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Fair and equitable sharing of benefits from the utilization of marine genetic resources in areas beyond national jurisdiction: Bridging the gaps between science and policy

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ABSTRACT

Marine genetic resources are a subject of a growing body of research and development activities, as demonstrated by the abundance of marine patented genes reported in GenBank. Given the lack of a comprehensive legal regime for the management of marine genetic resources in areas beyond national jurisdiction, the General Assembly of the United Nations met in 2006 to discuss whether there are regulatory or governance gaps and how to address them. Besides the crystallization of the different political positions, the process is now advancing towards making a decision about whether to develop an international instrument under the United Nations Convention on the Law of the Sea (UNCLOS) for the conservation and sustainable use of marine biological diversity, within which the regulation of access to genetic resources and the sharing of benefits from their utilization has emerged as an in-dissociable issue. In order to propose concrete options to be considered for the establishment of a legal framework addressing these issues, policy-makers need to better understand the feasibility, the costs and the modalities of scientific activities undertaken, together with the actual level of commercialization of new products. They also need to be aware of the already advanced practices in place within the scientific community, especially regarding sharing of non-monetary benefits. This paper particularly highlights and discusses practical scenarios to advance in the international process, based on the approaches adopted in other regional and international regimes for the management of genetic resources and on the best practices developed within the scientific community.

1. Introduction

The marine realm represents 70% of the biosphere and is home to 34 of the 36 living phyla described thus far. Life forms are estimated to have appeared at the bottom of the world's ocean about 3.6 billion years ago, compared to only several hundred million years ago for terrestrial life. Due to this ancient history and the diversity of life forms they encompass, the oceans are a unique reservoir for a broad range and diversity of molecules [1]. However, until recently, marine molecules remained nearly unexploited due to the difficulties of accessing them.

Our capacity to access remote parts of the ocean has greatly improved during the last century, and particularly in the last decades due to the advancement of oceanographic technologies, therefore knowledge of the diversity of life forms, the inventory of marine species, as well as threats impacting them, has also improved [2,3]. The technologies to screen molecules of interest have also advanced in the last decades. The most recent estimates

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show an exponential increase in the use of marine molecules or sequence of nucleic acids extracted from marine organisms in a variety of biotechnological fields. Industries involved encompass a broad range of applications including human health, agriculture or aquaculture, food, cosmetics and bioremediation [1,4,5] and [6]. In particular, marine molecules were used to develop pharmaceutical drugs such as anti-cancer medication, as well as for treatments against HIV or Alzheimer disease that have already been commercialized [7]. The market for such biotechnologies appears vast, consistently expanding over the past decades: depending on the products commercialized, the market has already reached several billion USD a year before 2010 [8].

The marine realm, besides its biological particularities in terms of evolution and diversity of life, is also subject to specific rules under international law. For more than a decade, the international community has expressed differing viewpoints regarding whether regulatory and governance gaps exist and how to address the exploration and exploitation of marine genetic resources (MGR) in areas beyond national jurisdiction (ABNJ), including issues concerning the fair and equitable sharing of the benefits arising from such exploitation. Furthermore, the question arises of how such gaps could be closed in practice, without hampering scientific research in the future. In order to find the right answers, it is first of all important to get a clearer understanding of what MGRs are, and how they are utilized in socio-economic terms. The following section of the present paper aims at providing the state of the art of research in this area, including terms of technological and expertise uneveness among countries; and at analyzing the feasibility and prospects of commercial exploitation and development of products. The third section will introduce the relevant political process under the United Nations, while the following will highlight the existing governance and regulatory gaps. Then section five will present best practices of the research community in terms of sharing data and materials, showing relatively advanced experiences that could inspire the way forward; and the next section will go through the lessons learnt from other access and benefit-sharing (ABS) international regimes on genetic resources with an emphasis on common pools[4] approach. The conclusive section will highlight and discuss practical scenarios to advance in the international process, based in particular on the approaches adopted in other regional and international regimes for the management of genetic resources and on the best practices developed within the scientific community.

2. The definition of MGR, their utilization and economic aspects

The primary definition of genetic resources (Table A.1) according to the Convention on Biological Diversity [9] (CBD) has been subject to many debates during the past two decades. The wider scientific interpretation of the term "functional units of heredity" seem to merely targets nucleic acids (and possibly some proteins or enzymes interfering with their expression) rather than any molecule of interest for biotechnology [10]. From the scope of application of regulatory requirements on access and benefit-sharing, such definition may misleadingly seem to discard a large amount of biotechnological applications based on naturally occurring molecules other than nucleic acids. As early as 1994, Glowka proposed that the definition of genetic resources should encompass "whole organisms, parts of organisms or biochemical extracts from tissues that would contain DNA or RNA" [11]. In 1999, it was already evident that very few commercial products contained unmodified genetic resources. Moreover, many access agreements (including some predating the CBD) contained benefit-sharing obligations attached to the sale or other uses of derivatives of the genetic resources themselves [12]. Altogether, with the precisions given by the definitions of the "utilization of genetic resources" and their "derivatives" in the Nagoya Protocol [13] (Table A.1), concepts are now better defined and allow ABS provisions to be reconciled with most biotechnological applications.

This can be better understood by distinguishing the different research paths that lead to the development of biotechnologies.

Four different pathways can be distinguished in the use of genetic resources (Fig. A1). The first three require physical access to the molecules of interest, while the fourth uses the information contained in genetic resources for any purpose other than molecule extraction or synthesis. The first pathway, known as the *in situ* path, consists in harvesting the biological material needed to extract molecules of interest. The second, that could be qualified as *ex situ*, corresponds to the controlled breeding and cultivation of organisms from which molecules would be extracted. The third, *in vitro*, consists in obtaining the molecules of interest by triggering their synthesis through gene expression; this involves the use of genetically modified organisms expressing the gene of interest which has been identified in another organism. The fourth, *in silico*, corresponds to the use of knowledge of a nucleic acid sequence for any purpose other than the *in vitro* synthesis. For example, this could include barcoding taxonomy based on laboratory amplification of a target gene to describe species or test the validity of morphological determination, as well as to infer protein structure and putative function. While the first three paths involve *in situ* harvesting or field sampling, the fourth one only requires access to information through data exchange or databases.

It is important to understand that the *in situ* and *ex situ* paths involve the use of material containing and sheltering the expression of functional units of heredity to synthetize molecules of interest, while the *ex situ*, *in vitro* and *in silico* paths require the use of functional units of heredity themselves. Breeding not only involves functional units of heredity but it is the result of their recombination. Therefore it is biologically clear that any of these paths require the use of functional units of heredity at some step of the biotechnological development and/or production process. Finally, considering that the definition of utilization of genetic resources of the Nagoya Protocol is broad enough to encompass all the four paths, they are all subject to the legal relevant obligations related to access and benefit-sharing.

The development of biotechnologies based on MGR requires high investment throughout the different steps, from the collection of organisms *in situ* to the eventual commercialization of products. In some cases, costs can be higher when compared to those associated to land molecules. Indeed while sampling in the marine realm can be rather simple and imply moderate costs for coastal organisms, budgets inflate substantially as oceanographic means are required to target high seas or deep sea organisms.

Indeed, access to non-coastal organisms is highly dependent upon access to specific research vessels or submersibles which are very limited in number globally, owned only by a few nations (mostly developed countries), and require great operation costs. For instance, direct costs for a scientific cruise operating on the high seas and involving a remotely operated vehicle are estimated to reach up to 5 million USD for a one month expedition [14]. Although these costs are primarily estimated to anticipate the

[4] A common pool of resources consists of a resource that is freely accessible for use by a number of persons. The resource can, for instance, be an agricultural land plot or a fish stock. It can also be a genetic resource. Common pool resources are often in common property, such as joint ownership of communal land by a local community. But this is not necessarily so. Common pool resources can also be owned by individual persons who have decided to put the resource in a pool and allow free use of it. Thus, GR pools may exist even though the resource is 'owned' by a state, a local community or a private landowner.

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