying general legal principles to specific cases to derive legal conclusions.

In summary, the legal dogmatic methodology follows a structured approach that systematically analyzes the law, primarily relying on the interpretation of existing legal norms related to the utilization of MGR.

3. International legal framework for the utilization of MGR

3.1. The legal importance of MGR

The theory of protected legal interests recognizes the existence of essential goods crucial to the development of life in all its forms and relationships, which must be guaranteed by law. The theory of protected legal interests or goods expands the scope of Criminal Law to encompass other areas, such as Environmental Law. Biodiversity is encompassed within the category of protected legal interests (Bodansky, 2012). Moreover, biodiversity plays a crucial role in ensuring human well-being, maintaining the health of our planet, and fostering economic prosperity for all (United Nations, 2022). The vast array of marine and terrestrial organisms plays pivotal roles in regulating biogeochemical cycles by influencing processes like organic matter decomposition, nutrient fixation, and the production and consumption of atmospheric gases. Moreover, biodiversity is essential for numerous fundamental human rights, including the right to health, food, housing, and the right to a healthy environment, among others. However, biodiversity, recognized as a protected legal interest, is rapidly declining within short periods of time (Cepic et al., 2022). This is due to a combination of specific and widespread human threats, including deforestation, overfishing, illegal hunting and trafficking of species, tourism, urbanization, poor agricultural and urban development practices, and anthropogenic climate change (García, 2020).

These human behaviors are limiting the range of both monetary and non-monetary benefits of biodiversity, encompassing intrinsic and instrumental values, while also generating economic impacts for society (Nobel et al., 2020). In the specific case of the utilization of MGR, when properly regulated, can generate a large number

of benefits. For instance, microbial utilization is a valuable tool for discovering intriguing microorganisms and biological metabolites that can be utilized in the development of medicines, energy sources, economic growth, and food production (Hosseini et al., 2022). Nevertheless, if conducted without proper oversight, the utilization of these resources it may result in injustices, unequal distribution of benefits, unethical actions, and violations of human rights, among other legal issues (Wynberg et al., 2015).

In the realm of marine resources, they possess at least two characteristics that confer significance upon them: 1) Some harbor the capacity to adapt, tolerate, and thrive in extreme natural and anthropogenic conditions, such as high salinity, low and high temperatures, increased pressure at depth, and reduced light (Fernandes, 2014); 2) Marine resources, especially those in the depths of the oceans, remain largely unexplored, and comparisons with terrestrial ecosystems highlight the incredible diversity of marine organisms. These resources possess immense potential for integrated biodiscovery through the utilization of molecular, genetic, bioinformatic, and analytical tools (Williams et al., 2020). Therefore, the adaptability of marine resources, coupled with their untapped genetic diversity potential, presents a vast opportunity for the advancement of bioprospecting and biotechnology.

The importance of both mentioned characteristics in the previous paragraph is due to the genetic diversity that marine resources possess. Environmentally, marine life depends on genetic diversity. The presence of diverse genetic codes encoding functional traits within species offers increased opportunities for evolution, enhancing their capacity to adapt, recover, and withstand external threats. This, in turn, influences the functional attributes, distribution, and adaptability of marine species (Blasiak et al., 2020). Furthermore, from economic, legal, sociocultural, and political perspectives, marine genetic diversity holds paramount importance. This encompasses both physical molecules and the genetic sequence information they carry. This significance stems from the capability to store DNA (deoxyribonucleic acid) and RNA (ribonucleic acid) nucleotide sequences as digital data. This information can be used to generate proteins, molecular processes, innovations, and even new organisms, all of which may be subject to commercialization and patent exploitation (Blasiak et al., 2023).

Thus, the utilization of MGR necessitates a legal framework that ensures both environmental conservation and the rights of all parties involved throughout the entire process. The term “utilization of GR” as outlined in Article 2 of the NP, refers to the research and development activities involving the genetic or biochemical properties of GR, including the use of biotechnology. However, this utilization is a multi-stage endeavor that involves diverse actors and ultimately leads to the commercialization and equitable sharing of benefits. This article thoroughly examines the legal implications of the initial stages of the utilization from the perspective of marine resources. Specifically, it focuses on two key elements for legal analysis: the collection of samples of MGR and the subsequent study or utilization.

3.2. Jurisdictions, concept and ownership of MGR

The MGR, recognized as a protected legal interest, are found within national jurisdictions as well as in areas beyond national borders, which complicates its legal

protection (Minnerop, 2023). Furthermore, there is a wide range of levels at which human activities can influence and exploit biodiversity, including ecosystems, habitats, species, and genetics, in both marine and terrestrial environments. Additionally, the influence of human activities on multiple levels of government-municipal, State, national, and international has limited efforts to protect and sustainably manage biodiversity through legislation.

Hence, measures to safeguard biodiversity have taken various forms, including the establishment of Protected Natural Areas, Environmental Impact Assessments, urban and rural planning initiatives, environmental education programs, and ecological land use planning. In addition, the legislation concerning biodiversity has adopted various forms, including codes of conduct, guidelines, best practices or standards, sectoral laws, framework laws, constitutional provisions, international agendas (Guifarro, 2023), and international soft and binding treaties.

During the initial stages of utilizing MGR at both national and international levels, the collection phase poses significant legal challenges. At this stage, it is essential to understand the concept of MGR and to determine their ownership. This task can be challenging due to the involvement of multiple stakeholders, authorities, and the diverse geographic locations where these resources are found. The complexity of determining ownership is one of the major legal issues concerning marine bioprospecting contracts (Bhatia and Chugh, 2015).

Historically, the concept of GR evolved alongside the determination of their ownership. As their scientific utility became better understood, the need for binding regulations to establish ownership increased. In the 1970s and 1980s, the focus on GR was related to agricultural plants in terrestrial contexts (Deplazes-Zemp, 2018). During this period, GR were considered the common heritage of mankind and were intended to be freely accessible (United Nations, 1983). However, unrestricted access at national or international levels to GR has predominantly led Northern countries to exploit them more, driven by their superior technological, scientific, and economic capabilities. This disparity adversely affected Southern countries, which possessed diverse GR but lacked the means to exploit them effectively. Moreover, in many cases, Southern nations did not receive benefit from the exploitation conducted by Northern nations, despite the South providing resources while the North patented them (Deplazes-Zemp, 2018; Pat Roy Mooney, 1983). Due to this context, there has been legal recognition that countries own the GR within their administration, while those located in international waters are considered the common heritage of mankind.

The definition of GR and the establishment of national ownership was defined under the CBD in 1992. This is one of the first legally binding provisions addressing the concept and ownership of GR at the national level or within a country's jurisdiction. Article 2 of the CBD defines key concepts, starting with biological diversity, which refers to the variability of living organisms from all sources. It includes biological resources, such as GR and other biotic components, and genetic material, meaning any material containing functional units of heredity. Finally, GR are defined as genetic material of actual or potential value.

With regard to ownership, it was conditioned according to the principles of international law and the sovereign rights (SR) of States over their resources. Two specific articles of the CBD are particularly noteworthy: Article 3 and Article 15.

Article 3 reflects a core principle of International Law (United Nations, 1992b), affirming the SR of States to utilize their natural resources according to their domestic policies and laws, free from external interference or pressure. This right of the States is constrained by the obligation to avoid causing damage to third parties or areas beyond theirs borders. Conversely, Article 15 (1) explicitly acknowledges the SR of States over their GR, granting them the authority to regulate access through national legislation. Similarly, Article 6 (1) of the NP reaffirms the SR of States over these resources.

The CBD does not explicitly cover MGR. Therefore, when aligning the content of this treaty with the marine context and the SR of States, an interpretation of Articles 1, 2, and 22 of the CBD is necessary to clarify SR over MGR. Article 1 establishes that the treaty's primary objectives revolve around biological diversity and GR. Biodiversity, as defined in Article 2 of the CBD, includes terrestrial, marine and other aquatic ecosystems, and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems. Furthermore, Article 22 of the CBD imposes the obligation on the Parties to apply the provisions of the CBD regarding the marine environment. It specifies that this application must align with the rights and obligations of States under the law of the sea, without specifying any particular treaty on the law of the sea.

In the specific case of marine natural resources at the domestic level, UNCLOS reinforces the principles outlined by asserting in Article 193 the SR of States to exploit their natural resources, particularly those of marine origin. The UNCLOS conditions this SR of States, stipulating that exploitation must be in line with their obligation to protect and preserve the marine environment, general obligation stipulated in Article 192. Moreover, UNCLOS recognizes the SR of States over each of the internal marine zones-Internal Waters, Territorial Sea, Contiguous Zone, and Exclusive Economic Zone (EEZ). For instance, Article 2 grants coastal States sovereignty extending to the airspace above the territorial sea, as well as to the seabed and subsoil of that sea. Article 56 outlines the SR of the coastal States in the EEZ for exploring and exploiting, conserving and managing the natural resources, whether living or non-living" (United Nations, 1982).

Additionally, Article 245 of UNCLOS specifies that coastal States possess the exclusive authority to regulate, permit, and conduct marine scientific research activities within their Territorial Sea as part of their sovereignty. Such activities may only proceed with the explicit consent of these States and must adhere to the conditions they establish. The Territorial Sea is a maritime zone fully under the sovereignty of coastal States (Kumala et al., 2023). The same situation is established in Article 246 (1) and (2) for marine scientific research in the EEZ and the Continental Shelf.

The UNCLOS addresses the conservation and utilization of living resources in Article 61 and 62, respectively. Nevertheless, the term marine living resources (MLR) was primarily associated with fisheries resources, strongly associated with fisheries law, mainly because UNCLOS predates treaties like the CBD or NG, which are essential components of international environmental law. Additionally, during the period of UNCLOS elaboration, activities such as the bioprospecting of MGR were not as advanced, limited by the development of current technology (Rafaly, 2022). While UNCLOS addresses concepts such as MLR and marine life, which contain

genetic material, it does not specifically regulate GR. The legal regime governing GR includes aspects such as access and benefit sharing (ABS), ownership, utilization, and commercialization. Moreover, UNCLOS does not recognize or address the specific rights and obligations of users and providers of MGR. However, UNCLOS does acknowledge the SR that States have over MLR resources with certain specific limitations. Neither the CBD, the NP, nor UNCLOS make a distinction between terrestrial and MGR.

While a comprehensive global legal definition for GR has been in place since 1992, it was not until 2023 that a precise definition specifically addressing MGR was formalized within an international treaty. This refinement was necessary due to the unique nature of MGR, which exist within two primary domains: national jurisdictions and the international or high seas jurisdiction. The BBNJ Agreement, Article 1 (8) precisely defines MGR as any material of marine plant, animal, microbial or other origin containing functional units of heredity of actual or potential value. On its part, the utilization of MGR is defined for the first time in an international treaty. Specifically, Article 1 (14) of the BBNJ defines it as "means to conduct research and development on the genetic and/or biochemical composition of MGR, including through the application of biotechnology.

With respect to the ownership of MGR at the international level, Article 136 of UNCLOS states that the resources of the Area are the common heritage of humanity. Article 137 further asserts that no State may claim or exercise sovereignty or SR over any part of the Area or its resources, and no State, individual, or legal entity may appropriate any part of the Area or its resources. These provisions are reinforced in the BBNJ Agreement, specifically in Article 11 (4) and (5), which states that no State shall claim or exercise sovereignty or SR over MGR in areas beyond national jurisdiction, and no such claim or exercise of sovereignty shall be recognized. Additionally, the in-situ collection of MGR from these areas shall not provide a legal basis for claiming any part of the marine environment or its resources.

3.3. Practical scenarios of bioprospecting MGR

Based on the treaties mentioned thus far, an approach emerges to address the question of who owns MGR at both national and international levels. At the national level, states are empowered to regulate access, utilization, and benefit-sharing of GR according to their internal laws and policies, grounded in their sovereignty over these resources. However, there will be no examination of specific national legislation on this matter. In the second case, MGR are considered the common heritage of mankind. However, in practice, the utilization of MGR becomes complex, particularly in situ conditions. The potential situations can vary significantly both nationally and internationally; therefore, the following cases will be discussed, along with an analysis of international law.

The first case occurs when MGR are within the national jurisdiction of a specific State but are located on the territory of IADP, the situation becomes more complex when traditional knowledge associated with MGR is involved. An example of this can be found on the island continent of Australia, where over 500 different IADP have lived for millennia. Their knowledge of plants has been fundamental in treating

various diseases. Four plant species, in particular, are used to treat stings from marine organisms such as rays, fish, and sea jellies (Turpin et al., 2022). In this context, another significant binding treaty is the Convention No. 169, Article 15 affirms the rights of IADP over the natural resources within their territories and mandates States to establish consultation processes, this topic is addressed in the following sections of this article. Regarding Soft Law, Article 31 of the UN Declaration on the Rights of IADP recognizes that IADP have the right to control, maintain, and protect their GR, seeds, and medicines (United Nations, 2007).

To address the question of whether MGR situated in the territories of IADP belong to them or to the States, the internal legislation of each country must be considered. However, many States have not aligned their domestic laws with Convention No. 169. As a result, conducting collection activities for bioprospecting MGR often face challenges. Furthermore, ownership of MGR remains unclear, with States typically asserting ownership rights rather than recognizing them as belonging to IADP in most cases. This topic transcends into the field of legal pluralism for Indigenous law and legal systems, whether complementary or not, to act upon Western intellectual property law and provide essential protection for Indigenous resources and intangible assets (Conway, 2023). It is important for user of MGR to consider that some countries, in their domestic legislation, recognize the rights of IADP over their traditional knowledge but not over the GR they have ancestrally preserved, which are closely tied to their traditions and customs.

The second scenario is when MGR are located within the authorities of two or more countries, transboundary or shared MGR. Transboundary marine natural resources are subject to greater overextraction compared to those within a single EEZ, and the costs are shared collectively (Liu and Molina, 2021). Regarding this situation and to determine ownership of this category of resources, international legislation first refers to the principle of international law on Transboundary Cooperation. Article 11 of the NP establishes that in instances where the same GR are found within the territory of multiple countries; they shall endeavor to cooperate. Furthermore, concerning the case discussed in previous paragraphs, the Article 11 of NP mentions that IADP concerned should be considered.

In this case, it is important to highlight two legal obligations: to establish a system of information on the status of shared MGR and to establish consultation processes before, during, and after carrying out actions that could have impacts on these transboundary resources. Such provisions are established in international legal treaties, the Charter of Economic Rights and Duties of States in Article 3 stablishes for the exploitation of natural resources shared by two or more countries, an information and prior consultation system must be established to optimize the use of these resources without undermining the interests of the countries involved (United Nations, 1974). However, the international legal protection of shared MGR is not as well-developed as that of other transboundary natural resources, such as transboundary waters.

Specifically, Article 242 of the UNCLS establishes the obligation to promote cooperation for scientific research based on mutual benefit and respect for sovereignty, providing relevant information to prevent harm to ecosystems and human health. When conducting bioprospecting activities and determining which country/countries own one or more shared MGR, the users must consider that one or several countries

have ownership of the resources. In any case, they should keep all parties informed about the scope, impacts, and outcomes of their bioprospecting activities. This topic has been further developed within the context of fisheries management, where the stock of species is classified into at least three categories: Transboundary—stocks that cross the EEZs of two or more bordering coastal States; Straddling—stocks that cross neighboring EEZs and the adjacent high seas; and highly migratory—stocks that cross non-neighboring EEZs and the high seas (Palacios-Abrantes et al., 2020).

The third case is when MGR are within the national area and the possession or under the administration of certain entities or people. This case can subdivide into two specific situations.

The first situation occurs when MGR belong to citizens or communities, who, to some extent, share the possession of these resources with the State. The second situation emerges when the resources are located within Protected Areas (PA). "Protected area" means a geographically defined area which is designated or regulated and managed to achieve specific conservation objectives. Article 2 CBD, Use of Terms. While marine resources are managed by the State, the establishment of Protected Areas or the possession by citizens or communities typically requires designated internal authorities responsible for overseeing and permitting all activities within their boundaries, including the collection of MGR. Therefore, when conducting bioprospecting of MGR located in Protected Areas, it must be acknowledged that the authority to administer the resources lies with the designated authorities, this mandate is established in Article 8 (c) of the CBD.

Since 2010, over 21 million km^2 have been designated as protected and conserved areas, with approximately one third of PA affected by intensive human activity. Therefore, before bioprospecting in these contexts, it is necessary to clarify the relationships and common issues between local authorities and policymakers. For instance, conflicts between conservation and development within PA often hinge on whether natural resources can be effectively protected and sustainably utilized. The complex ownership status of land and sea areas further complicates the division of space for use. Hence, adopting a bioprospecting approach that includes management strategies for PA and engages local communities is crucial to addressing these multifaceted issues in the interest of all stakeholders (Zhang et al., 2022).

In the international context, users must follow the legal mandates of the new BBNJ Agreement, which focuses on the conservation and sustainable use of marine biodiversity in areas beyond national jurisdiction. The treaty, open for signature until September 2025, will take effect once ratified by 60 countries. It addresses four key areas: MGR and benefit sharing, area-based management tools, environmental impact assessments, and capacity-building. The Agreement also incorporates the ABS regime from the CBD and NP, extending it to MGR and digital sequence information.

3.4. Technical requirements for collection of MGR samples

Once ownership of MGR has been established, users must adhere to international regulations regarding technical requirements for conducting bioprospecting activities, both domestically and internationally. For this analysis, the following criteria have been identified:

- Collection permits.
- Objectives to the utilization of MGR.
- MGR characterization.

For national jurisdiction, international legislation does not specify these requirements, leaving each State to regulate them at its discretion. Consequently, the requirements vary from one country to another. Notably, not all countries have specific legislation addressing technical requirements for collecting GR, including MGR. Likewise, these technical requirements for obtaining the collection permit and for conducting laboratory studies are outlined in a research proposal or project, this proposal must be shared with the providers of GR to obtain Prior Informed Consent (PIC). Subsequently, mutually agreed conditions must be established in model contractual clauses outlined in Article 6 (3) (g), Article 15 (1), and Article 19 of the NP. Additionally, for international jurisdiction or high seas, the BBNJ Agreement includes significant mandates that must be considered in the Part II MGR, including the fair and equitable sharing of benefits, Articles 9 to 16.

3.4.1. Permits to collect MGR

The first aspect to clarify is which collection permit is being referred to, without which bioprospecting is limited. To obtain the collection permit both domestically and internationally, bioprospectors must consider at least the following three key aspects in the process of accessing MGR: 1) ABS; 2) Technical requirements for collection; and 3) Rights and obligations of the involved parties. To do this, it is necessary to start with the CBD since it is the treaty where ABS is legally contemplated for the first time. During the stages of the utilization of MGR, the rights and obligations of the parties involved, along with the technical requirements for collection, each possess individual significance, characterized by unique traits within international legislation, which are found within the ABS regime. The Article 1 of the CBD establishes, as its third objective, the purpose of the fair and equitable sharing of the benefits arising out of the utilization of GR, which will be determined or subject to an appropriate access to GR. To achieve this objective, the CBD establishes in Article 15 (5) that access to GR shall be subject to the PIC of the contracting party providing such resources. In addition, Article 15 (4) includes Mutually Agreed Terms, where guidelines will be established on how access will be conducted, a topic that is not the subject of this article.

This PIC is further elaborated upon in Article 6 of the NP, Article titled Access to GR, in the paragraphs (3) (d) and (e) is established for States that require granting PIC to take the necessary legislative, administrative, or policy measures to provide their decision in writing by a competent national authority, considering time and costs. This written decision is the collection permit for GR. This permit or its equivalent granted by the authority once made available to the ABS Clearing-House, shall constitute an internationally recognized certificate of compliance, in accordance with the mandate of Article 17 paragraph (2) of the NP. Regarding the specific processes and requirements on how to obtain the collection permit in writing, it is in Article 13 (2) of the NP where it is Stated that competent national authorities, apart from granting access to GR, have the obligation to advise on applicable procedures and requirements for obtaining PIC and entering into mutually agreed terms.

More oriented towards marine resources at national level, Article 245 of UNCLOS establishes that scientific research in the territorial sea can only be conducted with the express consent of the coastal State, interpreted as a written collection permit, like what the NP refers to. Regarding activities of this nature in the exclusive economic zone and continental shelf, Article 246, paragraph (2) specifically States that consent from the coastal State is required for marine research. While these provisions apply to marine scientific research, it is important to consider if MGR bioprospecting is conducted for commercial purposes. In this latter case, Article 246 paragraph (5) establishes a list of conditions under which States may, at their discretion, withhold consent for marine scientific research projects conducted by another State or competent international organization in the exclusive economic zone or on the continental shelf.

Regarding the permit for marine bioprospecting in the high seas, the Clearing-House Mechanism established under Article 51 of the BBNJ Agreement will create a standardized batch identifier in accordance with Article 12 (3) of the Agreement, after the notification is made six months prior, or as early as possible before, the in-situ collection of MGR in international areas, as stipulated in Article 12 (2). Similarly, Party States must establish internal legal, administrative, or policy guidelines to ensure that future users notify the Clearing-House Mechanism as required by Article 12 (1).

Article 12 of the Agreement specifies that notification, rather than a permit application, is required for activities involving MGR and digital sequence information in international areas. Article 13 elaborates on this by referencing the CBD, the NP, and Convention 169, which pertains to traditional knowledge related to MGR held by IADP. Access to this knowledge can only be granted with the free, prior, and informed consent, or approval and involvement, of these communities. Although this Article does not explicitly State it, this consent must be in writing according to the interpretation of the other referenced treaties.

3.4.2. Objectives to the utilization of MGR

As discussed in the previous paragraphs, users must clearly define the purpose of the utilization of MGR. According to Article 2 of the NP, utilization of GR means conducting research and development on the genetic and/or biochemical composition of GR, including through the application of biotechnology. In marine and costal context, utilization of MGR means to conduct research and development on the genetic and/or biochemical composition of MGR, including through the application of biotechnology, Article 1 (14) BBNJ Agreement. The objectives of utilizing these resources may fall into two main categories:

A) **Utilization for commercial purposes:** involving biotechnology applications to develop or modify products for sale; and
B) **Utilization for non-commercial purposes:** typically associated with academic research but not exclusively.

Defining the utilization purposes of MGR is legally significant as it determines eligibility for benefit-sharing, whether monetary or non-monetary. Commercial objectives typically yield monetary benefits, while non-commercial ones are tied to research. Referenced in the NP, these distinctions outlined in Articles 5 and 17 (4) (i), as well as Annex 1. However, it may be the case that the original objectives of GR

collection and access are non-commercial and are subsequently changed to commercial, this scenario is in Article 6 (g) (iv) of NP. This situation is legally delicate since international treaties propose access to GR for non-commercial purposes and advocate for reducing or simplifying procedures for access and collection, Article 8 (a) of NP and Article 15 (a) of CBD, thus facilitating the process for users but to some extent leaving resource providers vulnerable. This also creates a mechanism for easy initiation of GR access or collection, with the potential for monetization upon discovery of a bioactive principle or commercial application. NP Article 6 (g) (iv) Establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms shall be set out in writing and may include, inter alia: Terms on changes of intent, where applicable.

This situation gains significance in the realm of bioprospecting MGR and digital sequence information in international jurisdiction, as the BBNJ Agreement has established institutional frameworks and guidelines for both monetary and non-monetary benefits. The obligation to establish objectives regarding MGR in areas beyond national jurisdiction is stipulated in Article 12 (2) (a) of the BBNJ Agreement. Article 14 (2) outlines a non-exhaustive list of types of non-monetary benefits. This includes non-monetary benefits related to access to samples, sample collections, and digital sequence information, aligned with current international practices. The users will share monetary benefits through the financial mechanism established in Article 52, which must be used for the conservation and sustainable use of marine in international jurisdiction, as outlined in Article 14 (5) of the Agreement. The modalities for sharing monetary benefits from the utilization of MGR and digital sequence information in international areas will be decided by the Conference of the Parties. This decision will consider the recommendations of the ABS committee established under Article 15 of the Agreement.

The payments shall be made through the special fund established under article 52. According to Article 14 (7), The modalities may include the following: (a) Milestone payments; (b) Payments or contributions related to the commercialization of products, including payment of a percentage of the revenue from sales of products; (c) A tiered fee, paid on a periodic basis, based on a diversified set of indicators measuring the aggregate level of activities by a Party; (d) Other forms as decided by the Conference of the Parties, taking into account recommendations of the access and benefit-sharing committee. Furthermore, when substantial changes occur, such as a shift from monetary to non-monetary interests, Article 12 (4) of the Agreement mandates notifying these changes to the Clearing-House Mechanism prior to the planned collection. Updated information must be communicated to the Clearing-House Mechanism within a reasonable time limit and no later than the commencement of in situ collection, where feasible.

3.4.3. MGR characterization

Before conducting collection activities, users must provide, at a minimum, the type, scientific, and common names, geographical areas, methods and means, as well as the quantity and volume of the species they intend to collect. For further information, refer to Article 12 (2) of the BBNJ Agreement. Also, it is crucial to determine whether the species threatened. Specifically, when species are threatened, Article 8 (k) of the

CBD determines the obligation for the countries to establish and maintain the necessary national legislation for the protection of threatened species and populations (Leal et al., 2012).

Likewise, to assess whether there will be adverse effects from collecting GR of threatened species, it is crucial to provide scientific evidence demonstrating that collecting marine or terrestrial GR will not result in harm. This requirement is outlined in the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES). Although this treaty focuses on trade in species and includes Appendices I, II, and III about threatened species. Understanding "trade" according to Article 1 means export, re-export, import, and introduction from the sea. Article IX establishes the Scientific Authority and the Management Authority, while Article III, IV and V determine these authorities have advised that trade of threatened species will not be detrimental to the survival of the species listed in Appendix I, II and III of CITES treaty. The Management Authority of the State of export must evaluate that the specimen was not obtained in contravention of the laws of that State for the protection of fauna and flora.

The utilization of threatened species and MGR, including digital sequence information, highlights a significant legal gap in the BBNJ Agreement. This gap is evident in Part II, where provisions from Articles 9 to 16 should have addressed these critical issues, particularly in safeguarding against the loss or degradation of MGR due to excessive or uncontrolled collection. Annex 1 (e) briefly acknowledges the importance of threatened, endangered, or declining species and habitats in criteria for identifying areas. Specifically, measures should ensure that the number of samples collected for MGR in areas beyond national jurisdiction is kept below the natural replenishment rate of the species.

The BBNJ Agreement includes significant provisions regarding post-collection activities of MGR samples in areas beyond national jurisdiction, specifically detailed in Article 12 (5) and 12 (8). Users are required to provide detailed information on how GR will be utilized and analyzed in laboratories or ex situ sites. Additionally, they must prioritize requirements and criteria for the preservation and sustainable utilization of these resources within facilities. It is crucial to establish preservation and conservation criteria tailored specifically for MGR. This includes implementing standards to ensure institutional or personnel security aimed at assessing and mitigating risks associated with the loss, degradation, and potential theft of MGR. The OECD has developed Guidelines on Good Practices for Biological Resource Centers in 2007, along with Good Practices in Biocustody for CRBs. While these guidelines are not legally binding, they serve as valuable references for preservation, conservation measures, and risk reduction. Furthermore, it is essential to establish a comprehensive system for registering and safeguarding information related to research on MGR.

4. Conclusions

The bioprospecting of MGR, both at national and international levels, involves considering legislation on biodiversity, IADP, human rights, endangered species under CITES, maritime law or coastal marine areas, GR, patents, the law of sea, among

others. Therefore, Users must seek specialized legal counsel to safeguard the rights of all parties involved.

According to international law, owners of MGR within national jurisdiction belong to the State. There is not complete clarity on whether GR located in the territories of IADP belong to these communities or to the State, with current inclination towards State ownership. This situation needs to be resolved to facilitate bioprospecting.

The NP addresses GR at national level, does not cover bioprospecting and focuses instead on access through consultation, consent, and contractual clauses, without regulating the key stages of bioprospecting. In contrast, UNCLOS does not address GR but includes robust regulations for research activities in coastal marine areas. Regarding the BBNJ Agreement, there is a need to strengthen both the institutional framework and the legal empowerment of party States and individuals or entities engaged in bioprospecting in areas beyond national jurisdiction. Additionally, the treaties create obligations for States, not for individuals such as users.

When establishing the purpose of MGR collection sample, a dependent relationship arises between accessing the GR, the type of utilization intended for the accessed resources, and the distribution of benefits resulting from their utilization. Therefore, it is necessary to clarify the objectives, purposes, and intentions of collecting and studying GR, and clearly define the processes for situations when transitioning from non-commercial to commercial research.

Finally, in the context of areas beyond national jurisdictions, it is anticipated that the initial applications and bioprospecting efforts under the BBNJ Agreement will highlight areas requiring enhanced institutional frameworks, including Information and Advisory Bodies. There is a pressing need to empower relevant stakeholders such as States, IADP, and prospective users.

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