Marine Policy 49 (2014) 176–185

Contents lists available at ScienceDirect

Marine Policy

journal homepage: www.elsevier.com/locate/marpol

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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ARTICLE INFO

Available online 18 March 2014

Keywords:
Marine genetic resources
Access and benefit-sharing
Common pool resources
Intellectual property rights
Marine scientific research
Public domain

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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http://dx.doi.org/10.1016/j.marpol.2014.02.012
0308-597X

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 5 years expedition [14]. Although these costs are primarily estimated to anticipate the global costs of

[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.

future restoration programs, similar amounts are to be expected for cruises dedicated to pure and/or applied research.

These costs do not account for subsequent steps in molecular screening and biodiversity assessment[5] that are common to the biotechnological development on genetic resources of any origin, including the storage of samples under appropriate conditions together with associated metadata, the generation of biomass for downstream uses or DNA isolation, purification, sequencing, and activity screening. The possibility to undertake biodiversity assessment is also characterized by an uneven spread of expertise, which is mostly concentrated in few developed countries [15]. The uneveness is echoed in the access to cutting edge molecular technologies and expertise required for molecular screening [16]. These disparities have barely improved since 2002 [17,18].

In certain fields of application, low yield, long development and investment time are expected before a product can effectively be commercialized. For example, in drug development, it is estimated that a time lag of at least 6 years would be required to successfully go through clinical trials, allowing an average retention of only one molecule for 250.000 samples collected and studied [19]. However, trials needed for other fields of application are usually much less time demanding. In addition, the rate of success is expected to increase, and the time needed to develop biotechnologies based on genetic resources continues to decrease as molecular tools and associated technologies improve exponentially (a trend seen in the last two decades and predicted also for the future). Sequencing speed is now indeed outpacing Moore's law [20] (Fig. A2), meaning that performances are more than doubling every two years. Such progresses is expected to yield exponential decreases in the time associated with screening molecules of interest to the inferences on their function and an increase of the amount of such processes. In parallel, the rate of simulation of protein shapes and functions based on DNA information is accelerated, with an estimated timescale of milliseconds at the horizon 2030 [21]. The accessibility, yield and speed of molecular technologies that are bridging the gap between marine sampling and the isolation of molecules of biotechnological interest is therefore expected to take-off, while their costs continue to decrease in the next several decades, further fueling the rate of marine based biotechnological developments.

It can be concluded that the state of the art of the development of biotechnologies on MGR clearly shows a situation of uneven access to oceanographic means and molecular expertise between countries. The improvement and importance of molecular skills are likely to enhance this inequality in the near future. These considerations need to be addressed in the ongoing discussions that are underway at the level of the United Nations, the origin and development of which are illustrated in the following section.

3. History of international discussions on MGR in ABNJ

To better understand the current state of the political and legal debate regarding MGR from ABNJ, it is important to define these areas in legal terms, to have a closer look at the history of the international discussions on the conservation and sustainable use of biodiversity in ABNJ, as well as how issues around ABS have been addressed in this context so far.

According to the United Nations Convention on the Law of the Sea (UNCLOS) [22], marine areas beyond national jurisdiction are made up of the Area and the high seas. The Area is the seabed and ocean floor and subsoil thereof beyond the limits of national jurisdiction. The high seas are all parts of the sea that are not included in the exclusive economic zone, in the territorial sea or in the internal waters of a state, or in the archipelagic waters of an archipelagic state. Almost 2/3 of the ocean and 60% of the seabed are outside of national jurisdiction [23].

UNCLOS is considered the foundation of the currently existing international law governing the marine environment. It "sets out the legal framework within which all activities in the oceans and seas must be carried out and is of strategic importance as the basis for national, regional and global action and cooperation in the marine sector" [24]. UNCLOS establishes rights and obligations of States regarding the use of the oceans and their resources, including general obligations "to protect and preserve the marine environment" (Article 192 of the UNCLOS); to take measures "to protect and preserve rare or fragile ecosystems as well as the habitat of depleted, threatened or endangered species and other forms of marine life" (Article 194.5 of the UNCLOS); or to cooperate on a global as well as a regional basis in the development of "international rules, standards and recommended practices and procedures […], for the protection and preservation of the marine environment" (Article 197 of the UNCLOS). However, the conservation and sustainable use of marine biodiversity is not explicitly addressed, and are therefore not specifically regulated by UNCLOS for areas beyond national jurisdiction.

While the conservation of biological diversity, the sustainable use of its components, and access to genetic resources and the fair and equitable sharing of the benefits arising out of their utilization are the objectives of the CBD (Article 1), the scope of the CBD is mostly limited to areas within the limits of national jurisdiction (Article 4(a)). Regarding ABNJ, the CBD only applies in relation to processes and activities carried out under the jurisdiction or control of its parties (Article 4(b)).

A particular need for action for the sustainable use and conservation of marine living resources in ABNJ was already recognized by the 1992 United Nations Conference on Environment and Development in Rio de Janeiro, Brazil [25]. The issue was recalled by the 2002 United Nations World Summit on Sustainable Development in Johannesburg, South Africa, which set goals to maintain the productivity and biodiversity of important and vulnerable marine and coastal areas (including in ABNJ) and to develop and facilitate the use of diverse approaches and tools for halting the loss of marine biodiversity [26]. Based on this, in 2004 the United Nations General Assembly (UNGA) established an Ad Hoc Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction (BBNJ Working Group) [27]. It is important to note that throughout its six meetings until present, the BBNJ Working Group did not only discuss the development and implementation of different conservation instruments, but also provided the main international forum to address ABS issues around MGR from ABNJ. At the same time, the value of MGR in terms of their socio-economic benefits, the importance of related research to enhance the scientific understanding, potential use and management of marine ecosystems were reiterated in different UNGA resolutions [28,29].

Based on the recommendations adopted at the fourth meeting of the BBNJ Working Group, the UNGA in its 66th session in December 2011 agreed to initiate a process to "address the conservation and sustainable use of marine biodiversity in areas beyond national jurisdiction, in particular, together and as a whole, marine genetic resources, including questions on the sharing of benefits, measures such as area-based management tools, including marine protected areas, and environmental impact assessments, capacity-building and the transfer of marine technology"; and to ensure that those issues are effectively addressed "by identifying gaps and ways forward, including through the

[5] Biodiversity assessment is the evaluation of biodiversity and the identification of species leading to the characterization of communities present in a given area.

implementation of existing instruments and the possible development of a multilateral agreement under the United Nations Convention on the Law of the Sea" [30]. The first meeting of the BBNJ Working Group within this process in 2012, which was also the fifth meeting of the working group in total, did not lead to any further considerable progress. However, the United Nations Conference on Sustainable Development (Rio+20) held in the same year with states committing themselves "to address, on an urgent basis, building on the work of the Ad Hoc Open-ended Informal Working Group and before the end of the sixty-ninth session of the General Assembly, the issue of the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction, including by taking a decision on the development of an international instrument under the United Nations Convention on the Law of the Sea" [31]. This commitment was recalled by the UNGA in its 67th session [32], and reaffirmed in the recommendations to the UNGA developed at the sixth meeting of the BBNJ Working Group in 2013. At the same meeting, the Group also recommended to establish a process within the working group to prepare for the decision to be taken at the 69th session of the UNGA in 2015.

The status quo of this process at the end of 2013 can therefore be summarized as follows: UN Member States envisage making a decision by 2015 as to whether to begin the negotiation of an international instrument, including amongst other options, the possibility to consider an UNCLOS Implementing Agreement that would address the conservation and sustainable use of marine biodiversity in ABNJ, including issues related to ABS for MGR in ABNJ. While the vast majority of States seems to be in favor of such negotiations, a handful of developed countries appear more reluctant to engage in the elaboration of another international legal instrument that will without doubt impose great challenges in terms of implementation. Consequently, the scope, parameters and feasibility of such an international instrument under the UNCLOS will be further discussed in 2014 and 2015 by the BBNJ Working Group [33]. It is clear that ABS issues are a key concern in these discussions and one of the main triggers of these negotiations. Developing practical solutions for the fair and equitable sharing of benefits from the utilization of MGR accessed in ABNJ will thus be an important trigger to create further support for the launch of negotiations on the aforementioned international legal instrument.

One critical issue to consider in this context will be the definition of the scope of such a potential ABS regime. Apart from a clear determination of the substantive scope (*i.e.* the actual resources and activities to be captured), specific questions around the geographical scope (*i.e.* the maritime zones to be covered) will also need to be carefully addressed. In particular, it will be of utmost importance that future discussions in the BBNJ Working Group find practical answers for the management of straddling/transboundary MGR. For this it is important to understand that MGR move horizontally between areas within national jurisdiction, *i.e.* the territorial sea, the exclusive economic zone and the continental shelf; and areas beyond national jurisdiction, *i.e.* the high seas and the Area. Therefore, any ABS regime for MGR in ABNJ should be compatible with and complementary to the existing ABS regime for areas within national jurisdiction, in particular the ABS provisions under the CBD and its Nagoya Protocol.

In addition to such horizontal transboundary movements, vertical transboundary situations need to be taken into consideration. MGR also move between the benthic zone (*i.e.* the seafloor) and the pelagic zone (*i.e.* the water column above). Thus, an ABS regime distinguishing between MGR from the high seas and the Area should be avoided. Indeed, from a scientific and managerial point of view, a comprehensive regime covering the entire ABNJ appears to be indispensable.

4. Gaps in the existing legal framework

Before possible ABS approaches for ABNJ can be further suggested in Section 6 below, Section 4 shall analyze the relevant gaps in the existing international legal framework regarding ABS for MGR from ABNJ. When doing so, it is necessary to consider the UNCLOS, the CBD and its Nagoya Protocol on ABS together, as these instruments need to be implemented consistently and in a mutually supportive manner in accordance with Article 311 of the UNCLOS and Articles 22.2 of the CBD and 4.3 of the Nagoya Protocol.

The fair and equitable sharing of benefits from the utilization of genetic resources is one of the three core objectives of the CBD (Article 1). The implementation of this objective is regulated by Article 15 of the CBD and – in more detail – by the Nagoya Protocol. The ABS regime of the CBD and its Nagoya Protocol also applies to MGR, however, the geographical scope of both instruments is limited to areas within national jurisdiction [34]. While this is not obvious from the provisions regulating the instruments' scope (Article 4 of the CBD and Article 3 of the Nagoya Protocol), it is clear from Articles 15.1, 15.4, 15.5 of the CBD and Articles 5, 6 of the Nagoya Protocol that the ABS regime envisaged is based on the sovereignty of States over their genetic resources and on a bilateral approach. Since no State has sovereignty over MGR from ABNJ (neither the resources found in the deep seabed, nor the ones floating in the water column above), this bilateral approach, which is based on the prior informed consent of a provider country, unless otherwise determined, and on mutually agreed terms between a provider and a user, is not applicable [35].

In this context, it should be noted that Article 10 of the Nagoya Protocol refers to a global multilateral benefit-sharing mechanism "to address the fair and equitable sharing of benefits derived from the utilization of genetic resources […] for which it is not possible to grant or obtain prior informed consent". While the exact situations covered by such a global mechanism are not further defined, triggering contentions to subsume MGR from ABNJ under this provision, it nonetheless needs to be understood that Article 10 "only" provides an enabling clause for Parties to consider the need for and modalities of such a global mechanism. This means that the overall implementation of Article 10, as well as the potential establishment and scope of a global multilateral benefit-sharing mechanism under the Nagoya Protocol, depend entirely on the will of the Parties that still needs to be built.[6]

As aforementioned, UNCLOS provides the legal framework for all activities in the oceans and seas, thus also for ABS with regard to MGR from ABNJ. However, it does not explicitly mention MGR in any part, possibly due to the unforeseen take-off of interest in the exploration of such resources more than ten years after the Convention was adopted. While there seems to be disagreement amongst States whether this leads to a regulatory gap under UNCLOS, such disagreement is based to a great extent on their different strategies for the discussions in the BBNJ Working Group and the UNGA.

From a purely legal standpoint, MGR in ABNJ are not covered by the regime established under Part XI of the UNCLOS regulating the Area. Resources of the Area which are considered to be the common heritage of mankind (Article 136 of the UNCLOS), are clearly defined in Article 133(a) of the UNCLOS as *mineral* resources, meaning only non-living resources, therefore not including MGR. Thus, the benefit-sharing obligations under Article 140 of the UNCLOS do not cover MGR from ABNJ. On the other

[6] In line with CBD COP 11 Decision XI/1, a consultation on Article 10 was undertaken in 2013. The views received will be considered at the third meeting of the Intergovernmental Committee for the Nagoya Protocol in 2014.

hand, the exploration and exploitation of MGR can be considered as part of the freedom of the high seas under Article 87 of the UNCLOS, which in fact provides only a non-exhaustive list of activities covered by the freedom of the high seas [36].

Still, this freedom is not unlimited, as indicated in Article 87.1 and 87.2, and Article 88 of the UNCLOS. In particular, it is subject to the provisions of Part XIII of the UNCLOS regulating marine scientific research (MSR), including research in ABNJ. Moreover, unlike Part XI (regulating the Area) Part XIII is not limited to any kind of resources; therefore it is applicable also to research on genetic resources.

Facilitating and promoting MSR for MGR in ABNJ could be a pragmatic and realistic approach to move forward in the ABS discussions. Therefore, the ABS relevance of MSR provisions under the UNCLOS shall be further explored in the section below.

5. ABS in MSR: best practices and "common pools"

5.1. Legal framework

As explained above, UNCLOS does not specifically provide for an ABS regime with regard to MGR in ABNJ. However, Part XIII related to marine scientific research is relevant for this aspect, as it provides for some obligations to share non-monetary benefits arising out of scientific research, as illustrated below.

The aim of the regulation of MSR in the UNCLOS is to balance different interests: the interests of coastal States keen to protect their sovereignty over the resources within their national jurisdiction; the interests of researching States in unimpeded scientific research; and the interests of States that do not have research-at-sea capacity. In this context, it is important to note that all States, irrespective of their geographical location, have the right to conduct MSR in accordance with the UNCLOS. Furthermore, marine scientific activities shall not constitute the legal basis for any claim to any part of the marine environment or its resources, according to article 241 UNCLOS. With regards to benefit-sharing, the general provisions on MSR under UNCLOS require States and competent international organizations to:

- Promote international cooperation in MSR for peaceful purposes (Article 242.1 of the UNCLOS).
- Cooperate to create favorable conditions for the conduct of MSR (Article 243 of the UNCLOS).
- Make available by publication and dissemination through appropriate channels a) information on proposed major programs and their objectives, and b) knowledge resulting from MSR (Article 244.1 of the UNCLOS).
- Actively promote the flow of scientific data and information and the transfer of knowledge resulting from MSR, especially to developing states, as well as the strengthening of the autonomous MSR capabilities of developing states through programs to provide adequate education and training of their technical and scientific personnel (Article 244.2 of the UNCLOS).

The UNCLOS provisions on MSR apply both in areas within and beyond national jurisdiction, and also both to the high seas and the Area. Therefore, these benefit-sharing obligations could provide a legal basis for the development of a benefit-sharing regime related to MGR in ABNJ. Moreover, they are already implemented in practice to some extent, as illustrated in Sections 5.2 and 5.3. They are useful to address the uneven research means and expertise highlighted in Section 2. However, further implementing regulations would be necessary in order to provide more concrete guidance leading to legal certainty and clarity in building such an ABS regime, as well as an effective and efficient operationalization of the regime.

Besides the aforementioned general provisions, MSR is regulated in every maritime zone, including ABNJ. In both the high seas and the Area, UNCLOS affirms the right of all States, irrespective of their geographical location, and of competent international organizations to conduct MSR, in conformity with the Convention, and especially in the Area in conformity with Part XI. The latter describes the legal regime applicable to the exploration and exploitation of mineral resources in the Area, where specific provisions are dedicated to MSR, which is not limited to mineral resources but embraces also natural living resources, including MGR. The main characteristic of MSR in the Area is that it must be conducted exclusively for the benefit of mankind as a whole. Since progress in scientific research is based on the widest possible access and share of research results, the creation of a common pool of research results from MSR in the Area could be one possible implementation of the obligation to benefit the whole mankind, together with a legal tool that avoids the enclosure of innovative technologies (See Section 6). However, distinguishing the water column from the seabed would be counterproductive in light of the considerations about the scope of the future instrument on ABNJ highlighted in Section 3.

5.2. Voluntary codes of conducts

Beyond the binding provisions of the UNCLOS, it is useful to refer to important steps undertaken at the level of soft law and to have a look at the practice in the research communities. Within the marine research community a number of voluntary frameworks have been developed to provide guidance on different research-related aspects, including the exchange of information and knowledge, as well as capacity-building.

The InterRidge Code of Conduct for Responsible Research Practices at Deep-sea Hydrothermal Vents [37] focuses on information exchange and commits to open international sharing of data, ideas and samples in order to avoid unnecessary re-sampling and impact on hydrothermal vents, and to further global understanding of these habitats. As a result, open databases have been developed; in addition, many national ridge programs are hosting open-access databases of geological, chemical, and biological hydrothermal vent data. With regard to marine research, including research on MGR, the Convention for the Protection of the Marine Environment of the Northeast Atlantic (OSPAR) Code of Conduct [38] provides guidelines on international cooperation as well as open access bio-repositories for the collected samples and sharing of data, results and samples. The Mediterranean Science Commission (CIESM) is in the process of adopting a Charter on ABS [39] to be applied in future sampling campaigns within and beyond national jurisdiction. The Charter introduces the idea of Concerted Handling of Commons according to which, in cases of non-commercial use, scientists are called to simultaneously share the data with all the active partners in the project and the provider country, to deposit the data in the public domain, and to make materials, related information and results (*in situ* and *ex situ* collections) openly accessible as soon as possible. The CIESM ABS Charter is fostering the idea of common pools of MSR results, at least within non-commercial research activities. Moreover it calls for cooperation of the scientific communities (including from the provider country) in all aspects from the design of campaigns to data analysis, and for capacity-building of experts from the provider country on technical and legal aspects.

5.3. Research best practices

It is also interesting to consider some scientific research practices that are already implementing principles of benefit-sharing in respect to MGR within and beyond national jurisdiction. Since one of the most promising source of marine genetic diversity are microbes [40], it is interesting to focus on the microbial

research community, organized around the World Federation of Culture Collections (WFCC) which is concerned with the collection, authentication, maintenance and distribution of cultures of microorganisms and cultured cells. Most of the collections are publicly funded, with a strong commitment to the public availability of biomaterials. ABS awareness is generally very low in the field of microbial genetic resources [41], however the culture collections have undertaken steps towards the practical implementation of ABS principles and the CBD [42], such as the development of the Microorganisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC),[7] the World Data Center for Microorganisms[8] and the Global Unique Identifier.[9] All these efforts go in the direction of re-constructing a "microbial commons" [43] in making available microbial data, information and materials and thus creating common pools of resources, research results and data. The microbial research community provides interesting experiences for several reasons:

- It applies a global framework for the exchange of microbial genetic resources, in line with the CBD framework, and also covering MGR from ABNJ.
- At least in the case of culture collections established with public funds and embracing the open access policy, this framework implements the concept of common pools [44].
- The geographical origin of the resources (more and more often their GPS coordinates) is usually specified at the time of the deposit of the strains.
- While there is no general benefit-sharing policy for the use of marine microbes from ABNJ, culture collections handle this loophole on a case-by-case basis.

The standard material transfer agreement (MTA) of the European Culture Collection Organization (ECCO) also contributes to the reconstruction of the "microbial commons". The agreement aims at making biological material from ECCO collections available under the same core conditions. It allows, in case of non-commercial purpose, transfer to third parties involved in "legitimate exchanges" (*i.e.* scientists working in the same lab or partners in different institutions collaborating on the same project) if they use the same licensing conditions, through a viral license clause. Moreover, in case of commercial utilization, recipients have to negotiate in advance and in good faith the terms of benefit-sharing with the country of origin.

Another interesting best practice in the field of microbial diversity is the European funded project Micro B3.[10] The project aims at creating an open bio-informatics system of integrated data that will constitute a common pool of data extracted from MGR collected within and beyond national jurisdictions. The innovative ABS model agreement [45] developed within the framework of the project is based on the distinction between research for the public domain on the one hand, which aims at making the associated knowledge publicly available without being protected by patent rights or further restricted by other intellectual property rights, and proprietary research on the other hand. It also contains a viral license clause that guarantees that all obligations of the initial ABS agreement (conditions for use and transfer of the genetic resources and dissemination of the knowledge) will be imposed on any third party receiving the material and/or the knowledge associated with the genetic resource. This fosters the creation of common pools of data described above.

Finally, global and regional research on the world oceans is usually organized within research programs and initiatives, although research is also conducted independently. Such programs and initiatives often develop data-sharing principles and promote full and open exchange of data [46]. These are also subject to rules and practices in course for scientific research in general, including the obligation – common to the vast majority of now recognized scientific publications – to share genetic data at the origin of a published scientific article on GenBank database,[11] or some more specific databases such as the recent Dryad[12] setup by the community of molecular ecologists and evolutionary biologists.

Notwithstanding these emerging best practices implementing the MSR provisions of the UNCLOS in the context of MGR, confidentiality issues and patents over MGR are growing: a study [47] in 2011 showed that 10 countries own 90% of the patent claims on marine microorganisms,[13] with 3 of them (USA, Germany and Japan) owning 70% of the total. Moreover, another study [48] (examining the data that accompanies scientific literature) revealed networks of collaboration, knowledge transfer and funding in scientific research on MGR, and showed that more or less the same developed countries occupy the first places. However it is important to notice that the institutions that are involved in these networks of collaborations are publicly funded.

These findings suggest that a better and more coordinated implementation of the MSR obligations of the UNCLOS in relation to MGR (benefiting all states) is surely needed. This could be a practical way forward to start building an instrument for the fair and equitable sharing of benefits from the utilization of MGR in ABNJ.

6. Lessons learnt from other international ABS regimes, with an emphasis on common pools approaches

In international law, other global regimes have been already established to regulate access to genetic resources and benefit-sharing on a multilateral basis, such as in the food and agriculture,

[7] MOSAICC aims to facilitate access to microbial genetic resources and help partners in the development of appropriate material transfer agreements (MTA) in line with the obligations of the Convention on Biological Diversity and other applicable international and national law. MOSAICC combines the need for easy transfer of microbial genetic resources and the need to monitor such transfer. The MOSAICC MTA contains terms on training, technical and scientific cooperation, technology transfer, capacity-building, exchange of information and publication policy.

[8] The World Data Center for Microorganisms is a database system aimed at registering the culture collections through a unique acronym and numerical identifier in its official list and urging them to catalog their microbiological resources.

[9] The Globally Unique Identifiers are electronic markers that allow the tracking of the flow of the genetic resources and all the related information, including the location and the movement of the resources, thus helping the implementation of ABS.

[10] The project aims at developing innovative bioinformatic approaches and a legal framework to make large-scale data on marine viral, bacterial, archaeal and protists genomes and metagenomes accessible for marine ecosystems biology, and to define new targets for biotechnological applications. The research target are marine metagenomes, within and beyond national jurisdiction. www.microb3.eu.

[11] GenBank® (http://www.ncbi.nlm.nih.gov/genbank/) is the NIH genetic sequence database, an annotated collection of all publicly available DNA sequences. GenBank is part of the International Nucleotide Sequence Database Collaboration, which comprises the DNA DataBank of Japan (DDBJ), the European Molecular Biology Laboratory (EMBL), and GenBank at NCBI. These three organizations exchange data on a daily basis http://www.ncbi.nlm.nih.gov/genbank/.

[12] The Dryad Digital Repository (http://datadryad.org/) is a curated resource that makes the data underlying scientific publications discoverable, freely reusable, and citable. Dryad provides a general-purpose home for a wide diversity of datatypes. http://datadryad.org/

[13] The study screened records in the patent division of GenBank to extract international claims valid in all countries subscribing to the World Trade Organization (WTO) agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and deposited in the World Intellectual Property Organization (WIPO). Gene patents claims from marine organisms make up only 2% of the WIPO gene patents. The study could not differentiate between patents over marine microorganisms coming from areas within national jurisdiction and from areas beyond national jurisdiction.

and health sectors [49]. This section describes and provides an assessment of the lessons learnt from the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and the WHO Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits.

The ITPGRFA provides an internationally agreed legally-binding framework for the conservation and sustainable use of crop diversity and the fair and equitable sharing of benefits, in harmony with the CBD, with the view to promoting sustainable agriculture and global food security [50]. The Treaty defines a subset of genetic resources of particular importance for agriculture and food security – *i.e.*, plant genetic resources for food and agriculture (PGRFA) – and it limits the scope of application of its norms to them. In this respect, the Treaty could be considered as a *lex specialis* for this particular agriculture sector, whereas the CBD provides the general framework for the conservation and sustainable use of biodiversity.

The core feature of the ITPGRFA is a Multilateral System (MLS) of ABS that assures "facilitated access" to a common pool of germplasm from 64 designated food and forage crops including many – but not all – of the world's major food crops. The MLS operates as a common pooling, exchange and benefit-sharing system for the genetic material that it covers. "Facilitated access" means, inter alia, that access is granted under a standard contract – the Standard Material Transfer Agreement (SMTA). Designated crop species are listed in Annex I of the ITPGRFA. These pooled resources are available only for the purpose of utilization and conservation for research, breeding and training for food and agriculture.

The benefit-sharing mechanism of the ITPGRFA differs from the bilateral, contract-based approach of the CBD, inter alia, because the benefits are shared on a multilateral basis in the MLS. The ITPGRFA also establishes that facilitated access to the PGRFA constitutes itself a major benefit of the MLS, according to Article 13.1 of the ITPGRFA.[14] The Treaty envisages four different tools through which benefits can be shared, namely:

- the exchange of information;
- access to and transfer of technology;
- capacity-building; and
- the sharing of monetary and other benefits from commercialization.

Although much attention is paid to the monetary aspects, non-monetary benefits are also extremely important in the context of MLS implementation [51]. Besides, the Benefit-sharing Fund of the ITPGRFA provides funding for the operationalization of the above tools to implement activities, plans and programs for farmers in developing countries, according to Article 18.5 of the ITPGRFA. If certain requirements are met, compulsory benefit-sharing of 1.1% of income from the sale of seeds must be paid by recipients to the Benefit-sharing Fund, in accordance with the Standard Material Transfer Agreement:

- the first requirement is that the commercialized "product" must incorporate "the material" received from the MLS[15];
- the second requirement is that payments are due only if the "product" (*i.e.*, seeds) is not freely available for further research and breeding. In essence, this requirement entails the existence of a patented product (legal restrictions) or restrictions deriving from particular technologies, such as Genetic Use Restriction Technologies (GURT), or certain restrictive licensing practices. Thus, under the International Treaty the existence of intellectual property rights (IPRs), which restrict access to a product based on genetic resources/PGRFA, is a precondition for the sharing of monetary benefits arising from the commercialization of such a product.

However, interpretative problems may arise because both the Treaty and the SMTA prohibit recipients to claim "any intellectual or other property rights that limit the facilitated access to the Material […] or its genetic parts or components, in the form received from the Multilateral System" [52].[16]

While a strong link between patenting and (potential) benefit-sharing appears to exist for many biotechnology sectors (*e.g.*, pharmaceutical), it is also true that in the PGRFA sector this particular benefit-sharing trigger – based primarily on (patent-related) access restrictions – has demonstrated not to be effective. To date no companies or recipients have ever reported to meet the benefit-sharing requirements of the SMTA. No payments were ever made to the Benefit-sharing Fund of the Treaty by recipients of PGRFA.

In addition, the development of a new plant variety may take more than ten years. During this period recipients are not normally required to make payments to the MLS. Therefore, the SMTA also envisages an alternative payment scheme, which may provide an immediate flow of financial resources to the Benefit-sharing Fund of the Treaty. This scheme provides that recipients may voluntarily choose to make crop-based payments at the discounted rate of 0.5 per cent of the overall sales of seeds pertaining to the same crop species obtained from the MLS by the recipient, according to article 6.11 of the SMTA.

In conclusion, important analogies can be drawn between a key underpinning of the ITPGRFA – namely, the interdependence of states on continuous exchange of plant genetic resources for agricultural uses – and a fundamental motivation for improving MSR under UNCLOS, that is the importance for researchers to get facilitated access to samples and data. However, there are also crucial differences between the subject matter regulated by the ITPGRFA and MGR in ABNJ. The scope of the ITPGRFA is relatively narrow since it covers only 64 plant species and its monetary benefit-sharing obligations only apply to a single category of "products", namely, PGRFA sold on the market as seeds or other propagating materials for direct cultivation or resale. By contrast, the scope of an instrument to further regulate MSR in ABNJ could potentially apply to all biodiversity found in such areas, which encompasses millions of species. The products and processes issued from such research may be extremely heterogeneous and encompass applications spanning across multiple technological domains (food and agriculture, including aquaculture, health, biofuels, cosmetics and several others). Thus, an important consideration is that the administration of a potentially huge number of transactions through a SMTA-like mechanism could prove more burdensome than in the context of the ITPGRFA. Besides, there is a clear trade-off between the possible standardization of benefit-sharing obligations (and of their triggers), which reduces transaction costs, and the need to adapt such obligations to the heterogeneous types of products, processes, applications and benefits derived from MGR.

[14] International Treaty Article 13.1.

[15] The definition of "product" which is given in Article 2 of the SMTA excludes products other than PGRFA and other products used for food, feed and processing. Hence, the commercialization of bulk goods that are 'sold or traded as commodities' shall not be considered.

[16] Thus, it is questionable whether patent claims to materials in the MLS should be allowed. This is because such claims can restrict access to germplasm, genome sequences and their functional characterisations, which may be deemed to be international public goods.

The second international ABS instrument referred to above is the Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (PIP Framework) [53], which was adopted in 2011 as a non-legally binding international agreement that provides for a multilateral benefit-sharing arrangement [54]. The objective of the PIP Framework is to improve pandemic influenza preparedness and response, and strengthen the protection against the pandemic influenza by improving and strengthening the WHO Global Influenza Surveillance and Response System ("WHO GISRS"), with the objective of a fair, transparent, equitable, efficient and effective system for:

(i) the sharing of H5N1 and other influenza viruses with human pandemic potential; and
(ii) access to vaccines and sharing of other benefits (WHO PIP Framework, Article 2)

The PIP Framework provides for the use of two different model contracts, also called Standard Material Transfer Agreements, for regulating the obligations of providers and recipients of virus samples that are exchanged in accordance with the PIP Framework:

- SMTA 1 is used to regulate the exchange of viruses among institutions that operate within the WHO GISRS – *i.e.* "[…] Influenza laboratories that have been designated or recognized by WHO and have accepted to work under agreed WHO terms of reference" (WHO PIP Framework, SMTA 1, Article 1.1);
- SMTA 2 is to be used for exchange of samples between the WHO (on behalf of relevant WHO laboratories) and third parties, which operate outside the WHO-GISRS – *i.e.* all entities that received "PIP biological materials" from the WHO-GISRS, such as influenza vaccine, diagnostic and pharmaceutical manufactures, as well as biotechnology firms, research institutions and academic institutions (WHO PIP Framework, SMTA2, Article 1, footnote 1).

As regards benefit-sharing, SMTA 1 provides that: "The Recipient shall actively seek the participation of scientists […] from originating laboratories […], especially those from developing countries, in scientific projects associated with research on clinical specimens and/or influenza virus from their countries and actively engage them in preparation of manuscripts for presentation and publication. The Recipient shall appropriately acknowledge in presentation and publications, the contributions of collaborators, including laboratories/countries providing clinical specimens or influenza Virus with pandemic potential or reagents, using existing scientific guidelines" (WHO PIP Framework, SMTA1, Articles 5,2 and 5.3). SMTA 1 also expressly prohibits parties to seek to obtain any IPRs on the received materials (WHO PIP Framework, SMTA1, Article 6.1), while it does not provide for monetary benefit-sharing obligations.

On the contrary, SMTA 2 does not limit the possibility of recipients to obtain IPRs over the received materials and it provides for specific compulsory benefit-sharing obligations between the WHO and the recipient of the material in accordance with a given list of options (WHO PIP Framework, SMTA1, Article 4.1.1). Additionally voluntary benefit-sharing options are provided (WHO PIP Framework, SMTA1, Article 4.1.1.C). Finally, third party transfers of PIP materials are allowed if the subsequent recipient has concluded an SMTA with the WHO and the transfer is reported to the latter (WHO PIP Framework, SMTA1, Article 4.4).

Besides the obligations contained in these SMTAs, other benefit-sharing obligations are directly specified by the PIP Framework, which states that: "Influenza vaccine, diagnostic and pharmaceutical manufactures, using the WHO GISRS, will make an annual partnership contribution to WHO for improving global pandemic influenza preparedness and response. […] the sum of the annual contributions shall be equivalent to 50% of the running costs of the WHO GISRS[17]" commencing in 2012 (WHO PIP Framework, Articles 6.14.3 and 6.14.4). The distribution between companies will be based on transparency and equity, and their nature and capacities.

Similarly to the conclusions provided for the ITPGRFA, the WHO PIP Framework is also characterized by a narrow scope of application and focuses on a specific scientific and technological domain that targets a relatively homogenous set of applications in the field of influenza vaccine, diagnostic and pharmaceutical production. It also relies on the WHO Global Influenza Surveillance and Response System, which include an elaborated research infrastructure with a clear global public health mandate and a structured policy framework for international cooperation. This has also allowed a differentiation between the rights, duties and obligations of public research institutes and those of other for-profit research entities. These important characteristics have certainly helped both in identifying relevant stakeholders as well as in involving them in negotiating appropriate benefit-sharing options, while providing more flexibility as compared with the ITPGRFA. By contrast, the marine scientific research community has only played a relatively marginal role in discussions concerning MGR and benefit-sharing at the UN AHWG so far. This should be avoided in the future.

7. Conclusions: how to establish a regime for access and benefit-sharing in ABNJ?

The multidisciplinary analysis of this paper aims at highlighting the need to bridge the gaps between science and policy when discussing how to eastablish a regime for access and benefit-sharing for MGR in ABNJ. To this end, it would be useful for policy-makers and legal experts involved in the political process to better ground their views on a clearer understanding of the scientific pipelines. In this regard the inauguration of two intersessional workshops of experts held at the United Nations in between the meetings of the BBNJ Working Group, is a positive signal to focus the discussion on concrete options for the way forward.

It should be borne in mind that only few countries dispose of the molecular and oceanographic means that allow the development of marine biotechnologies. Therefore, capacity-building and the development of cooperative programs should be fundamental elements of a future regime. Moreover, the increase in biotechnological developments and patents associated with MGR is likely to continue in the next decades due to the improvements of molecular skills and technologies. However, this will also augment technological disparities between countries. Bridging the gap between those countries that hold knowledge, resources and technologies, and those that do not, is therefore a priority in order to achieve a more "[…] equitable and efficient utilization of their (seas and oceans) resources" as it is stated in the Preamble to UNCLOS, paragraph IV.

This article has highlighted that some (non-monetary) benefit-sharing provisions under UNCLOS are already applicable in the field of marine scientific research and that – to some extent – such benefits are routinely shared by the scientific community in

[17] "The running costs of the GISRS for 2010 were approximately US$ 56.5 million […]." This footnote is included in the text as footnote 1 of the WHO PIP Framework.

relation to MGR from ABNJ. Even though their implementation needs to be strengthened, they can represent the legal basis for a future ABS regime and provide a pragmatic and realistic approach to move forward at least in the discussions on non-monetary benefit-sharing. The best practices adopted and implemented by the scientific community are important efforts towards awareness-raising and voluntary standard setting (*e.g.* concerning the origin of genetic resources, including from ABNJ).

As regards the geographical scope of the regime, practical (and uniform) solutions for the management of MGR straddling in both horizontal and vertical transboundary situations need to be found.

Regarding the regulatory options for sharing benefits from the utilization of MGR from ABNJ, the comparative analysis of other international ABS instruments highlights the need to further consider the following elements [55]:

- the relationship between intellectual property rights and benefit-sharing as a trigger of users' obligations, including information and data sharing as well as royalty and/or milestone-type payments to a multilateral fund, a system similar to that of a patent pool [47];
- the possible introduction of prohibitions on obtaining exclusive rights on MGR from ABNJ in accordance with UNCLOS Article 241; or the introduction of limitations on obtaining such exclusive rights when they restrict access to the knowledge associated with MGR, as proposed by the public domain approach of Micro B3 ABS model agreeement;
- the need to envisage establishing monitoring mechanisms, notification requirements and dispute settlement procedures and mechanism which could be alinged and/or harmonized with the ones being developed under the Nagoya Protocol (such as national checkpoints);
- the use of standard material transfer agreements, the possible role of third party beneficiary's rights and the regulation of third party transfers, including an obligation to pass onto any subsequent recipient the benefit-sharing obligations through a viral license clause in such agreements;
- the need to envisage material and information sharing requirements, as well as capacity-building and technology transfer related to MGR and biotechnologies as fundamental forms of non-monetary benefit sharing, through a more effective implementation of the UNCLOS provisions on MSR; and
- the possible establishment of benefit-sharing obligations in the form of partnership contributions for commercial partners interested in accessing materials and metadata from institutions that belong to a global public MGR research infrastructure or network.

Finally, the policy option of establishing common pools of resources, and/or research results and data may offer the advantages of preserving the public domain condition of common or shared resources, such as MGR from ABNJ, and of providing, without impairing commercial applications, the main benefit-sharing that is usually sought by those involved in marine scientific research: facilitated access to resources, data and research results for the advancement of science as a public good.

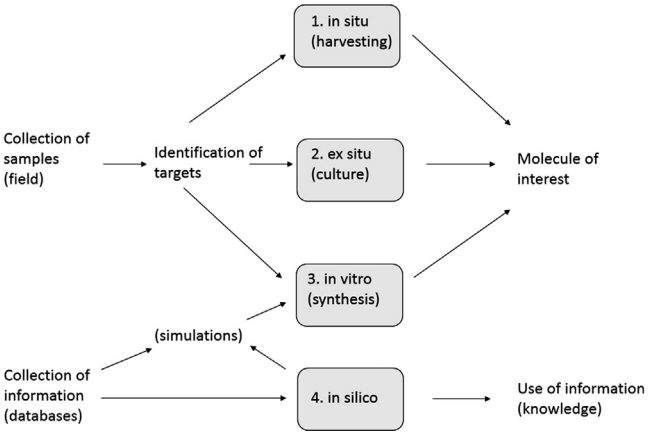

Fig. A1. Illustration of the four pathways that can lead to the use of Marine Genetic Resources after sampling and identification of targets for Biotechnologies: 1. Harvest of biological material (*in situ*) 2. Culture of biological material (*ex situ*) 3. Synthesis of molecules of interest in laboratory (*in vitro*) 4. Use of information contained in databases (*in silico*), occasionally resulting in the use of information to synthesize molecule (illustrated by the loop with the *in vitro* path).

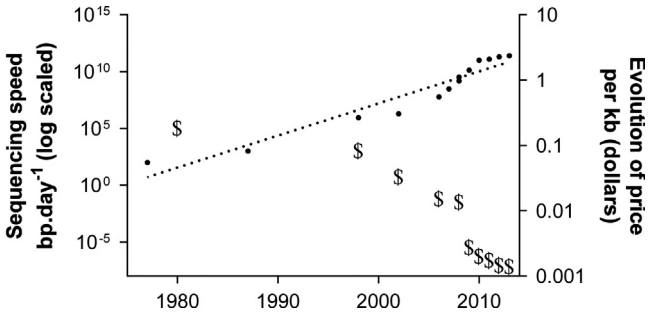

Fig. A2. Evolution of sequencing speed (number of base pair sequenced per 24 h), and speed (costs in US dollars per base pair) on a log log scale, illustrating a decrease of costs beyond predictions based on Moore's law.

Table A1
Definition of genetic resources and related terms in the Convention on Biological Diversity and the Nagoya Protocol.

	CBD	Nagoya Protocol
"Genetic material" (Article 2 of the CBD)	"**Any material** of plant, animal, microbial or other origin **containing functional units of heredity**."	
"Genetic resources" (Article 2 of the CBD)	"**Genetic material of actual or potential value**."	
"Utilization of genetic resources" (Article 2(c) of the Nagoya Protocol)		"To conduct research and development on the **genetic and/or biochemical composition of genetic resources**, including through the application of biotechnology as defined in Article 2 of the Convention."
"Biotechnology" (Article 2 of the CBD)	"**Any technological application that uses biological systems, living organisms, or derivatives** thereof, to make or modify products or processes for specific use."	
"Derivative" (Article 2(d) of the Nagoya Protocol)		"A **naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity."**

Appendix A

See Figs. A1 and A2 and Table A1.

Acknowledgments

Part of this paper is based on research funded by the Micro B3 project, funded from the European Union's Seventh Framework Programme (Joint CallOCEAN.2011-2: Marine microbial diversity – new insights into marine ecosystems functioning and its biotechnological potential) under the grant agreement no 287589. The authors would like to thank Dominique Cowart for proof reading the paper.

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