

Research Article

Protection and Utilization of Marine Resources: Between the Challenge of A Unified Legal Framework and the Issue of Sequenced Information

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Abstract

The exploitation and utilization of patentable inventions based on genetic resources (GRs) and traditional knowledge is a major concern for innovators, who are encouraged to incorporate the issues raised by the Convention on Biological Diversity (CBD) and the Nagoya Protocol into their intellectual property strategy.

Marine resources present a unique case due to the specific territorial fragmentation of territorial waters and the potential movement of these resources across different maritime zones, most of which cannot be claimed by any particular state.

This article summarizes the situation concerning the use of marine genetic resources and presents key elements of the High Seas Treaty (Marine Biodiversity of Areas beyond National "BBNJ" Agreement"), which echoes the principles of the CBD and the Nagoya Protocol for marine resources by covering the protection of the oceans outside the exclusive economic zones (EEZs) and continental shelves of coastal state. It will also discuss challenges to be addressed upon its entry into force, taking into account future rules regarding the disclosure of resources in patent applications and the issues related to the use of digitized sequences.

INTRODUCTION

The exploitation of genetic resources derived from biodiversity is a major challenge for both the states that hold these resources and the users of such resources. This is primarily due to the conflicting claims between the Northern countries, which are the main users of genetic resources and advocates of open science, and the Southern countries, which are the primary holders of these resources and seek a fair return on benefits and control over access [1].

The rules governing the use of biodiversity-derived resources are primarily governed by the 1992 Convention on Biological Diversity [2], and the Nagoya Protocol, adopted in 2010 [3]. These legal texts, particularly Article 2, provide key definitions in this domain. However, these texts do not define concepts of "Provider" or "Users" of genetic resources.

For this article, the following definitions will be used

- The Provider is an entity wishing to transfer genetic resources. It can be the providing country directly (where the organism naturally occurs, the in-situ conditions

refer to the natural habitats where this organism grows), suppliers of resources such as private or academic institutes, universities or landowners, but also ex-situ collections (i.e. genetic resources preserved outside their natural environment).

- The User is considered as the entity wishing to access genetic resources. It can represent, respectively, various actors, e.g., the bio prospectors, research institutes, universities, ex-situ collections, R&D or industrial companies [4].

The following figure outlines the principles of fair benefit sharing

However, the principles from CDB and Protocol of Nagoya are often ignored both by private and governmental stakeholders, either because they have simply never heard about it, or because they don't know how to comply and also they don't know if their falls in the scope of the Protocol [5].

Moreover, while the current exploitation of biodiversity requires partnerships between bioprospectors (universities,

private companies, etc.) and R&D structures (public or private laboratories) [6], which can be both Providers and Users of resources, the case of marine resources presents more challenges due to the territorial fragmentation related to their location (Figure 1).

Reminder of the Fragmented Nature of the High Seas, Origins of Marine Genetic Resources, and Incompatibility with the CBD and Nagoya Protocol

The biodiversity originating from various marine environments is already the source of many products with strong economic value. Examples include omega 3 fatty acids like EPA or DHA from fish oil, anti-viral drugs like Acyclovir (Zovirax®), an anti-viral chemical obtained from nucleosides isolated from a Caribbean marine sponge and used for the treatment of herpes infections, Trabectedin (Yondelis®), the marine-based drug developed by PharmaMar in partnership with Johnson & Johnson Pharmaceutical R&D. Trabectedin was discovered in the Caribbean sea squirt *Ecteinascidia turbinata*. It was the first drug of marine origin developed for fighting cancer [7].

The marine environment is rich in abundant genetic resources that could lead to promising industrial innovations in various fields, ranging from medicine and pharmacology to environmental applications, the agro-food industry, cosmetics, and molecular biology [8].

Therefore, the legal framework for the protection and utilization of marine biodiversity is more complex than that

of non-marine biodiversity due to the five zones that must be considered off the coastlines [9]:

- Territorial Seas extending up to 12 nautical miles from the coast (about 22 km).
- Exclusive Economic Zone (EEZ), covering the water column beyond territorial waters up to 200 nautical miles from the coast (approximately 370 km, subject to more restricted delimitations with other states).
- Continental Shelf, which refers to the underwater seabed extending up to 200 nautical miles from the coast or beyond, if geological data prove it is a natural extension of coastal landmasses. This extension must be validated by the UN's Commission on the Limits of the Continental Shelf. It cannot extend beyond 350 nautical miles (650 km) and does not include the water column above it.
- Ocean Floor, which extends beyond 200 or 350 nautical miles depending on the country, often referred to as "the Area".
- Water column beyond the EEZ, that is, beyond 200 nautical miles from the coast, known as the "High Seas" [10].

The CBD and the Nagoya Protocol are applied by states that have ratified them for resources found from the territorial coast to the EEZ of the respective state.

It is important to note that marine organisms can disperse

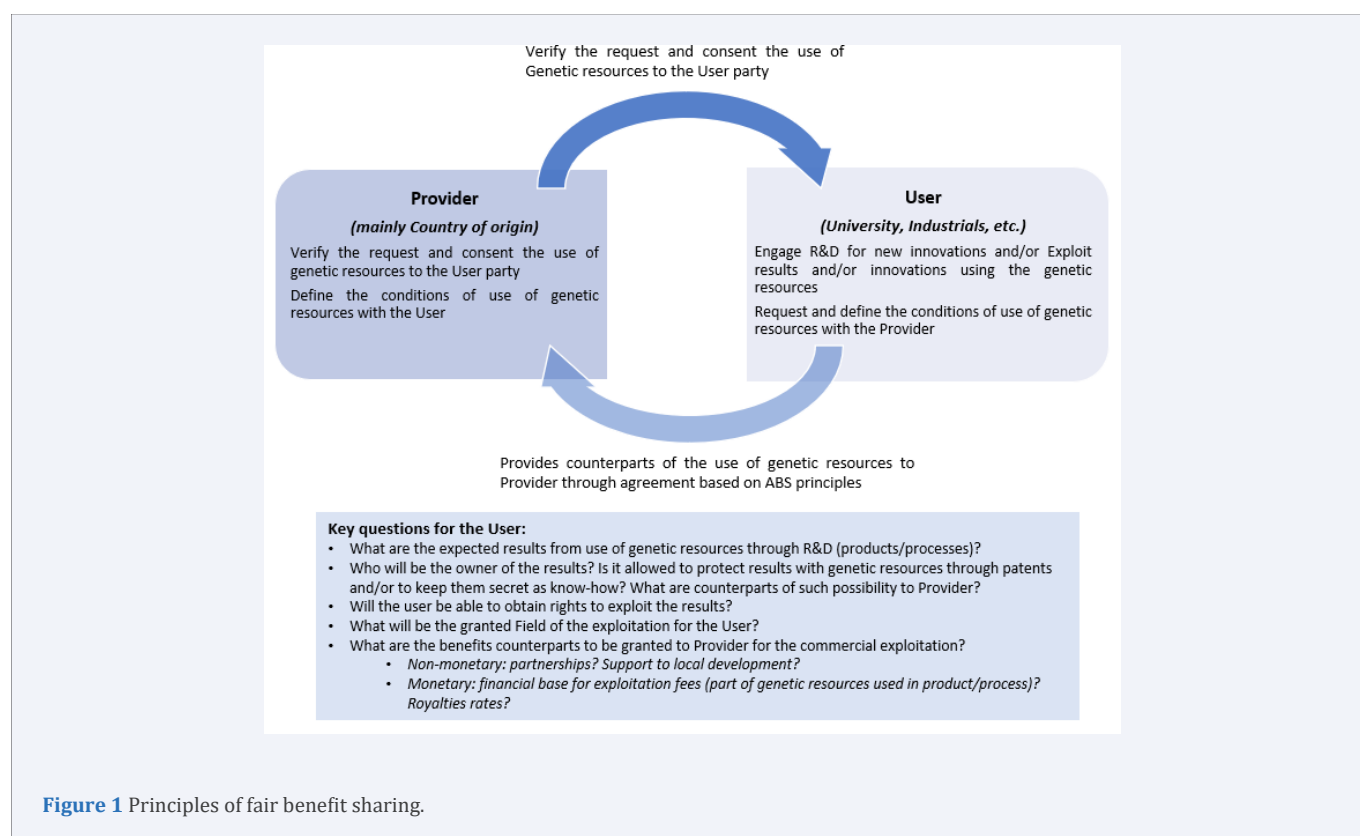


Figure 1 Principles of fair benefit sharing.

more widely than terrestrial organisms. This, for example, justifies the fact that a particular species carrying a specific genetic resource may be common to several geographical areas defined by different companies [11]. Moreover, this exacerbates the problem of defining the geographic origin of each marine genetic resource. Given the high mobility of marine genetic resources, what would be the consequences if it were decided that the marine environment belonged to all, without distinguishing States?

This is why discussions have taken place within the United Nations to find solutions to regulate the protection and exploitation of marine biodiversity through Access and Benefit-Sharing (ABS) measures.

In this context, rules concerning the use and exploitation of marine resources located beyond national jurisdiction were not clearly defined until the adoption, on June 19, 2023, of the first international treaty to protect the high seas (hereinafter referred to as the "BBNJ Agreement") [12].

The BBNJ Agreement: A Key Instrument Incorporating Nagoya Principles for Marine Resources

The purpose of the Agreement on Marine Biodiversity of Areas beyond National Jurisdiction, or BBNJ Agreement, as stated in its Article 2, is to ensure the conservation and sustainable use of marine biological diversity in areas beyond national jurisdiction in the short and long term through the effective implementation of the relevant provisions of the Convention and the strengthening of international cooperation and coordination.

The agreement also adopts principles and definitions from the CBD and the Nagoya Protocol in its Article 1, including new concepts, as mentioned below:

- "Biotechnology" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use In situ collection;
- "Collection in situ", in relation to marine genetic resources, means the collection or sampling of marine genetic resources in areas beyond national jurisdiction;
- "Marine genetic resources" means any material of marine plant, animal, microbial or other origin containing functional units of heredity of actual or potential value
- "Marine technology" includes, inter alia, information and data, provided in a user-friendly format, on marine sciences and related marine operations and services; manuals, guidelines, criteria, standards and reference materials; sampling and methodology equipment; observation facilities and equipment for in situ and laboratory observations, analysis and experimentation; computer and computer software, including models and modelling techniques; related biotechnology; and expertise, knowledge, skills, technical, scientific and

legal know-how and analytical methods related to the conservation and sustainable use of marine biological diversity.

- "Utilization of marine genetic resources" means to conduct research and development on the genetic and/or biochemical composition of marine genetic resources, including through the application of biotechnology.

Article 7 of the BBNJ indicates general principles, such principles including the principle of equity and the fair and equitable sharing of benefits (d), the use of the best available science and scientific information (i), and the use of relevant traditional knowledge of Indigenous Peoples and local communities, where available (j).

Based on such principles, the BBNJ Agreement pursues by indicating that one of the objectives of the agreement consists in the fair and equitable sharing of benefits arising from activities with respect to marine genetic resources and digital sequence information on marine genetic resources of areas beyond national jurisdiction for the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction (article 9 a).

The BBNJ Agreement was signed on September 20th, 2023, on the sidelines of the United Nations General Assembly. The Minister of Foreign Affairs signed the agreement on behalf of France, in the presence of the Secretary of State for the Sea. To date, 90 signatures have been recorded and the Agreement shall remain open for signature until 20 September 2025.

Ratification of the agreement should begin once national parliaments have given the go-ahead for countries to enact legislation and transpose the treaty's obligations at national level. At this stage, 12 ratifications have been registered in, Palau, Cuba, Mauritius, Monaco, Palau, Seychelles, Federation States of Micronesia Chile, Belize, Seychelles, Monaco and Mauritius [13].

It will enter into force once it has been ratified by 60 States. The European Commission will also be working to accelerate this process, and to help developing countries prepare for ratification in order to implement the agreement [14].

We can notice that principles from CBD and Nagoya Protocol for notifying activities and uses of genetic resources are present from Articles 10 to 15 (including notably the creation of an access and benefit-sharing committee at Article 15).

Specifically, the agreement also anticipates the case of digital sequence from Marine Genetic resources, as article 10.1 stipulates that "provisions of this Agreement shall apply to activities with respect to marine genetic resources and digital sequence information on marine genetic resources of areas beyond national jurisdiction collected and generated after the entry into force of this Agreement for the respective Party".

This agreement seems to have a large coverage of cases of use of marine genetic resources, by anticipating also the case of digital sequence.

Legal Instruments Lagging Behind Practices in Marine Genetic Resource Exploitation

However, while States work to ratify the BBNJ Agreement and harmonize rules for the exploitation of marine resources (to date, only eight Parties have ratified the agreement) [15], new technologies have already advanced, altering the practical rules for access to genetic resources for R&D or commercial purposes.

For example, future legal instruments related to patents and the exploitation of digitized sequences will be discussed.

In the field of patent law, the WIPO Treaty on Intellectual Property Related to Genetic Resources and Associated Traditional Knowledge was adopted at the Diplomatic Conference on Genetic Resources and Associated Traditional Knowledge from May 13-24, 2024 [16]. It is the first intellectual property treaty to incorporate principles from the CBD and the Nagoya Protocol, requiring in Article 3 that any patent applicant disclose the source of the genetic resource (such as the country of origin, research center, gene bank) and/or the traditional knowledge used, as long as the patent application is based on these sources. The requirement for disclosing the origin of GRs should not inflict unbearable burdens on applicants and examiners, but rather facilitate the connection of patent system to relevant protection mechanisms for GRs. In the absence of disclosure, Article 5 of the Treaty stipulates that it is up to the Contracting Parties to establish mechanisms for sanctioning this omission (Figure 2).

As example the Chinese Patent Law includes two clauses on protection for genetic resources and indication of the source of genetic resources-Article 5.2 and Article 26.5. The Article 5.2 so-called 'protection clause' for genetic resources-states that: "No patent right shall be granted for any invention-creation where acquisition or use of the genetic resources, on which the development of the invention-creation relies, is not consistent

with the provisions of the laws or administrative regulations." The Article 26.5-the so-called 'source indication clause' – states that: "Where an invention-creation is developed relying on genetic resources, the applicant shall indicate, in the application documents, the direct and original sources of such genetic resources; where the applicant fails to indicate the original source, he or it shall state the reasons thereof" [17].

In Brazil, there is also a strict and rigorous ABS policy in order to prevent massive bioprospecting for developing new innovations and to check the relevant use of its genetic resources (obligation to disclose the origin of genetic resources in patent application) [18].

Although an international treaty has been adopted in this area, there are differences at the national level regarding whether to require disclosure of the sources of genetic resources and/or the indigenous peoples responsible for the associated traditional knowledge. These differences may encourage patent applicants to select countries or regions with more lenient disclosure requirements or omit information to facilitate examination in stricter countries or regions.

Given the recent nature of the text, it will take time for the rules set by the WIPO Treaty to come into effect in various intellectual property offices. Moreover, even when the treaty comes into force, there is a four-year period for potentially updating its scope, such as extending disclosure practices to other fields beyond patents and accounting for new technologies (Digital Sequence Information, AI use, etc.).

Indeed, both marine and terrestrial genetic resources can be subject to digital sequencing, with the information made available to all via private databases. Such databases limit the ability to define access terms for sequenced resources, and it may be relevant to include them in legal texts governing access to

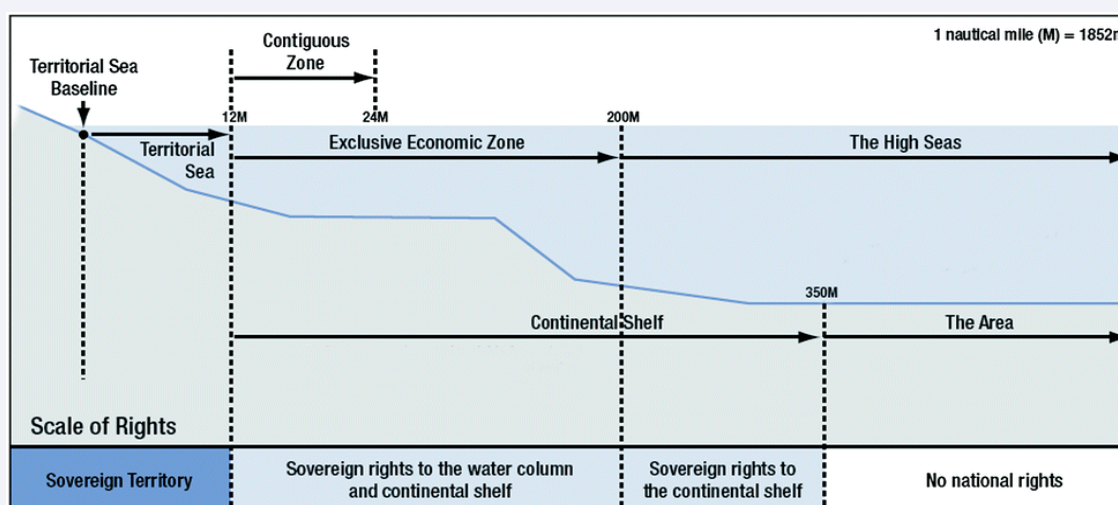


Figure 2 The legal framework for the protection and utilization of marine biodiversity.

genetic resources, while establishing a system for benefit-sharing derived from the use of digitized information.

It may also be worth considering new, efficient models for achieving fair and equitable benefit-sharing from the use of marine biodiversity, taking into account the various economic actors in the value chain and integrating the use of resources that have undergone digital sequencing.

On this subject, the Special Open-ended Working Group on Benefit-Sharing from the Use of Digital Sequence Information on Genetic Resources, following a meeting during COP16 from August 12-16, 2024, drafted a recommendation to continue developing a multilateral mechanism for benefit-sharing from the use of digital sequence information [19]. This would include a global fund accessible to the public, with the storage of resources under the prior informed consent of the resource provider. In return for using resources from this public database, the user would be taxed, although this tax has yet to be defined.

Based on this, a new conference of CBD signatories will be held in Colombia from October 21 to November 1, 2024, to discuss the benefit-sharing arising from the use of digital genetic resource based on this project [20]. Such text would potentially have an impact to the BBNJ Agreement, which is specific to marine resources.

CONCLUSION

While awaiting future legal instruments concerning marine genetic resources, it seems that access to non-sequenced marine genetic resources still falls into two categories:

- Either access is governed by the state associated with an EEZ.
- Or the resource is freely accessible.

In any case, challenges and issues remain in order to define proper rules for using marine resources that can be object to synthetic biology, or also digitalized.

It is then important for Users and Providers to monitor current practices in this matter, as they need to find a balance between securing the Users' freedom-to-operate regarding such resources, and granting to Providers a fair and equitable sharing of benefits arising from genetic resources from marine biodiversity.

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