

Marine Genetic Resources in Areas beyond National Jurisdiction: Access and Benefit-Sharing

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Abstract

This report examines whether it is possible for the research and use of marine genetic resources in areas beyond national jurisdiction (ABNJ) to follow an approach based on the system that is being used with plant genetic resources in areas within national jurisdiction, as developed by the Food and Agriculture Organization. Part IV of the International Treaty on Plant Genetic Resources for Food and Agriculture contains the multilateral system of access and benefit-sharing. In addition, the report considers the implications of relevant provisions as contained in the Law of the Sea Convention, the Convention on Biological Diversity, the Antarctic Treaty System, as well as instruments on intellectual property rights. The report concludes with an assessment of the options within existing legal frameworks for accommodating an access and benefit-sharing system for marine genetic resources originating from ABNJ, and provides suggestions to move the international debate forward.

Keywords

areas beyond national jurisdiction (ABNJ); access and benefit-sharing; marine genetic resources

Introduction

The exploration of the mineral resources of the Area¹ and the development of technologies for their exploitation attracted much attention during the 1960s

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¹ The “Area” means “the sea-bed and ocean floor and subsoil thereof, beyond the limits of national jurisdiction” as defined in LOSC Article 1(1). An examination of this regime can be

and 1970s.² An international legal regime for commercial mineral-resource exploitation was developed and is reflected in Part XI of the United Nations Convention on the Law of the Sea (hereinafter the LOSC).³ The primary focus of the regime was on poly-metallic manganese nodules. However, in the 1980s commercial-scale nodule mining, as originally envisaged, did not appear to be economically feasible. This situation continues until today.⁴

In contrast, the exploitation of marine genetic resources originating from the Area turned out to be much more feasible and lucrative in the short term, although only a few States are technically and financially capable of accessing the marine genetic resources in areas beyond national jurisdiction (hereinafter ABNJ) and developing them for exploitation. In the absence of a specific international regime addressing bioprospecting in ABNJ,⁵ discussions in the international community are ongoing on the options for a multilateral regime to regulate the access to and benefit-sharing of marine genetic resources in ABNJ.

The central research question of the present report concerns an assessment of the possibilities for the research on and use of marine genetic resources to follow an approach based on the system that is being used with plant genetic resources, developed through the 2001 International Treaty on Plant Genetic Resources for Food and Agriculture (FAO Treaty)⁶ in the framework of the Food and Agriculture Organization (FAO).

In the case of the FAO Treaty, benefit-sharing was basically seen as a necessary complement of the objective of promoting use of and securing access to these resources, and as an absolute condition to bring the FAO Treaty in harmony with the Convention on Biological Diversity (CBD).⁷ The distinction made in the Multilateral System (MLS) between genetic resources freely available for further research and breeding for the purpose of food and agriculture, and genetic resources for which this is not the case, underscored the notion that the free availability of genetic resources, including advanced materials,

found in the section on the 'Regime Applicable to Marine Genetic Resources in ABNJ' of this report.

² L Glowka, 'Genetic Resources, Marine Scientific Research and the International Seabed Area' (1999) 8(1) *Review of European Community and International Environmental Law* 58.

³ Adopted on 10 December 1982; entry into force 16 November 1994; 1833 UNTS 396.

⁴ E Egede, *Africa and the Deep Seabed Regime: Politics and International Law of the Common Heritage of Mankind* (Springer-Verlag, Berlin, 2011) at 218.

⁵ Glowka, *supra* note 2, p. 58.

⁶ International Treaty on Plant Genetic Resources for Food and Agriculture, 3 November 2001, in force 29 June 2004, 2400 UNTS 303.

⁷ Convention on Biological Diversity, done in Rio de Janeiro, 5 June 1992, in force 29 December 1993, 1760 UNTS 79.

constituted a major benefit of the FAO Treaty in itself. By making this distinction, the FAO Treaty “rewards” intellectual property rights that allow the free availability of genetic resources for the purpose of research, breeding and training.⁸

An assessment of the useful elements of, and experiences with, the FAO Treaty requires not only an examination of the FAO Treaty itself, but in addition requires an assessment of the implications of the regime applicable to ABNJ as contained in the LOSC, the CBD and international trade law. A preliminary assessment of the research question pointed out that it would also be helpful to look at the developments in the Antarctic Treaty System (ATS) in respect of marine genetic resources. Finally, the various legal frameworks that could accommodate a MLS on access to and benefit-sharing for marine genetic resources in ABNJ is evaluated by providing arguments pro and contra.

In view of the complexity and diversity of the legal regimes which needed to be analyzed to deal with the research question, the work was divided between Petra Drankier and Alex G. Oude Elferink of NILOS, Tamara Takács of the Europa Institute of Utrecht University and Bert Visser of the Centre for Genetic Resources of Wageningen University and Research Centre. As a result, various provisional reports were prepared to cover the different aspects of the research question. This synthesis report integrates the analyses of these reports into a whole and intends to contribute to the exploration of the options for The Netherlands, within the framework of the European Union (EU), to take initiatives to advance the international debate on access to and benefit-sharing of marine genetic resources in ABNJ.

International Treaty on Plant Genetic Resources for Food and Agriculture⁹

Introduction

The objectives of the FAO Treaty are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of benefits derived from their use, in harmony with the CBD, for sustainable agriculture and food security. Part IV of the FAO Treaty establishes the

⁸ B Visser and J Borring, ‘The European Regional Group: A European Perspective: Europe’s Role and Positions during the Negotiations and Early Implementation of the International Treaty’, draft version (2010) 1–2. To be published in C Frison, F López and JT Esquinas-Alcázar (eds.), *Plant Genetic Resources and Food Security* (Earthscan, London, 2011).

⁹ This section is based on written contributions by Bert Visser.

MLS, a facilitated system of access and benefit-sharing that covers the use of crops worldwide. The resources covered by the MLS are listed in Annex I of the FAO Treaty. The crops listed in Annex I of the FAO Treaty together contribute some 80% of the world's total energy food supply. The MLS only includes crops which are under the management and control of the Contracting Parties, and consequently excludes genetic resources originating from ABNJ. Under the MLS, a recipient of material from the MLS is obliged to share benefits if it restricts access to products derived from the material received. The MLS therefore guarantees free access to the original materials. It must be noted that States worldwide are heavily interdependent on plant genetic resources from other parts of the world for their agricultural development. No State or region in the world is entirely self-sufficient in terms of the plant genetic resources needed to sustain and improve its major crops.¹⁰

Practical Experience with the FAO Treaty

Negotiation of the FAO Treaty

From the start of the negotiations on the FAO Treaty, the objective was to create a legally binding instrument. The scope of the FAO Treaty and the position of the collections held by the International Agricultural Research Centres (IARCs) of the Consultative Group on International Agricultural Research (CGIAR), as well as the benefit-sharing arrangements, were major items of discussion. The negotiations took seven years because the FAO Treaty was the first legally binding instrument that put the access and benefit-sharing principles of the CBD into operation. As a result of mistrust between, *inter alia*, the G77 and the OECD States, very little progress was made for several years.

The FAO Treaty was developed in harmony with the CBD, which set the framework for the FAO Treaty negotiations. Although the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of Their Utilization,¹¹ adopted in 2002 by the CBD, were finalised in the same time period as the FAO Treaty, the development of the two instruments took place in separate negotiating communities (environment vs. agriculture). The voluntary Bonn Guidelines formed an attempt to put into operation the access and benefit-sharing principles of the CBD for generic

¹⁰ G Moore and W Tymowski, *Explanatory Guide to the International Treaty on Plant Genetic Resources for Food and Agriculture* (IUCN, Bonn, 2005) at 5–6.

¹¹ Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of Their Utilization, CBD COP VI Decision VI/24 (2002). Available at: <http://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf>.

purposes, whereas the scope of the legally binding FAO Treaty is limited to plant genetic resources for food and agriculture.

During the final stages of the negotiations of the FAO Treaty it had also been considered that it might become a Protocol to the CBD. In the end, this approach was rejected, and the FAO Treaty was adopted as an independent international agreement under Article XIV of the FAO Constitution. One of the main reasons for this approach was the view that the Treaty was essentially an agricultural rather than an environmental treaty and as such should be responsive to the needs of the agricultural sector.¹² The Preamble of the FAO Treaty states that the Contracting Parties are “convinced of the special nature of plant genetic resources for food and agriculture, their distinctive features and problems needing distinctive solutions”.

Multilateral System of Access and Benefit-Sharing

The MLS set up by the FAO Treaty offers certain advantages in comparison with the former International Undertaking on Plant Genetic Resources¹³ in relation to access and benefit-sharing. The Undertaking was a voluntary instrument and thus far less effective. It was based on the principle of common heritage of mankind rather than on the principle of national sovereignty. Access to and export of plant genetic resources in that period were much simpler and less regulated. The adoption of the CBD required a revision of the Undertaking. The Undertaking was still based on the principle of common heritage of mankind, and was only gradually transformed to recognize national sovereignty over biodiversity in areas within national jurisdiction, which is a cornerstone of the CBD. Thus, to have kept the Undertaking or an instrument with similar features was no longer appropriate.

The MLS of the FAO Treaty is motivated on two major grounds: (1) the need for global food security, and (2) the mutual interdependence of States regarding the use of plant genetic resources for food and agriculture. However, two additional criteria have been proposed, which are considered relevant as well for the MLS. The first criterion is a high number of transactions, and the second is the predictability of use, i.e., for the purpose of research, training and breeding. In fact, plant genetic resources for food and agriculture in the MLS of the FAO Treaty may only be accessed if they are going to be used for one of these purposes.

¹² Moore and Tymoswki, *supra* note 10, p. 11.

¹³ International Undertaking on Plant Genetic Resources, adopted by the FAO Conference in November 1983 under Resolution 8/83. Available at: <http://www.fao.org/ag/CGRFA/iu.htm>.

While the scope of the FAO Treaty in general is “plant genetic resources for food and agriculture”, the MLS (Part IV of the FAO Treaty) only applies to a specified list of crops (Annex I of the FAO Treaty). The MLS is being given the benefit of the doubt by many States of the G77: let us see whether it generates sufficient benefits to us, G77 States, in which case we might even consider expanding Annex 1. In contrast, Japan did not sign the FAO Treaty; the US has signed but so far did not ratify it.

In practice, the MLS mainly applies to *ex situ* collections, simply because these are relatively accessible and well described, whereas *in situ* diversity is dispersed, poorly accessible and hardly described. However, in principle the MLS covers both, with the notion that national legislation may also set conditions for access to plant genetic resources for food and agriculture *in situ* (including environmental assessment procedures, for instance, in the case of wild relatives). With regard to the *ex situ* collections, for those that were included in the MLS on an automatic or voluntary basis, States are not allowed to set any further conditions in their national legislation than those provided for under the MLS.

The only condition for access to genetic resources covered by Annex I of the FAO Treaty is the signing of the Standard Material Transfer Agreement (SMTA). The recipient agrees that the provider inform the secretariat of the FAO Treaty about all transfers. The recipient is allowed to use the material provided under the SMTA “for the purposes of research, breeding and training for food and agriculture” (Article 6.1 SMTA), and “to claim intellectual property or other rights on products incorporating the Material provided under this Agreement”¹⁴ under the following conditions:

- not to claim intellectual property or other rights that limit the facilitated access to the material provided under the SMTA (Article 6.2 SMTA);
- if a product that incorporates material provided under the SMTA which is not available without restriction to others for further research and breeding is commercialized, to pay a fixed percentage of the sales of the commercialized product (Article 6.7 SMTA);
- to make available to the MLS all non-confidential information that results from research and development carried out on the material (Article 6.9 SMTA);

¹⁴ Netherlands CBD Focal Point for Access and Benefit Sharing (2011), A Guideline for the Understanding of the Standard Material Transfer Agreement of the International Treaty on Plant Genetic Resources for Food and Agriculture, available under the section ‘Summary of the Standard Material Transfer Agreement of the Multilateral System’ at: <http://www.absfocalpoint.wur.nl/UK/SMTA+Guideline/>, last accessed 27 February 2012.

- if material provided under the SMTA, or a product under development incorporating the material provided under the SMTA, is transferred to another person or entity, to do so under the terms and conditions of the SMTA (Article 6.5 SMTA).¹⁵

There is no time limit (no expiration of obligations) on the sharing of benefits, one of the few elements in the SMTA that leads to caution among some of the recipients.

The SMTA is of central importance for the functioning of the MLS. It is in effect the legal instrument that allows the legal obligations provided for in the FAO Treaty to be passed on to the recipients and from them to subsequent recipients, by means of a contractual nexus. Any dispute concerning, or non-compliance with, the terms of the SMTA is to be dealt with by the parties to the SMTA in national courts.¹⁶

It may be difficult to find a balance between an ill-defined and a detailed SMTA. This concerns the type of data required and the appropriateness of these data for monitoring the use of genetic material. Incomplete and improper reporting on transfer of material from the MLS, as well as too much bureaucracy, should be avoided. The level of detail should allow a proper evaluation of the SMTA. Moreover, whether the data concerned are to be kept confidential (as in the case of the FAO Treaty), or whether the data are to be published on a website and freely accessible (or subject to an intermediate form of accessibility), must be considered.

The FAO Treaty does not make a distinction between prospecting, exploration and exploitation, terms which are being used in other legal frameworks (e.g., the deep seabed mining provisions of LOSC Part IX and its Implementing Agreement). The only acts that count are the realization of access and the transfer of material, which are regulated by the SMTA. If prospecting implies the existence of a recipient that studies and/or uses the material collected, the SMTA will apply, including the provisions on benefit-sharing that have an impact on the commercialization of products derived from the materials accessed.

Neither does the FAO Treaty make a distinction between private companies and research institutions in the process of access and benefit-sharing. Currently this is well justified because many research institutes carry out work under contract with private companies or commercialise products themselves. They act as recipients, and as such they may share either obligatory or voluntary benefits arising out of these products.

¹⁵ *Ibid.*

¹⁶ Moore and Tymoswki, *supra* note 10, pp. 98–100.

Monetary benefits to which the obligatory benefit-sharing provisions of Article 13.2(d) apply arise out of the commercialisation of products incorporating genetic materials obtained from the MLS and not freely available to third parties for research, training and breeding (this limited availability is true for patents but not for breeder's rights). Non-monetary benefits comprise information exchange, technology transfer, and capacity building, which are all described in quite some detail in Article 13 of the FAO Treaty.

Details of the monetary benefit-sharing provisions remained to be settled, because this issue could not be fully negotiated before the adoption of the FAO Treaty.¹⁷ According to Article 13.2(d)(ii):

... The Governing Body shall, at its first meeting, determine the level, form and manner of the payment [by a recipient], in line with commercial practice. The Governing Body may decide to establish different levels of payment for various categories of recipients who commercialize such products...

The first session of the Governing Body of the FAO Treaty was organized in Madrid in 2006, where the SMTA¹⁸ was adopted and herein the issues of payment were solved.

Under Article 13.2(d)(ii), one voluntary monetary transfer into the Benefit Sharing Fund has been made so far. Such a long time lag was to be expected, since breeding processes take many years. In addition, so far USD 15 million from 5 different donors have been obtained for the Benefit-Sharing Fund.¹⁹ The five-year target was set at USD 116 million.

Institutional Arrangements

An *Ad Hoc* Advisory Committee was established for the implementation of the SMTA to handle issues of interpretation. This Committee issues opinions and reports these to the Governing Body of the FAO Treaty, which remains the final responsible body.

Furthermore, a Compliance Committee was established to elaborate compliance measures. Contracting Parties may report on lack of compliance in their own State and for activities under their own control and responsibility and ask for capacity-building and external support, but also about lack of compliance by other Contracting Parties.

¹⁷ Moore and Tymoswki, *supra* note 10, p. 104.

¹⁸ Standard Material Transfer Agreement (SMTA), adopted in Resolution 1/2006 of 16 June 2006. Available at: <ftp://ftp.fao.org/ag/agp/planttreaty/agreements/smta/SMTAe.pdf>.

¹⁹ To promote the cause of the FAO Treaty, and to promote adaptation to climate change for the sake of food security.

Finally, a Third-Party Beneficiary Committee was established. The idea is that the States Parties to the FAO Treaty comment on the implementation of the FAO Treaty as an integrated instrument, whereas the Third-Party Beneficiary can act on behalf of providers regarding compliance with individual SMTAs. For some Contracting Parties a provider can be the State. A distinctive aspect of the FAO Treaty's MLS and SMTA is that the FAO may act as Third-Party Beneficiary on behalf of the provider or recipient in any dispute about or suspected breach of the SMTA. This measure was adopted because many collection holders, in particular but not only in developing States, lack the means to take legal and other action in cases of possible breach.

Enforcement

Considering the feasibility of enforcement of the access and benefit-sharing elements of the FAO Treaty, a distinction may be made between legal enforcement (enforcement in a strict sense) and enforcement through publicity and raising awareness. The latter might be more important, certainly for the private sector, which is generally wary of negative publicity.

Enforcement of access will often concern collections held in the public sector. These are under the control of governments, either formally or informally, and enforcement depends on the individual Contracting Parties. In the case of the FAO Treaty, the provision of access is balanced against the expectation of benefit-sharing. In other words, enforcement of access will depend to a large extent on the success of the Benefit-Sharing Fund, the mechanism through which the benefit-sharing is and will be put into operation.

Enforcement of benefit-sharing is more complex and depends to a large extent on mutual trust and good will. Obligatory benefit-sharing depends on the turn-over of products incorporating genetic material obtained from the MLS, but in practice this is difficult to monitor for outsiders to the breeding process. Voluntary benefit-sharing is likely to be far more important in the long run. Enforcement is not relevant to these situations.

Weaknesses

Non-universal ratification of the FAO Treaty is a potential weakness, although the number of Contracting Parties is already quite high (126). Much also depends on the formal allocation of collections in the MLS; the gene pool under the MLS needs to be filled in order to make the ratification of the FAO Treaty attractive. These weaknesses form inherent political weaknesses and can only be overcome by demonstrating the contribution of the FAO Treaty to the international accessibility and export of plant genetic resources as well as to benefit-sharing, and in relation to these two objectives, to food security.

Lack of reporting or incomplete and improper reporting on transfer of material from the MLS, hampering effective monitoring of use, is another potential weakness. Such a weakness can only be overcome by detailed agreement in the Governing Body on the type of data required and the appropriateness of these data for monitoring the use of genetic materials in cases where the provider, the recipient or the Third-Party Beneficiary regards this as desirable.

Lack of benefit-sharing, be it voluntary or obligatory, is another potential weakness. Threats do not so much emanate from individual cases as from the overall lack of generating sufficient funds for benefit-sharing. A dedicated, well-resourced fund-raising campaign is an absolute requirement to generate the necessary funds.

Lessons Learned from the FAO Treaty

Which lessons can be learnt from the FAO Treaty for the purpose of a future legal instrument on access to and benefit-sharing of marine genetic resources in ABNJ?

1. If a high economic value and many benefits for genetic resources are estimated for specific stakeholders, there will be little support among them for a special international legal instrument imposing both obligatory access and obligatory benefit-sharing. In the case of the FAO Treaty this resulted in a specified list of crops, because there was no international support yet for a system which would apply to the full range of plant genetic resources for food and agriculture. In the case of the FAO Treaty, the decision to include certain genetic resources in the MLS was based on the following arguments:
 - Food security;
 - Mutual interdependency;
 - High number of transactions;
 - Predictability of type of use (research, training and breeding).
2. The negotiation of a treaty is likely to take much time if there is much mistrust between (groups) of States, especially where the first legally instrument of its kind is concerned.
3. The development of other relevant instruments may take place in separate negotiation communities, as was the case with the Bonn Guidelines under the CBD and the FAO Treaty.

4. Users of a MLS of access and benefit-sharing are likely to have reservations if the following is not included in the treaty concerned:
 - A start- or end date for the sharing of benefits;
 - A provision stipulating that a limited share of a particular marine genetic resource in the end product does not lead to the exclusion from the MLS on access and benefit-sharing.
5. It can take a long time before any monetary transfer takes place under a MLS of access and benefit-sharing, since research and development processes take many years.
6. It is necessary to pay much attention to building trust in order to convince certain (groups of) States that benefits will be generated. This concerns monetary as well as non-monetary benefits. Regarding the former, voluntary payments can be made, as is done by, *inter alia*, the UN Development Program in the case of the FAO Treaty.
7. Obligatory benefit-sharing is in practice difficult to monitor for outsiders to the breeding process. Voluntary benefit-sharing is likely to be far more important in the long run.
8. Enforcement of access and benefit-sharing will depend to a large extent on the individual Contracting Parties and on the success of the benefit-sharing fund.
9. Non-universal ratification, as well as failure to implement the core of the FAO Treaty, i.e., the MLS, is a potential weakness.
10. Enforcement through publicity and raising awareness might be more important than legal enforcement, especially in ABNJ.
11. It may be difficult to find a balance between an ill-defined and a detailed SMTA, with respect to the type of data required and the appropriateness of these data for monitoring the use of genetic material.
12. Existing institutions might be reluctant to delegate power to other or new institutional structures. Much depends on which sectoral interests are at stake and in which institutional forum the discussion on the potential new regulation concerned is the most advanced.
13. It is recommended to establish institutions as a part of the legal framework of an MLS on access and benefit-sharing. A governing body might work out those details that could not be decided before the adoption of the treaty, an advisory committee might sort out issues of interpretation, a compliance committee might deal with lack of compliance reported by States, and a third-party beneficiary committee might act on behalf of providers or recipients in any dispute.

Intellectual Property Rights²⁰

Introduction

Instruments on Intellectual Property Rights (IPRs), including the 1977 Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure,²¹ and the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS),²² have a role in regulating the use of information, data, and inventions ensuing from biological material, including marine genetic resources in ABNJ.

Patents confer on their holders more or less extensive and exclusive rights to offer their invention for sale, in exchange for publication of or information on their invention, including the right to exclude others from “making, using, or selling or importing the protected invention into a jurisdiction where the patent protection is in force, or to charge others for any uses or purposes involving the protected invention within such jurisdiction” (i.e., through licensing).²³ TRIPS sets minimum standards for intellectual property protection to help trade, i.e., to establish conditions in which intellectual property standards are harmonised to facilitate trade in (patented) goods. In this way WTO Members will know what standards to expect when they trade their goods with other WTO Members.

TRIPS lays down minimum standards for WTO Members in their implementation of patent laws, but patent laws are still a matter of national jurisdiction: it is the patent law of the State where the patent was registered and granted that applies—and this national law must be in accordance with international obligations, such as TRIPS. The patent holder, therefore, can only enforce its rights to exclusive use in the jurisdiction where the patent has been registered.

²⁰ This section is based on written contributions by Tamara Takács.

²¹ Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, adopted on 28 April 1977, entered into force 19 August 1980, 9 ATS 1987.

²² Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 869 UNTS 299.

²³ PD Oldham, *Global Status and Trends in Intellectual Property Claims: Genomics, Proteomics and Biotechnology* (Centre for Economic and Social Aspects of Genomics, Lancaster, UK, 2004), cited by C Salpin and V Germani, ‘Patenting of Research Results Related to Genetic Resources from Areas Beyond National Jurisdiction: The Crossroads of the Law of the Sea and Intellectual Property Law’ (2007) 16 *Review of European Community and International Environmental Law* 12–23.

Article 8 of TRIPS lays down two principles that allow WTO Members to adjust intellectual property protection to particular concerns and to take appropriate measures within their jurisdiction. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of TRIPS.²⁴ Appropriate measures, provided that they are consistent with the provisions of TRIPS, may be needed to prevent the abuse of IPRs by right holders or prevent the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.²⁵

Regarding benefit-sharing, TRIPS is not concerned with whether an applicant for a patent will have to pay a fee to obtain it or how much a patent holder will gain from exploiting the patent. As to the actual rights conferred on the patent holder ('benefit' can only be understood in this sense under TRIPS), Article 28 of TRIPS states that:

A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing²⁶ for these purposes that product;

(b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

Case Study: Compulsory Licenses under the WTO to Promote Access to Medicines
Under the TRIPS system governments may in certain cases require compulsory licenses to produce the patented product without consent of the patent owner. This is the result of long debates revolving around access to medicines and the right to health and responds to the concerns of primarily developing States. Given the fact that samples taken from hydrothermal vents and marine genetic resources from ABNJ have proven to be useful for medical scientific

²⁴ Article 8(1) TRIPS.

²⁵ Article 8(2) TRIPS.

²⁶ This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.

research and show positive anti-viral effects and potential use for anti-cancer medicines, the issue of compulsory licences will be discussed below.

The TRIPS system clearly defines the rules for the use of compulsory licenses. Article 31 of TRIPS sets forth a number of conditions for the granting of compulsory licenses. These include a case-by-case determination of compulsory license applications, the need to demonstrate prior (unsuccessful) negotiations with the patent owner for a voluntary license and the payment of adequate remuneration to the patent holder. Where compulsory licenses are granted to address a national emergency or other circumstances of extreme urgency, certain requirements are waived in order to expedite the process, such as having had prior negotiations to obtain a voluntary license from the patent holder. Although TRIPS refers to some of the possible grounds (such as emergency and anti-competitive practices) for issuing compulsory licenses, it leaves Members full freedom to stipulate other grounds, such as those related to non-working of patents, public health or public interest.²⁷ The Doha Declaration states that each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted. The patent owner still has rights over the patent, including a right to be paid for the authorized copies of the products. A specific transitional regime applies to Least Developed Countries, which can now delay protecting pharmaceutical patents until 2016. So long as a medicine is not patented in a least-developed State, the government does not need to issue a compulsory license to import. However, the supplying country would still have to issue a compulsory license to export a generic copy of a medicine that is patented in that State.

Patentability

One of the standards, important from the perspective of this report, is the issue of patentability. Article 27(1) of TRIPS requires that WTO Member make patents available for any inventions, whether products or processes, in all fields of technology. Patents shall be available for inventions that are new, involve an inventive step and are capable of industrial application. The WTO dispute settlement system has so far not rendered an interpretative adjudication on these criteria. There are three permissible exceptions to the rule on patentability: (1) for inventions contrary to *ordre public* or morality (including inventions dangerous to human, animal or plant life or health or seriously

²⁷ DOHA Declaration on TRIPS and Public Health, available at: www.who.int/medicines/areas/policy/doha_declaration/en/.

prejudicial to the environment); (2) for diagnostic, therapeutic, surgical methods for the treatment of human beings and animals; and (3) for plants and animals other than micro-organisms and biological processes for the production of plants or animals other than non-biological and microbiological processes. It follows that marine micro-organisms are patentable under TRIPS and in fact cannot be excluded from patenting.

Tymowski and Moore note that the European Patent Convention permits exclusion of plant varieties from patentability and European States exclude these accordingly, in contrast to the US, Australia and Japan where plant varieties can be patented.²⁸ Within the TRIPS system, plants are protectable either by patents or by a special system such as the Breeders' Right under the UPOV Convention.²⁹ As pointed out in the Gold and Joly study:³⁰

[as] for plants, a system for the protection of plant varieties “[meaning] a plant grouping within a single botanical taxon of the lowest known rank [...]”,³¹ has to be implemented by member countries.³² However, the term “plant”, as opposed to the expression “plant varieties” probably refers to a grouping larger than a “single botanical taxon”. Therefore, it seems as though member countries may exclude groupings larger than a “single botanical taxon” from patentable subject matter.

Discoveries of substances occurring freely in nature cannot be patented. In contrast, biological material isolated from its natural environment through a technical process, as well as the process itself, can be patented. However, in many States discoveries of substances that already existed in nature are being patented.³³ Another difference is that while in Europe patent protection permits experimentation with the patented material even for commercial purposes, US patent law restricts the use of protected material for further research

²⁸ Convention on the Grant of European Patents, 13 I.L.M. 268 (1974) (amended by Decision of the Administration Council of the European Patent Organization of 21 December 1978).

²⁹ International Convention for the Protection of New Varieties of Plants, done in Brussels, 2 December 1961, in force 10 August 1968, 15 UNTS 89.

³⁰ R Gold and Y Joly, 'The Patent System and Research Freedom: A Comparative Study', prepared for The World Intellectual Property Organization, submitted 2 August 2010, Annex VI, SCP/15/3/, 4. Available at: http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex6.pdf.

³¹ Article 1(iii) UPOV.

³² Article 27(3)(b) TRIPS.

³³ WTO, Minutes of TRIPS Council Meeting held on 26–27 October 2010, IP/C/M/64, 17 February 2011 (2011) 5. Available at: http://www.wto.org/english/tratop_e/trips_e/intel6_e.htm.

and variation, hence it offers the exclusive rights attached to the use and exploitation of the patented material in its entirety for a limited period.

Zewers observes that a particular challenge to the patentability of marine genetic resources lies in basic taxonomy. To meet patentability requirements, the inventor must disclose the invention fully, so that others reading the patent document will have enough information to reproduce the invention. This may entail, for instance, giving the full botanical name of plants used in the claimed invention, or references to deposits of micro-organisms in recognized international collections. However, because some recently discovered marine genetic resources have unique properties and their taxonomy has not been settled, establishing a sufficiently precise reference in a patent document can be problematic.³⁴

Furthermore, Zewers points out that much international debate surrounds the patentability of whole or partial strands of DNA and RNA. Different States have taken very different approaches to this matter. The US, for example, has generally permitted patentability of genetic sequences, provided a specific utility is disclosed (merely identifying the existence of a sequence is not enough, for instance). But US case law (e.g., the *In re Fisher* decision,³⁵ which held that genetic markers, known as 'expressed sequence tags', lack substantial and specific utility unless the underlying gene function is identified), and legislative action, such as the bill presented in the US Congress in February 2007 to prohibit the patenting of human genetic material, suggest a trend towards more restrictive patentability standards for whole or partial strands of DNA and RNA.³⁶

Disclosure Requirement

When applying for patent protection, the applicant has to disclose the invention in a manner sufficiently clear and complete for the invention to be reproduced by a person skilled in the art. The applicant may also be required to indicate the best mode for carrying out the invention known to the inventor at the filing date, or, where priority is claimed, at the priority date of the application.³⁷ At present, this is the disclosure requirement in TRIPS, but

³⁴ KE Zewers, 'Debated Heroes from the Deep Sea' (2008) *WIPO Magazine*, available at: http://www.wipo.int/wipo_magazine/en/2008/02/article_0008.html; KE Zewers, 'Bright Future for Marine Genetic Resources, Bleak Future for Settlement of Ownership Rights: Reflections on the United Nations Law of the Sea Consultative Process on the Access to Marine Genetic Resources' (2008) 5 *Loyola University Chicago International Law Review* 164.

³⁵ *In re Dane K. Fisher et al.*, No. 04-1465. In *Federal Circuit*, 7 September 2005.

³⁶ Zewers, *supra* note 34, p. 162.

³⁷ Article 29 TRIPS.

discussions are ongoing to introduce disclosure of origin of genetic resources and associated knowledge as well. If patent applications were required to include disclosure of origin, this requirement could possibly also be made applicable to the Area or ABNJ as area of origin.

According to the Budapest Treaty, Contracting Parties recognize a deposit made in the specified culture collections, or 'International Depository Authorities' (IDAs), as adequate for the purposes of their patent procedure.³⁸ In order to designate a culture collection to an IDA, the Contracting Party must assure that the IDA will comply with the Budapest Treaty's requirements, including that the IDA will be available to other depositors on equal terms, accept and store deposited micro-organisms for the period specified in the Budapest Treaty, and provide samples only to those entitled to them.³⁹ The Budapest Treaty contains procedures governing the behaviour of depositors and IDAs, the duration of micro-organism storage and the mechanism for providing samples. Accordingly, samples are to be furnished at any time to the depositor, a person having the depositor's written authorization, and any industrial property office. Provisions guarding against the loss of deposited micro-organisms stipulate that the IDA must have the necessary expertise and facilities to keep micro-organisms viable and uncontaminated during the prescribed storage period.⁴⁰ In addition, exceptions to patent rights⁴¹ and compulsory licenses⁴² might serve as mechanisms that provide access and benefit-sharing and as such curb the patent holder's otherwise exclusive right over the invention within the period of protection.

Discussions have been ongoing for several years within the TRIPS Council regarding a possible amendment of TRIPS to introduce a mandatory requirement for disclosure of origin of genetic resources and associated knowledge in patent applications, in order to harmonize it with the principles of the CBD.⁴³ The issue has been on the TRIPS Council's agenda for an inordinately long time without tangible results.⁴⁴ Several States argue that the CBD principles

³⁸ Article 3(1) Budapest Treaty.

³⁹ Articles 7 and 6(2) Budapest Treaty.

⁴⁰ Rules 6, 2, 9 and 11 Budapest Treaty Regulations.

⁴¹ Article 30 TRIPS.

⁴² Article 31 TRIPS.

⁴³ M Vierros, G Hamon, D Leary, S Arico and C Monagle, 'An Update on Marine Genetic Resources: Scientific Research, Commercial uses and a Database on Marine Prospecting', report to side event at UNICPOLOS-8 held on 25–29 June 2007, supported by UNU-IAS University and UNESCO (2007) 39. Available at: http://www.ias.unu.edu/resource_centre/Marine%20Genetic%20Resources%20UNU-IAS%20Report.pdf. See also footnotes about positions below.

⁴⁴ WTO, *supra* note 33, p. 13, para. 35.

could be satisfied without amending TRIPS, and that the current proposal of incorporating mandatory disclosure requirements in TRIPS is too narrow and restrictive. It has also been argued that the WTO and its binding dispute settlement system are not the right fora to explore various avenues to reach the common goal of promoting benefit-sharing.⁴⁵ The EU supports amending TRIPS to introduce the disclosure requirement, provided it is properly calibrated. In this case, it would positively contribute to the mutual supportiveness between patent systems and access and benefit-sharing regimes, and would generate more effective access and benefit-sharing regimes, thus creating a win-win situation for both providers and accessors.⁴⁶

Within the forum of the WIPO IGC⁴⁷ the discussions on intellectual property and genetic resources are also still ongoing. In March 2011 experts discussed options on the basis of three clusters: defensive protection; disclosure requirements; and options for mutually agreed terms. In the May 2011 session of the IGC, Members clashed over disclosure once again. The African Group and Brazil made clear that they want an exclusive focus on mandatory disclosure first. Without a strong proposal on mandatory disclosure they are not willing to discuss either of the other two clusters. Moreover, disagreement over the role of the CBD Nagoya Protocol⁴⁸ affected the latest WIPO negotiations. While developing States expressed the hope that the agreement on the Nagoya Protocol would speed up talks at WIPO (in particular on issues such as definitions and scope), a number of developed States object to any direct reference to the Nagoya Protocol in favour of a more narrow substantive scope at WIPO. This is particularly true for the definition of genetic resources, which lies at the heart of the misappropriation discussion.

In the end, the IGC developed a draft text on objectives and principles for the relationship between intellectual property and genetic resources. This is complemented by certain options for future work, including a proposed mandatory disclosure requirement and intellectual property clauses in mutually

⁴⁵ *Ibid.*, p. 7, para. 17.

⁴⁶ *Ibid.*, p. 16, para. 47.

⁴⁷ IGC means the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. The IGC was established by the WIPO General Assembly in October 2000. One of its three primary themes is the access to genetic resources and benefit-sharing. Source: WIPO, Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. Twenty-Sixth (12th Extraordinary) Session, Geneva, WO/GA/26/6, 25 August 2000 (2000) 5–6. Available at: http://www.wipo.int/edocs/mdocs/govbody/en/wo_ga_26/wo_ga_26_6.pdf.

⁴⁸ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, done in Nagoya, 29 October 2010, not yet in force. Available at: <http://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf>.

agreed terms for access and equitable benefit-sharing.⁴⁹ In July 2011 the IGC will meet one last time before the WIPO's annual General Assembly in September 2011, which will then decide on convening a diplomatic conference. It remains to be decided whether any instrument(s) produced would be in the form of legally binding agreements or simple declarations, although most States favour the former option.⁵⁰

Intellectual Property Rights and the FAO Treaty

Introduction

The FAO Treaty created a MLS where commercial use, such as patenting, has particular standing. Article 12.3(d) of the FAO Treaty states that:

Recipient (from the Multilateral System) shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System.

Tymowski and Moore note that this provision on IPRs was one of the most controversial points in the negotiation of the FAO Treaty. This provision serves to ensure the free and equal accessibility and use of genetic material from the MLS. No IPRs can be taken out over products derived from the material if the effect of those IPRs is to limit access to the original material, or their genes or any parts thereof, in the form received.⁵¹

In the case that the recipient conserves the material supplied, the recipient shall make the material and the related information available to the MLS. Recipients can choose between freely sharing any new products with others for further research, or, if they want to keep these products to themselves by taking out patent rights, to pay a percentage of any commercial benefit derived from their research into a common fund. Under the SMTA, companies that develop a commercial product using material provided pursuant to the SMTA are required to pay to the Fund Strategy of the MLS either 1.1% of the sales of the product, or products less 30%, or alternatively 0.5% of the sales of any products and of the sales of any other products that are plant genetic resources

⁴⁹ WIPO, IGC 19 Update: WIPO negotiators refine texts on traditional knowledge, genetic resources and traditional cultural expressions. Update 13 May 2011. Available at: http://www.wipo.int/tk/en/news/2011/news_0011.html, last visited 17 May 2011.

⁵⁰ International Centre for Trade and Sustainable Development, 'Disclosure of Origin: Source of Contention in WIPO Negotiations' (2011) 11(9) *Bridges Trade BioRes* 1–3.

⁵¹ Moore and Tymowski, *supra* note 10, p. 93.

for food and agriculture belonging to the same crop.⁵² These funds are used for the benefit-sharing mechanisms of building capacity, for access to and transfer of technology, for information sharing, and for projects directly benefiting the small-scale farmers who maintain a substantial part of the global plant genetic resources.

The FAO Treaty illustrates that the international community has been able to develop a functional MLS for handling plant genetic resources in the public domain. As such it may provide promising avenues for dealing with marine genetic resources in ABNJ.

Assessment in Relation to TRIPS

With regard to accessed material that is not modified in any way, no conflict arises between the FAO Treaty and TRIPS, because the latter grants patents only to ‘novel’ inventions, a requirement not fulfilled by unmodified material. However, if the material has gone through subsequent modification/improvement by the recipient and this latter commercializes it, an obligation of sharing the monetary and other benefits will be imposed on the recipient: Article 13.d(ii) of the FAO Treaty provides that a recipient:

“who commercializes a product that is a plant genetic resource for food and agriculture and that incorporates material accessed from the Multilateral System, shall pay...” “an equitable share of the benefits arising from the commercialization of that product, except whenever such a product is available without restriction to others for further research and breeding, in which case the recipient shall be encouraged to make such payment”.

TRIPS lays down the common grounds for intellectual property protection, the requirements for national treatment (foreigners should be treated as nationals), respect of most-favoured nation principle (treatment offered to one State should be offered to others as well), the requirements for effective protection of IPRs and dispute settlement procedures.

The MLS designed for the FAO Treaty stands for “open access” for the Contracting Parties and makes sure that the genetic material obtained from the MLS may not, without any modification, be patented and hence excluded from access by others. Exclusive exploitation that the patent secures is only allowed if the genetic material to be patented has been obtained through some form of transformation, modification, or incorporation and the product of one or more of these processes can be patented. Even then, because the genetic material was originally obtained from an openly accessible pool, the benefits

⁵² Annexes 2 and 3 SMTA.

of commercialisation and patent protection must be shared with the MLS in an equitable manner, following the ratio laid down in the FAO Treaty.

As pointed out by Gerstetter *et al.*, in cases where potential conflict might arise between the duties under FAO Treaty and the rights under TRIPS, it should be kept in mind that this would not be a conflict between the treaties themselves, but that it would arise from the way in which some States have implemented TRIPS. As mentioned before, TRIPS prescribes a minimum standard of protection for IPRs, and as such TRIPS can be considered as (only) providing a framework for measures taken at the national level. Accordingly, Article 1 of TRIPS allows States great leeway to actually implement TRIPS and design intellectual property regimes within their jurisdiction.⁵³ For example, whether it is legally possible to patent individual genes, certain substances extracted from patent genetic resources or even characteristics of the material and plant varieties differs from State to State.⁵⁴

Intellectual Property Rights in ABNJ

Access and Benefit-Sharing

Both products and processes may be patented, which means that not only the invention but also the process (for example the steps used to isolate a micro-organism from ABNJ) could be patented. Leary points out that granting a patent is the sovereign act of a State. Thus, when it comes to marine genetic resources, the fact that the genetic resources were gained in ABNJ is irrelevant: in seeking the patent, the invention will have to fulfil the patent law requirements for patentability in the jurisdiction where patent protection is sought. The rights of the patent holder will be determined by the patent law of the State in which the patent was granted. The patent law of the State will have to be in line with international intellectual property treaties, such as TRIPS, for example, and as has been seen above, TRIPS is a framework treaty setting minimum standards, and permits discretion by WTO Members to implement the treaty and design their intellectual property regime to fit their own individual public policy considerations.

⁵³ Article 1 TRIPS: “Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.”

⁵⁴ C Gerstetter, B Görlach, K Neuman and D Schaffrin, ‘The FAO Treaty within the Current Legal Regime Complex on Plant Genetic Resources’ (2007) 10(3/4) *Journal of World Intellectual Property* 271.

Leary explains that IPRs are economic incentives for commercially oriented bioprospecting, inasmuch as they offer exclusive commercial use of patented marine genetic resources. He suggests that States may use as a policy choice the granting of a patent conditional on the contribution to a global trust fund, and as a policy consideration it indeed lies with their sovereignty. Again, although the micro-organism was found in ABNJ, the granting of patent is a sovereign act by the state where its own laws apply.⁵⁵

Marine Scientific Research and Non-Appropriation

Articles 256 and 257 of the LOSC emphasize the freedom of access for all States to conduct marine scientific research in the Area and in the water column beyond the limits of the EEZ. The provisions of Part XIII of LOSC on marine scientific research make no reference to IPRs over data, samples and results derived from marine scientific research. Any rights to these data, samples and results under the LOSC must be assessed in light of international treaties dealing with IPRs to which Parties to LOSC may be Parties and *vice-versa*.

Article 241 of the LOSC is especially crucial with respect to the non-appropriation provisions of the LOSC. It provides: “Marine scientific research activities shall not constitute the legal basis for any claim to any part of the marine environment or its resources.”

This provision relates to the non-recognition of marine scientific research activities as a legal basis for claims in general terms. The problem here is that patent rights do offer exclusive rights of use and exploitation for the period of protection which seems to go counter to what Article 241 requires, in general terms, for the furtherance of marine scientific research. While patent rights will not limit access to the Area, “access to the invention/resource”⁵⁶ might be restricted to the inventor/patent holder. Solutions to this might include exemptions from patent rights for the purpose of further experimental use and research as well as exemptions in the form of compulsory licenses provided.⁵⁷

The main question in this context is what activities fall under marine scientific research, given the fact that the LOSC lacks a definition of marine scientific research. One aspect of that question relates to the type of activities that fall under such research. Another aspect relates to the different phases of marine scientific research. For example, if samples are taken in the context of marine scientific research, at what point does further research on those samples cease to be part of that specific marine scientific research?

⁵⁵ DK Leary, *International Law and the Genetic Resources of the Deep Sea* (Nijhoff, Leiden, 2007) at 178.

⁵⁶ Salpin and Germani, *supra* note 23, p. 21.

⁵⁷ *Ibid.*, pp. 20–22.

Another non-appropriation provision of the LOSC is included in its Article 137(1):

No State shall claim or exercise sovereignty or sovereign rights over any part of the Area or its resources, nor shall any State or natural or juridical person appropriate any part thereof. No such claim or exercise of sovereignty or sovereign rights nor such appropriation shall be recognized.

The question here is whether this excludes patentability of genetic resources sampled from this area. For a patent to be granted according to the requirements in national jurisdictions and TRIPS, the invention will have to be novel, thus resources found in nature by themselves cannot be patented, they will have to include an innovative step. However, mere isolation and characterization of a resource may often be considered an invention if sufficient inventive ingenuity is exercised. Conflict between the prohibition laid down in Article 137 of the LOSC and commercial interest in bioprospecting and/or marine scientific research may arise if it is the material itself that will be made exclusive, but this is less likely to occur if exclusivity is granted for the invention that is based on the material with the added inventive element.

The Applicable Regime

A final point of interest is the discussion on the regime applicable to marine genetic resources in ABNJ (common heritage of humankind or freedom of the high seas). It is expected that the rights of a patent holder will not be affected by the lack of clarity on the applicable legal regime, because the applicable law for obtaining the patent will be the jurisdiction where patent application was submitted and patent granted. However, it seems that developing States, given their persistent position demanding the application of the common heritage of mankind principle, will not accord IPRs to products derived from marine genetic resources originating from ABNJ, in the absence of a benefit-sharing scheme.

Finally, it might be noteworthy that Parties to the LOSC include 120 Members of the WTO (out of 153 Members). This means that the discussions will definitely overlap and the Parties to the LOSC will consider their WTO rights and obligations, and *vice-versa*.

Concluding Remarks

Which factors have to be taken into account concerning the IPRs on marine genetic resources in ABNJ?

1. Marine micro-organisms are patentable under TRIPS.
2. To minimise barriers to trade, TRIPS sets minimum standards for Member States in their implementation of patent law, but patent law is still a matter for national jurisdiction. The patent holder, therefore, can only enforce its rights to exclusive use in the jurisdiction where the patent has been registered.
3. Granting a patent is the sovereign act of a state. The fact that the marine genetic resources were obtained in ABNJ is irrelevant.
4. Both products and processes can be patented. This might be important for sampling from ABNJ where not only the invention but also the process could be patented.
5. The TRIPS Council is discussing the possible amendment of TRIPS to include a disclosure of origin requirement.
6. A particular challenge to the patentability of marine genetic resources lies in basic taxonomy. To meet patentability requirements, the inventor must disclose the invention fully, so that others reading the patent document will have enough information to reproduce the invention. However, because some recently discovered marine genetic resources have unique properties and their taxonomy has not been settled, establishing a sufficiently precise reference in a patent document can be problematic.
7. Patent rights do offer exclusive rights of use and exploitation for the period of protection, but Article 241 of the LOSC provides that marine scientific research activities shall not constitute the legal basis for any claim to any part of the marine environment or its resources.
8. It is not expected that conflicts will arise between the FAO Treaty and TRIPS, but they possibly may arise from the way in which some States implement TRIPS.
9. The Budapest Treaty provides an access and storage regime, i.e., by designating IDAs. Furthermore, the Budapest Treaty establishes procedures governing the behaviour of depositors and IDAs, the duration of micro-organism storage and the mechanism for providing samples.
10. Parties to the LOSC include 120 Members of the WTO (out of 153 Members). This means that discussions on the characterization of ABNJ will overlap and the Parties to the LOSC will be aware of their WTO rights and obligations, and *vice-versa*.

In conclusion, when establishing a MLS on access to and benefit-sharing for marine genetic resources, no contradiction with TRIPS is expected. However, three deficiencies can be identified regarding IPR instruments and traditional

systems of protection of intellectual property in relation to marine genetic resources in ABNJ:

- they may be inadequate with regard to inventions stemming from biological resources, which are of common public interest;
- they lack a clear definition of what can be considered as micro-organisms or resources suitable for patentability; and
- the current design of patent classification systems and databases does not permit clearly tracking and identifying marine micro-organisms.⁵⁸

Regime Applicable to Marine Genetic Resources in ABNJ⁵⁹

Introduction

The current international debate on ABNJ indicates that States have different views on the legal regime applicable to marine genetic resources in ABNJ. On the one hand, the view has been expressed that these resources fall under the regime of freedom of the high seas,⁶⁰ which is contained in Part VII of the LOSC. On the other hand, it has been argued that these resources fall under the common heritage regime contained in Part XI of the LOSC.⁶¹ A choice in this respect would have far-reaching implications for the elaboration of a specific regime for marine genetic resources. If no choice is made in this connection, such a specific regime should accommodate the diverging views on the relevance of Parts VII and XI of the LOSC. It should be noted that the LOSC does not employ the term ‘marine genetic resources’. Marine genetic resources

⁵⁸ S Arico and C Salpin, *Bioprospecting of Genetic Resources in the Deep Seabed: Scientific Legal and Policy Aspects*, UNU-IAS Report (2005) at 56–57. Available at: <http://www.ias.unu.edu/binaries2/DeepSeabed.pdf>.

⁵⁹ The subsections on ‘Marine genetic resources of the seabed and subsoil in ABNJ’ and ‘Delineating the water column and the seabed of ABNJ’ of this section draw on an article by Alex G. Oude Elferink, A.G. Oude Elferink, “The Regime of the Area: Delineating the Scope of the Application of the Common Heritage Principle and Freedom of the High Seas” 2007(22) *International Journal of Marine and Coastal Law* 143–176. The relevant sections of the article have been adapted by Alex G. Oude Elferink in connection with their inclusion in this report. In particular, most footnotes included in the article have either been edited or omitted.

⁶⁰ See, e.g., Letter dated 16 March 2010 from the Co-Chairpersons of the *Ad Hoc* Open-ended Informal Working Group to the President of the General Assembly (A/65/68 of 17 March 2010), para. 72. Available at: <http://daccess-dds-ny.un.org/doc/UNDOC/GEN/N10/277/20/PDF/N1027720.pdf?OpenElement>.

⁶¹ *Ibid.*, para. 72.

are subsumed in the term 'living resources' which is employed by the LOSC. Both terms are used in this section.

The next two subsections of this section deal, respectively, with the regime of marine genetic resources of the water column of ABNJ and the regime of marine genetic resources of the seabed and subsoil of ABNJ. If the regime of the Area is applicable to living resources of the seabed of ABNJ, the legal regime applicable to marine genetic resources in the water column and the seabed differs. The regime of the living resources of the water column of ABNJ is governed by the regime of the high seas contained in Part VII of the LOSC.⁶² This possible distinction also requires briefly examining the limit between the seabed and the water column, as that limit would determine the exact extent of the spatial scope of application of each regime. This latter issue is considered in the fourth subsection, and the final subsection contains a number of concluding remarks.

Marine Genetic Resources of the Water Column of ABNJ

The debate in the *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) on the regime applicable to marine genetic resources focuses on marine genetic resources of the seabed of ABNJ, that is, the Area. There are two reasons to also briefly consider the water column of ABNJ. First, the reports on the meetings of the BBNJ Working Group at times are somewhat ambiguous in this respect. For instance, it is reported in respect of the 2010 BBNJ Working Group that:

Several delegations expressed the view that an implementing agreement on marine biodiversity beyond areas of national jurisdiction to the Convention should address marine genetic resources, and recognize the applicability of the concept of common heritage of mankind in this respect.⁶³

This statement in arguing the relevance of the common heritage concept refers to ABNJ in general and is not limited to the Area.

⁶² It should be noted that the water column of the ABNJ in part overlaps with the continental shelf beyond 200 nautical miles of coastal States. The coastal State exercises sovereign rights over the sedentary species of its continental shelf. Sedentary species are defined as organisms which, at the harvestable stage, either are immobile on or under the seabed or are unable to move except in constant physical contact with the seabed or the subsoil (Article 77 LOSC). These organisms as a consequence do not fall under the regime of the high seas. The concept of sedentary species has not been employed in the context of the regime of the Area.

⁶³ Co-Chairpersons' Letter, *supra* note 60, para. 75.

A second reason to also briefly consider the water column of ABNJ is that views may differ on how to distinguish between the water column and the seabed in ABNJ. This latter issue is briefly considered in the subsection ‘Delimiting the Water Column and the Seabed of ABNJ’ of this section.

The common heritage regime contained in Part XI of the LOSC is applicable to the Area. Article 134(1) on the scope of Part XI reads: “This Part applies to the Area.” Article 1 of the LOSC provides that the “Area” means the seabed and ocean floor and subsoil thereof, beyond the limits of national jurisdiction. Part XI of the LOSC is thus not applicable to the water column of ABNJ. Instead, the basic provisions of that regime are contained in Part VII of the LOSC dealing with the high seas. Article 87 provides that the high seas are open to all States and contains a non-exhaustive list of high seas freedoms. This list thus also allows States to carry out activities related to marine genetic resources of the water column of ABNJ as a high seas freedom in accordance with Part VII of the LOSC. As set out in the following subsection, the regime of the high seas does not necessarily apply to the seabed of ABNJ. In that case, the implications of the applicability of Part XI to the seabed of ABNJ have to be taken into consideration.

Marine Genetic Resources of the Seabed and Subsoil of ABNJ

The Scope of Application of Part XI of the LOSC

Part XI of the LOSC is to a large extent focused on the mineral resources of the Area. Part XI is replete with references to those resources. It has been suggested that the use of other resources in the Area falls under the freedom of the high seas and are excluded from the scope of application of Part XI.⁶⁴

The absence of a regime in Part XI specifically addressing other resources of the Area does not dispose of the question whether or not those resources are part of the Area. Article 136 of the LOSC provides that the “Area and its [mineral] resources are the common heritage of mankind”.⁶⁵ Article 136 makes the common heritage principle not only applicable to the mineral

⁶⁴ See, e.g., J Beurier and C Noiville, ‘La Convention sur le Droit de la Mer et la Diversité Biologique’ in *International Colloquy in Tribute to the Memory of Cyrille de Klemm* (Council of Europe, Paris, 2001) 112; WT Burke, ‘State Practice, New Ocean Uses, and Ocean Governance under UNCLOS’ in TA Mensah (ed.) *Oceans Governance: Strategies and Approaches for the 21st Century* (Law of the Sea Institute, Honolulu, 1996) 231; RR Churchill and AV Lowe, *The Law of the Sea* (Third Edition, Manchester University Press, Manchester, 1999) at 239 and fn. 49; MH Nordquist, *United Nations Convention on the Law of the Sea 1982: A Commentary* Vol. III (Martinus Nijhoff Publishers, Dordrecht, 1995) at 29.

⁶⁵ It should be noted that Article 133 of the LOSC provides that for the purposes of Part XI the term “resources” means mineral resources. References to “resources” in Part XI thus do not include the living resources of the Area.

resources of the Area, but also to the Area as such. To establish the consequences of Article 136 and the other principles governing the Area contained in Section 2 of Part XI, it has to be established what the “Area” comprises.

Article 1 of the LOSC provides that the “Area” means the seabed and ocean floor and subsoil thereof, beyond the limits of national jurisdiction. The terms “seabed”, “ocean floor” and “subsoil” are not defined in the LOSC. The principal rule of treaty interpretation is that a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.⁶⁶ In principle, the ordinary meaning of the terms “seabed”, “ocean floor” and “subsoil” comprises the living and non-living resources that are found in those areas. These are general terms that have a specific spatial application, which does not exclude certain natural components from that spatial scope of application. The same applies for all other maritime zones. All resources located in a zone form part of that zone. For the Area, this is explicitly confirmed by the reference to “the natural resources of the Area” in Article 145(b) of the LOSC. This indicates that the natural resources of the seabed and subsoil of the deep sea are not excluded from the spatial definition of the Area. Of course, the location of resources in a zone does not of itself determine the applicable legal regime.

The principal argument for excluding living resources from the regime of Part XI seems to be Article 133 of Part XI on use of terms. That Article provides that “[f]or the purposes of this Part ‘resources’ means all solid, liquid or gaseous mineral resources *in situ* in the Area at or beneath the seabed, including polymetallic nodules”. The view exists that this definition implies that living resources of the Area are excluded from the common heritage regime of Part XI. For instance, Allen submits that the *expressio unius est exclusio alterius* (the expression of one thing is the exclusion of another) canon of construction supports the conclusion that Article 133 excludes resources other than mineral resources. Allen concludes that no living marine resources thus fall within the common heritage regime established by Part XI.⁶⁷ However, Article 133 does not provide an exhaustive definition of the term “resources” for the purposes of Part XI, but stipulates that one specific category of resources, that is, mineral resources present in the Area, for the purposes of Part XI will be referred to as “resources”. Moreover, Article 133 does not provide that Part XI is only applicable to mineral resources. In that case the *expressio unius est*

⁶⁶ Article 31(1) of the Vienna Convention on the Law of Treaties of 23 May 1969 (1155 UNTS 331).

⁶⁷ CH Allen, ‘Protecting the Oceanic Gardens of Eden: International Law Issues in Deep-Sea Vent Resource Conservation and Management’ (2001) 13 *Georgetown International Environmental Law Review* 630.

exclusio alterius principle would have been applicable. Furthermore, Article 133 as it is worded does not exclude living resources or other non-mineral resources from the scope of application of Part XI. As the terms “living resources” or “non-mineral resources” are not defined for the purposes of Part XI it should be presumed that the meaning that is normally given to those terms also is applicable for the purposes of Part XI.

The drafting history of Part XI includes references to both living and mineral resources.⁶⁸ The drafting history does not suggest that agreement existed that the living resources of the Area would be excluded from the scope of application of Part XI of the LOSC. As far as can be ascertained, there does not seem to have been any discussion of the living resources of the Area in the Second Committee of the Conference, which dealt with the regime of the high seas.

The focus on mineral resources in the negotiations concerning Part XI is explained by the fact that at the time of the Third Conference only the mineral resources of the Area, in particular polymetallic nodules, were considered to be of economic interest and required the elaboration of a detailed regulatory regime.

When the 1994 Agreement,⁶⁹ which revises the mining regime of Part XI, was negotiated, the value of genetic resources of organisms of the deep seabed had been recognized. It has been observed that it is particularly interesting that during the negotiations of the 1994 Agreement no one proposed to broaden the definition of resources in Article 133 to include living resources.⁷⁰ That observation warrants some comment. The negotiations leading up to the 1994 Agreement intended to address the aspects of the mining regime contained in the LOSC's Part XI that prevented universal participation in the Convention. That purpose would not have been served by including other controversial issues on the agenda.

Another argument to exclude the living resources of the Area from the scope of application of Part XI could be the subsequent practice of the States Parties to the LOSC. Article 31(3)(b) of the Vienna Convention on the Law

⁶⁸ According to Article 32 of the Vienna Convention on the Law of Treaties, recourse to the preparatory work of a treaty may be had if the meaning resulting from the principal rule of treaty interpretation leaves the meaning ambiguous or obscure or leads to a result which is manifestly absurd or unreasonable.

⁶⁹ Agreement relating to the implementation of Part XI of the United Nations Convention on the Law of the Sea of 10 December 1982 of 28 July 1994 (in force 28 July 1996; 1836 UNTS 42).

⁷⁰ MF Hayes, 'Charismatic Microfauna: Marine Genetic Resources and the Law of the Sea' in MH Nordquist, R Long, TH Heidar and JN Moore (eds.) *Law, Science & Ocean Management* (Nijhoff, Leiden, 2007) at 688–689.

of Treaties provides that any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation shall be taken into account in its interpretation. There is practice in respect of the living resources of the Area that suggests that it is considered that they can be exploited in accordance with Part VII of the LOSC. This concerns the regulation of certain sedentary fish stocks in the framework of regional fisheries management organizations and arrangements. However, the fact that this practice is limited in extent suggests that it does not establish the agreement of the Parties regarding the interpretation of the LOSC. From recent debates on the law of the sea in, *inter alia*, the framework of the General Assembly, it is clear that States Parties to the LOSC disagree over the interpretation of the LOSC on this point.

The exclusion of living resources from the regime contained in Part XI of the LOSC could lead to a curious result as far as marine scientific research is concerned. Part XIII of the LOSC distinguishes between the Area and the superjacent water column.⁷¹ If Articles 87, 256 and 257 are read together, it is clear that the freedom of scientific research in accordance with Article 87 is only applicable to the water column. The regime for marine scientific research in the water column does not include the Area. Marine scientific research in the Area has to be conducted in conformity with Part XI. If the regime for marine scientific research contained in Part XI were not to apply to the living resources of the Area, those resources would be wholly excluded from the regime for marine scientific research established by the LOSC.

The Implications of the Scope of Application of Part XI of the LOSC

If the living resources of the Area were covered by the regime contained in Part XI of the LOSC, the follow-up question is what consequences this has for the use of those resources. Section 2 of Part XI on principles governing the Area contains a number of provisions which are potentially relevant in this respect. Article 136 declares that the Area is the common heritage of mankind. If the living resources of the Area were covered by the regime contained in Part XI, they would constitute part of the common heritage of mankind. It could be argued that this inclusion implies that if these resources are exploited they have to be covered by a specific regime which does justice to their being a part of the common heritage of mankind. In the case of the mineral resources of the Area, their being the common heritage of mankind was the justification for the detailed regime of prospecting, exploration and exploitation contained in Section 3 of Part XI of and Annex III to the LOSC and the 1994 Agreement.

⁷¹ Respectively, Articles 256 and 257.

Article 137(1) of the LOSC may also be relevant for the status of living resources found in the Area if they were to fall under the regime of Part XI of the LOSC. This Article reads:

No State shall claim or exercise sovereignty or sovereign rights over any part of the Area or its resources, nor shall any State or natural or juridical person appropriate any part thereof. No such claim or exercise of sovereignty or sovereign rights nor such appropriation shall be recognized.

If the living resources of the Area fall under the regime of Part XI, the prohibition on appropriation would also be applicable. This prohibition in this case would seem to extend to the exploitation of the living resources of the Area, unless there is a specific regulatory regime in place, which should in this case be developed in accordance with the principles governing the Area contained in Section 2 of Part XI.

It should be noted that there is an exception to the prohibition on appropriation of the living resources of the Area. The LOSC states that States have the right to conduct marine scientific research in the Area in conformity with the provisions of Part XI.⁷² The right to conduct marine scientific research includes the right to gather samples of living resources. Another question in respect of Article 137(1) is whether the prohibition on appropriation implies that it is prohibited to acquire a patent in relation to genetic resources derived from living resources of the Area. Different answers to this question seem to be possible. It could be argued that such a patent does not imply an appropriation of the resource as such. On the other hand, it could be argued that this constitutes an appropriation because a specific application of a resource is removed from the common heritage of mankind.

Article 143 on marine scientific research in the Area may also be relevant to considering the regime applicable to living resources of the Area. Article 143(1) provides that marine scientific research in the Area shall be carried out for the benefit of mankind as a whole. The implications of this requirement are not clear. It could be argued that this requirement is fully elaborated in paragraphs 2 and 3 of Article 143. These provisions set out the rights and obligations of, respectively, the Authority and States Parties in carrying out marine scientific research in the Area. However, it could also be argued that if there are financial and other benefits derived (indirectly) from marine scientific research, there should be an equitable sharing of those benefits. Such equitable sharing

⁷² Article 256 of the LOSC.

of benefits is currently envisaged for the mineral resources of the Area,⁷³ which already are subject to a detailed regulatory regime.

Delineating the Water Column and the Seabed of ABNJ

As has been set out in the preceding subsections, there may be a difference between the regime applicable to living resources in the water column, and to those of the seabed in ABNJ. As will appear from the present subsection, the distinction between these two areas is less straightforward than might appear at first glance.

Article 1 of the LOSC states that the “Area” means the seabed and ocean floor and subsoil thereof, beyond the limits of national jurisdiction. The terms “seabed”, “ocean floor” and “subsoil” are not defined in the LOSC. The meaning of the term seabed is particularly relevant to define the limit of the Area in relation to the superjacent water column. Does the seabed only refer to solid materials that make up the bed of the sea, or does it also include solids, water or other liquids or gasses in contact with those materials? For instance, are the waters, flowing from a hydrothermal vent and the materials it contains, part of the Area or the superjacent water column? Another example is provided by so-called brine pools, which are small lakes on the seafloor with a distinct surface and shoreline. These pools are bodies of water that have a salinity three to five times greater than the surrounding ocean, such that the dense brine does not easily mix with overlying seawater. Are these pools part of the Area or the water column?

A number of Articles of the LOSC seem to suggest that a distinction is made between the seabed, and all the waters and materials contained in them above the seabed. Article 135 of the LOSC states that Part XI shall not affect the legal status of the waters superjacent to the Area. Articles 256 and 257 distinguish between marine scientific research in the Area and in the water column beyond the exclusive economic zone. However, these Articles do not define the Area and the superjacent waters, but only indicate that different rules apply to the two. These Articles also do not establish a precedence of the water column over the seabed in connection with the establishment of the exact limit between the two.

Two criteria would seem to be relevant for establishing whether features are part of the seabed or the superjacent waters. One is their location in relation to the seabed, the other whether or not they can be clearly distinguished from

⁷³ Article 140(2) of the LOSC.

the surrounding waters. For instance, water flowing from a hydrothermal vent that is an integral part of that hydrothermal vent system and that can be clearly distinguished from the surrounding waters because of its chemical and physical characteristics would seem to be part of the Area and as such would not form part of the waters superjacent to the Area.⁷⁴ A brine pool at the seabed could also be considered to be part of the Area. The waters of the pool are different in composition from the waters that overlay them and the pool's shape is the result of the morphology of the surrounding seabed.

Article 133 of the LOSC supports the conclusion that the definition of the upper limit of the Area should not be based on a restrictive interpretation of the term "seabed". Article 133 of the LOSC refers to *all* solid, liquid or gaseous mineral resources "in the Area *at* or beneath the seabed".⁷⁵ This definition indicates that the Area may not be limited to the seabed *strictu sensu*, but that it may include certain areas above the actual seabed. Article 133 indicates that this at least includes the areas in which the mineral resources "at the seabed" are located. Article 133 thus also may be cited in support of the conclusion that such features as hydrothermal vents and brine pools are part of the Area. They may contain mineral resources that are located at the seabed, hence the water of a hydrothermal vent and of a brine pool, if they contain mineral resources, could also fall under the term "mineral resource" as employed in Article 133 of the LOSC.⁷⁶

Concluding Remarks

To determine the regime applicable to living resources and marine genetic resources in ABNJ, it is necessary to look at Parts VII and XI of the LOSC dealing, respectively, with the high seas and the Area. The analysis of this section points to the following conclusions:

1. As is set out in the subsection on 'Marine genetic resources of the water column in ABNJ', the living resources in the water column of ABNJ fall under the regime of freedom of the high seas. These resources can be

⁷⁴ See also Burke, *supra* note 64, p. 231, where it is argued that the minerals that are in the hot water that is responsible for the term "smoker" (hydrothermal vent) are subject to Part XI of the LOSC.

⁷⁵ Emphasis provided.

⁷⁶ Under certain scientific definitions water is not considered to be a mineral as it is not a solid, but naturally occurring ice is classified as a mineral. Article 133 of the LOSC refers to "solid, liquid or gaseous mineral resources".

exploited in accordance with the regime contained in Part VII of the LOSC.

2. As is set out in the section on 'Marine genetic resources of the seabed and subsoil in ABNJ', views differ as to whether the living resources of or at the seabed of ABNJ are covered by the regime contained in Part VII of the LOSC or the regime contained in its Part XI. The arguments which have been advanced to support the view that these resources are covered by the regime contained in Part VII do not seem to be altogether convincing. If these resources fall under the regime of Part XI of the LOSC, the principles⁷⁷ governing the Area contained in Section 2 of Part XI are applicable to these resources. The implications of the applicability of these principles are not completely clear, however. It could be argued that these principles imply that the living resources of the Area may only be used in accordance with a regime which operationalizes the common heritage of mankind principle.
3. If different regimes apply to the water column and seabed of ABNJ it will be necessary to precisely delineate these two areas. As is set out in the section on 'Delineating the Water Column and the Seabed of ABNJ', there may be different views as to which features in the interface between these two areas form part of respectively the water column and the seabed.

The Convention on Biological Diversity

Access and Benefit-Sharing within the Framework of the CBD

Introduction

The CBD was adopted in 1992 and aims at: the conservation of biological diversity; the sustainable use of its components; and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources.⁷⁸ The latter objective is the leading topic of this section. The CBD-related provisions on access and intellectual property rights will also be further examined. The goal of this section is to explore the possibility of establishing a multilateral system on access and benefit-sharing for marine genetic resources in ABNJ within the framework of the CBD. Furthermore, the relation to the LOSC is assessed in the

⁷⁷ Such as the common heritage of mankind principle (Article 137 LOSC) and the benefit of mankind principle (Article 140 LOSC).

⁷⁸ Article 1 CBD.

subsection on ‘Assessment in Relation to the LOSC’, which mainly points at some difficulties related to definitions within both conventions.

Under Article 4(a), the jurisdictional scope of the CBD is limited to components of biological diversity within the limits of national jurisdiction. Genetic resources *per se* in ABNJ are therefore excluded from the CBD’s scope. However, according to Article 4(b) CBD, its provisions apply to:

processes and activities, regardless of where their effects occur, carried out under [a Party’s] jurisdiction or control, within the area of its national jurisdiction or beyond the limits of national jurisdiction.

It follows that activities undertaken in the high seas or the Area, including marine scientific research, bioprospecting, exploration and exploitation, fall within the scope of the CBD when these activities are under the control or jurisdiction of a CBD Party. With respect to these areas in ABNJ, in accordance with Article 5 CBD, Parties are required to cooperate directly, or through competent international organisations, for the conservation and sustainable use of biological diversity.⁷⁹

The Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization,⁸⁰ adopted by the CBD COP in April 2002, provide voluntary guidance and apply to all genetic resources covered by the CBD (without prejudice to the access and benefit-sharing provisions of the FAO Treaty and taking into account the relevant work of the WIPO).⁸¹ The Guidelines were prepared with a view to ensuring, *inter alia*, their flexibility in order “to be useful across a range of sectors, users and national circumstances and jurisdictions” (Article 7(g) CBD Bonn Guidelines). Furthermore, they recognize that “States and stakeholders may be both users and providers” (Article 16 CBD Bonn Guidelines) of genetic resources, and that:

Access and benefit-sharing systems should be based on an overall access and benefit-sharing strategy at the country or regional level” (Article 22 CBD Bonn Guidelines)

In 2004 the CBD Working Group on Access and Benefit-Sharing was given a new mandate at COP7 in order to elaborate and negotiate an international

⁷⁹ Arico and Salpin, *supra* note 58, p. 38.

⁸⁰ Annex to Decision VI/24 Access and Benefit-sharing as Related to Genetic Resources, UNEP/CBD/COP/6/20).

⁸¹ CBD Bonn Guidelines, p. 2, Article 10.

regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument to effectively implement the provisions contained in:

- Article 15 of the CBD on access to genetic resources; and
- Article 8(j) of the CBD on knowledge, innovations and practices of indigenous and local communities; and
- the three objectives of the CBD [conservation of biological diversity; sustainable use of its components; fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access].⁸²

An early draft version of the later Nagoya Protocol of 28 July 2010 included between brackets two options concerning its scope: (1) genetic resources beyond national jurisdiction, genetic resources contained in Annex I of the FAO Treaty, and genetic resources located in the Antarctic Treaty Area would fall outside the scope of the Protocol, or (2) genetic resources from the Antarctic Treaty Area, and genetic resources from marine ABNJ would fall within the scope of the Protocol. The Nagoya Protocol adopted at COP10 in October 2010 does not provide an explicit reference to the inclusion or exclusion of marine genetic resources in ABNJ or the Antarctic Treaty Area. According to Article 3 the scope of the Protocol is limited to genetic resources within the scope of Articles 15 and 8(j) CBD, which only refer to areas within national jurisdiction.⁸³

Worth mentioning are Articles 4(3) and 4(4) of the Nagoya Protocol, which respectively refer to “useful and relevant ongoing work or practices under other international instruments and relevant international organizations” and provide:

Where a specialised international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the

⁸² CBD Working Group on Access and Benefit-Sharing. The original webpage accessed on 25 June 2010 is not longer available because of the conclusion of the Nagoya Protocol; a comparable website on the background of the Protocol is available at: <http://www.cbd.int/abs/background/>.

⁸³ It must be noted that during the 7th meeting of the Working Group on Access and Benefit-sharing of the CBD (April 2009), the EU stated in plenary that certain marine genetic resources should remain outside the scope of the regime, including marine genetic resources outside national jurisdiction and genetic resources in the Antarctic Treaty area. Source: 9(465) *Earth Negotiations Bulletin* 5.

Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialised instrument in respect of the specific genetic resource covered by and for the purposes of the specialised instrument.

Another relevant provision of the Nagoya Protocol concerns Article 10 on a global multilateral benefit-sharing mechanism:

Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilisation of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.

This provision, especially the phrase “or for which it is not possible to grant or obtain prior informed consent” seems to suggest that the Parties could consider the establishment of such a multilateral benefit-sharing mechanism for ABNJ.

Access

With regard to access to genetic resources, Article 15 CBD states that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation. Access is made subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party. Access to genetic resources in ABNJ remains unregulated under the CBD. At the most, genetic resources acquired in ABNJ and stored in *ex-situ* collections might be assumed to be subject to the provisions on access in Article 15 CBD. However, this might be incompatible with Article 15(3), which provides that the genetic resources are only those that are provided by the Parties that are countries of origin of such resources or by Parties that have acquired the genetic resources in accordance with the CBD. It does appear that the term ‘genetic resources’ refers to Article 4(a) rather than to Article 4(b) CBD.

Under the Bonn Guidelines access to genetic resources is to be subject to prior informed consent of the Party providing the resources, unless otherwise determined by that Party (Article 24). Article 27 provides that elements of a prior informed consent system may include identification of the competent authority granting or providing evidence of prior informed consent, timing and deadlines, specification of use, procedures for obtaining prior informed

consent, process, and mechanisms for consultation of stakeholders.⁸⁴ In the Nagoya Protocol the prior informed consent (PIC) clause is repeated and further elaborated in Article 6.

Intellectual Property Rights

The CBD refers to IPRs in relation to the access to and transfer of technology. Article 16(2) CBD states that in the case of technology subject to patents and other IPRs, access and transfer of technology shall be provided on terms which recognize and are consistent with the adequate and effective protection of IPRs. Article 16(3) CBD states that access to and transfer of technology shall take place on mutually agreed terms, to be laid down in national legislative, administrative or policy measures, including technology protected by patents and other IPRs, where necessary, and in accordance with international law. Finally, Article 16(5) CBD, recognizing that patents and other IPRs may have an influence on the implementation of the CBD, requires the Contracting Parties to cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

Article 43 of the Bonn Guidelines lists four elements that “could be considered as guiding parameters in contractual agreements”, as well as basic requirements for mutually agreed terms. One of these elements is the provision for the use of IPRs, including joint research, and the obligation to implement rights on inventions obtained and to provide licenses by common consent. Another element is the possibility of joint ownership of IPRs according to the degree of contribution. Moreover, Appendix I(B)(4) to the Guidelines suggests that material transfer agreements may contain a provision to answer the question whether IPRs may be sought and if so, under what conditions.

Benefit-Sharing

Article 1 of the CBD distinguishes three elements of fair and equitable benefit-sharing:

- appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies;
- appropriate access to genetic resources;
- appropriate funding.

⁸⁴ D Lohan and S Johnston, *Bioprospecting in Antarctica*, UNU-IAS Report (2005) 26. Available at: http://www.ias.unu.edu/binaries2/antarctic_bioprospecting.pdf.

Article 15(7) CBD requires each Contracting Party to take legislative, administrative or policy measures, as appropriate and where necessary, through the financial mechanism established under the CBD, with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources. Article 19(2) CBD requires each Contracting Party to take all practicable measures to promote and advance, on a fair and equitable basis, priority access to the results arising from biotechnologies based on genetic resources. Furthermore, Articles 18 and 19(1) CBD address technical and scientific cooperation and participation in biotechnological research activities.

The Bonn Guidelines provide in Article 41 for the adoption of mutually agreed terms to ensure the fair and equitable sharing of benefits. A separate section (Articles 46–50) is included on benefit-sharing, which highlights what could be covered under the terms, such as: type (monetary and non-monetary types of benefits), timing (short-term, medium or long-term benefits) and distribution mechanisms among the different stakeholders (such as the government and industry).⁸⁵ Appendices I and II elaborate on, respectively, the elements for Material Transfer Agreements and examples of monetary and non-monetary benefits.⁸⁶

Article 5 of the Nagoya Protocol is concerned with fair and equitable benefit-sharing. Article 5(4) refers to the Annex, which lists possible monetary and non-monetary benefits. Finally, Article 9 of the Nagoya Protocol states that:

The Parties shall encourage users and providers to direct benefits arising from the utilization of genetic resources towards the conservation of biological diversity and the sustainable use of its components.

Assessment in Relation to the LOSC

Introduction

As mentioned earlier in this section, the negotiations on the CBD were completed in 1992, which is a decade after the conclusion of the LOSC. The CBD came into force in December 1993, almost a year before the entry into force

⁸⁵ MS Suneetha and B Pisupati, *Benefit Sharing in ABS: Options and Elaborations*, UNU-IAS Report (2009) 10. Available at: http://www.ias.unu.edu/resource_centre/UNU_ABS_Report_Final_lowres.pdf.

⁸⁶ Lohan and Johnston, *supra* note 86, p. 26.

of the LOSC. Virtually all States Parties to the LOSC are also Parties to CBD. The United States are neither party to the LOSC nor to the CBD.⁸⁷

Article 3 CBD repeats Article 194(2) of the LOSC that States have the responsibility to ensure that activities under their jurisdiction or control do not cause damage to the environment. This provision also reaffirms the general obligation included in Article 192 of the LOSC, which requires States to protect and preserve the marine environment. Moreover, Article 22(2) CBD provides that parties shall implement the CBD with respect to the marine environment consistently with the rights and obligations of States under the LOSC.

The second CBD Conference of the Parties (COP-2) adopted in November 1995 a Decision which requested the CBD Secretariat, in consultation with the UN Office for Ocean Affairs and the Law of the Sea, to undertake a study of the relationship between the CBD and the LOSC with regard to the conservation and sustainable use of the genetic resources on the deep seabed. A preliminary investigation by the Secretariat pointed out the following foreseeable scenarios: a) leaving marine genetic resources unregulated and freely available to those who spend the resources to collect them; b) bringing them within the regime governing the Area and the International Seabed Authority; c) bringing them within the CBD regime; and d) establishing an entirely new regime to deal with these special and new resources.⁸⁸ Almost 8 years later, the final report of the study confirmed the existence of a legal lacuna with respect to the genetic resources of the deep sea. The scenarios as mentioned in the 1996 report were presented in the 2003 report as the options available to the international community, except for the option of an entirely new regime. However, it is argued in paragraph 114 of the explanation to the option of 'maintaining the status quo', that this option would run counter to the regulatory intent of the LOSC as a whole and to the specific regime of the Area. The 2003 report suggested that "a precautionary and equity-based approach could be adopted and a specific regime established".⁸⁹

⁸⁷ CBD List of Parties. Available at: www.cbd.int/convention/parties/list, accessed 3 November 2010.

⁸⁸ CBD, Bioprospecting of Genetic Resources of the Deep Sea-Bed. Second Meeting SBSTTA, 2–6 September 1996, Montreal. Note by the Secretariat, UNEP/CBD/SBSTTA/2/15, 24 July 1996, paras. 3–5 and 14.

⁸⁹ CBD, Study of the Relationship between CBD and UNCLOS [LOSC] with Regard to the Conservation and Sustainable Use of Genetic Resources on the Deep Seabed. Marine and Coastal Biodiversity: Review, Further Elaboration, and Refinement of the Programme of Work. UNEP/CBD/SBSTTA/8/INF/3/Rev.1. For discussion at SBSTTA-8, 10–14 March 2003, Item 5.2 of provisional agenda, paras. 114 and 128.

The results of the final study were considered during by the 8th Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) in 2003 and CBD COP-7 in 2004. The debate in relation to the report at the SBSTTA meeting revealed significant differences of opinion between States on this issue. For example, Brazil, Argentina, Colombia and Peru and several other developing States objected to the competence of both the SBSTTA and the CBD to deal with issues related to ABNJ. In contrast, the European Union, Greece and the Seychelles stated their position that these issues fell within the CBD's mandate under Articles 3 and 4. The impasse was 'resolved' by calling for further study of the issue, although this has not resulted in any concrete results to date.⁹⁰

Genetic Resources

Prior to the CBD, 'genetic resources' was not a commonly used legal concept. To the extent that there is no common agreement concerning its details, the CBD COP has discretion to specify and clarify the meaning of the concept. Lack of consistency creates legal uncertainty in access and benefit-sharing transactions. Article 2 CBD provides several relevant definitions relevant to (marine) genetic resources:

"Biological resources" includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity;

"Biotechnology" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use;

"Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity;

"Genetic resources" means genetic material of actual or potential value.

Article 2 of the Nagoya Protocol adds the following definition: "*Derivative* means 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."

In contrast to the CBD, the LOSC does not employ the term genetic resources explicitly, although it uses a number of terms which include genetic resources, such as "natural resources" (e.g., Article 145 in Part XI and Article 193 in Part XII), "species and other forms of marine life" (Article 194(5) in Part XII) and "living resources" (e.g., Articles 117–119 in Part VII). Views

⁹⁰ Leary, *supra* note 55, pp. 56–58.

differ on whether genetic resources in ABNJ are covered by the common heritage regime or not. A further elaboration on this specific issue can be found in the previous section of this report.

Distinction between Scientific and Commercial Research

Article 23 of the Bonn Guidelines makes a distinction between research and development of genetic resources, their commercialization and other uses. Under the LOSC a distinction is made between marine scientific research and the exploitation of natural resources. For example, Article 87(f) of the LOSC refers to the freedom of scientific research on the high seas and Part XIII is entirely dedicated to marine scientific research. By contrast, the Implementing Agreement of Part XI on the Area includes many references to the exploitation of mineral resources, and its Annex includes many references to commercial terms, conditions and principles, for example in Section 5(1)(a) and (b), and Section 6(1)(a). Finally, the knowledge resulting from marine scientific research must be published and disseminated under Article 244 of the LOSC, while the results of commercial bioprospecting may remain confidential, which it has been argued may run counter to the non-appropriation provision of Article 241 of the LOSC. Apart from legal uncertainty, the current lack of a clear distinction between scientific and commercial research is often impracticable. Due to the high costs and risks associated with marine research in ABNJ, research institutions and biotechnology companies often set up joint cruises. It remains unclear whether samples collected during such cruises should be treated as results of scientific or commercial research.⁹¹

Access and Benefit-Sharing under Different Regimes

The CBD does not make a distinction between the different spatial and physical layers in ABNJ. It only refers to areas within or beyond the limits of national jurisdiction, while the LOSC makes an explicit distinction between marine scientific research in relation to the water column (of the high seas) and to the seabed and the subsoil (the Area). Article 257 of the LOSC provides that all States have the right to conduct marine scientific research in the water column beyond the limits of the EEZ. Article 256 of the LOSC establishes the right to conduct marine scientific research in the Area in conformity with the provisions of Part XI.

As mentioned before in this report, different views exist on whether genetic resources in ABNJ fall under the common heritage regime or under the

⁹¹ N Leroux and MM Mbengue, 'Deep-Sea Marine Bioprospecting under UNCLOS and the CBD' (2010) 7. Available at: <http://www.gmat.unsw.edu.au/ablos/ABLOS10Folder/S3P1-P.pdf>.

freedom of the high seas. This distinction made by the LOSC between the freedom of the high seas and the common heritage of mankind is of crucial importance for access and benefit-sharing. Under the freedom of the high seas there is freedom of access and no benefit-sharing requirement. By contrast, Article 143(1) of the LOSC states that marine scientific research in the Area shall be carried out exclusively for the benefit of mankind as a whole. Moreover, Articles 143(2) and 143(3)(c) of the LOSC require the dissemination of the result of research and analysis when available.

Concluding Remarks

It can be concluded that the framework of the CBD, including the Bonn Guidelines and the Nagoya Protocol, contains useful elements for access to and benefit-sharing of marine genetic resources. However, the CBD provisions are based on the assumption of national sovereignty over resources. Therefore these would need to be adapted to the specific characteristics of marine genetic resources in ABNJ and based on the framework provided by the LOSC (either the freedom of the high seas or the common heritage of mankind).⁹² Further conclusions and additional comments are provided in the final section of this report.

Antarctic Treaty System

Introduction

This section focuses on the relevant legal mechanisms within the Antarctic Treaty System (ATS) for access and benefit-sharing. The ATS does not directly regulate biological prospecting activities. Nevertheless, provisions relevant in considering the issue of bioprospecting are contained in:

- the Antarctic Treaty;⁹³
- its Protocol on Environmental Protection (Madrid Protocol);⁹⁴

⁹² Arico and Salpin, *supra* note 58, p. 56.

⁹³ The Antarctic Treaty, done in Washington, 1 December 1959, in force 23 June 1961, 402 UNTS 71.

⁹⁴ Protocol on Environmental Protection to the Antarctic Treaty, done in Madrid, 4 October 1991, in force 15 January 1998, (1991) 30 ILM 1455.

- the Convention on the Conservation of Antarctic Marine Living Resources (CCAMLR);⁹⁵ and
- the Convention on the Regulation of Antarctic Mineral Resource Activities (CRAMRA),⁹⁶ which is not in force.⁹⁷

It should be borne in mind that the ATS provisions are based on conflicting claims to sovereignty over parts of the Antarctic and its waters. The ATS is a regional MLS which as such cannot be transferred to ABNJ. However, it is worth considering whether certain elements of this system might be included in a future MLS of access and benefit-sharing for genetic resources in ABNJ. When focusing on access, IPRs and benefit-sharing, what are the current rules and limitations of the ATS?

Access

Regarding access to marine genetic resources in the Antarctic Treaty area, compliance with various general and more specific requirements within the ATS is mandatory. Under Article II of the Antarctic Treaty, Contracting Parties agree to the principle of freedom of scientific investigation in Antarctica and cooperation to that end. Article VII.5 of the Antarctic Treaty contains a notification requirement for all expeditions to and within Antarctica. Pursuant to Decision 10 of the Antarctic Treaty Consultative Meeting (ATCM) in 2005, collecting biological specimens from the Antarctic Treaty area for biological prospecting requires prior notification through the Electronic Information Exchange System. Furthermore, collecting specimens may require a permit pursuant to Article 3 of Annex II and Article 7 of Annex V to the Madrid Protocol.⁹⁸ Finally, any harvesting of Antarctic marine living resources, or associated activities, must comply with the conservation principles and measures under CCAMLR, such as referred to in Articles II.3 and IX.2.⁹⁹

⁹⁵ Convention on the Conservation of Antarctic Marine Living Resources, done in Canberra, 20 May 1980, in force 7 April 1982, 1329 UNTS 47.

⁹⁶ Convention on the Regulation of Antarctic Mineral Resource Activities, done in Wellington, 2 June 1988, not in force (1988) 27 ILM 868.

⁹⁷ Lohan and Johnston, *supra* note 86, p. 17.

⁹⁸ Antarctic Treaty Secretariat, WP 26: A Gap Analysis of the ATS Regarding the Management of Biological Prospecting, agenda item ATCM-17 (2009) 15. Available at: http://www.ats.aq/devAS/ats_meetings_doc_database.aspx?lang=e&menu=2.

⁹⁹ ATCM, Decision 10: Establishment of an Electronic Information Exchange System, adopted 17-6-2005 at ATCM XXVIII-CEP VIII in Stockholm. Available at: http://www.ats.aq/documents/ATCM28/fr/ATCM28_fr001_e.pdf.

An important limitation in respect of these regulations is that they do not cover all organisms, resources and collections, although they may be of major interest for the purpose of biological prospecting. For example, access to micro-organisms and marine living resources does not require a permit under Annex II of the Madrid Protocol, and *ex situ* collections are also outside the scope of existing rules. However, some of these drawbacks are overcome by domestic implementing legislation.¹⁰⁰

CRAMRA (not in force) makes a distinction between access for prospecting, which requires notification (Article 37(7)), and access for the exploration and the development of mineral resource activities, which requires an Exploration Permit (Article 44(1)) and a Development Permit, respectively (Article 53(1)).

Intellectual Property Rights

The ATS does not provide specific rules with respect to IPRs in general or IPRs for marine genetic resources in particular. However, the issue of IPRs, being interwoven with the commercialization of marine scientific research, has given rise to concern in ATS bodies. As described in an ATCM Working Paper,¹⁰¹ a major concern is that the “patent may result in excluding others from freely using” and exploiting a certain genetic resource without a license from the patent holder. This would seem to be contrary to the freedom of marine scientific research, according to the ATCM Working Paper. However, as suggested in the same paper, this drawback may be partially overcome by introducing at State level an ‘experimental use exemption’ for non-commercial purposes. Another concern raised in the Working Paper relates to the confidentiality aspect of the patenting process which may result in delays in publication. Such delays may be contrary to the requirement that ‘scientific observations and results from Antarctica shall be exchanged and be made freely available’, as stated in Article III.1(c) of the Antarctic Treaty.¹⁰² However, it must be noted that Article 16 of CRAMRA provides that data and information shall be made freely available “to the greatest extent practicable and feasible”, but “data and information of commercial value deriving from prospecting” “may be retained by the Operator in accordance with Article 37” CRAMRA.

¹⁰⁰ Antarctic Treaty Secretariat, *supra* note 98, p. 15.

¹⁰¹ *Ibid.*, p. 16.

¹⁰² *Ibid.*, p. 16.

Benefit-Sharing

The ATS provides mechanisms to ensure that scientific knowledge generated from biological prospecting is shared, although commercialization might be a threat to this free exchange of scientific knowledge. The sharing of monetary benefits is not regulated in the ATS. However, CRAMRA includes in Article 21(1)(p-q) and Article 35 interesting provisions on the charging of fees and levies on operators engaged in exploration and development, although these are not very detailed.¹⁰³ For example, it is not clear which criteria are taken into account when determining the amount of the levies. Also, it seems that the distribution of any possible surplus revenues, as stated in Article 21(1)(r) of CRAMRA, is left to some kind of *ad hoc* negotiation. According to Article 35(7)(b) of CRAMRA it shall be ensured that:

the interests of the members of Regulatory Committees having the most direct interest in the matter in relation to the areas in question are respected in any disposition of that surplus.

The Way Forward

The Netherlands has drafted a list of 'Principles for the Access and Use of Biological Material in the Antarctic Treaty' and introduced these 10 guiding principles in the ATCM 2010. The emphasis of the list of principles is on the promotion of access to biological materials. It contains requirements which are based on existing provisions in the ATS, as well as several innovative principles, such as the establishment of an 'Antarctic System for Biological Material' (ABM System) for *in situ* Antarctic biological material and the requirement that *ex situ* biological material shall remain in the ABM System after their collection. The key message is that the access to the Antarctic biological material in the ABM System shall be free. Only two principles are related to benefit-sharing, namely the requirement to exchange scientific observations and results from scientific investigations, and in the case of patent rights the obligation to share benefits. It remains to be seen in the coming years to what extent the list of principles will win the support of the other parties to the Antarctic Treaty.

In exploring the options for better regulation of bioprospecting activities in the Antarctic Treaty area, while at the same time safeguarding the ATS principles on freedom of scientific research and information exchange, one has to be aware that access, IPRs and benefit-sharing are interrelated elements.

¹⁰³ *Ibid.*, p. 17.

Overall, debates on access to and benefit-sharing for marine genetic resources in ATS bodies, as well as in other international fora, focus on regime and instrument issues and tend to be less solution-oriented.

Several concrete and innovative suggestions for access to and benefit-sharing of bioprospecting activities are made by Jabour-Green and Nicol:

1. Commercial developers could be required to pay a fee for access to Antarctic material and this fee could be deposited into a common fund administered by the *Antarctic Treaty* Secretariat. Perhaps the successful development of downstream products should attract royalty payments, also deposited into a common fund. In this regard, there are a number of precedents that may provide guidance on how a multinational regime could be set up for ensuring facilitated access to Antarctic resources and benefit-sharing. In particular, three components in the appendices to the *Bonn Guidelines* relating to material transfer agreements, monetary and non-monetary benefits and capacity building would seem relevant. The purpose of the fund would be to sponsor ongoing scientific cooperation.
2. All Antarctic samples could be deposited in a common receptacle, to which any researcher, anywhere in the world, could have access for non-commercial research. The clearing house mechanism in paragraph 13 of the *Bonn Guidelines* could provide a framework for this.
3. Individual *Antarctic Treaty* parties could create their own regimes for depositing Antarctic samples and making them available to commercial and non-commercial researchers in accordance with standardised terms. This arrangement would be similar to that envisaged by the *Bonn Guidelines* in its advice on national focal points.
4. Individual institutions could enter into their own negotiations with commercial partners, which is the current position. If this option is chosen, institutions should be educated on the value of the resources that they are bargaining with and the nature of the restrictions that are being imposed on their own research and research undertaken by others.
5. Some mechanism for licensing 'brand Antarctic' should be considered, for example, through the certification trade mark process in the Australian *Trade Marks Act 1995* (Cth). [...] [m]aterial originating in the Antarctic should be [...] acknowledged as being unique and beneficial to humankind. Accordingly it should have a value attached to it as a means of securing sustainable development of Antarctic resources into the future.
6. For the *Antarctic Treaty* parties to retain control over access, use and benefit-sharing of the resource, there would need to be some requirement in the patent application process to confirm the origin of the biological material and arrangements for access and benefit-sharing.¹⁰⁴

¹⁰⁴ J Jabour-Green and D Nicol, 'Bioprospecting in Areas Outside National Jurisdiction: Antarctica and the Southern Ocean' (2003) 4 *Melbourne Journal of International Law* 110–111.

When considering the above-mentioned options in relation to marine genetic resources in ABNJ, opportunities for guaranteeing access can be found in option 2, a common *ex situ* collection. Option 1, the establishment of a common fund, could be an appropriate option for benefit-sharing. Finally, options 5 and 6 are interesting, but only likely to be feasible if the current discussions under TRIPS would indeed lead to a future disclosure of origin obligation in the application process for intellectual property protection. It is worth considering whether variants of the options, as presented above, could be developed for ABNJ outside the ATS.

Accommodating a Multilateral System on Access and Benefit-Sharing for Marine Genetic Resources in ABNJ

Introduction to the Options

The previous sections addressed the different options to address the development of a regime on access to and benefit-sharing of marine genetic resources in ABNJ, as well as the identification of the legal questions and implications which would need to be addressed in that connection as a result of, in particular, the existing legal regime of ABNJ and international trade law.

The remainder of this section is dedicated to an overview of the options to proceed with the discussions in international fora with respect to the governance of marine genetic resources in ABNJ. This overview does not consider the option of the FAO Treaty, since it is not expected that marine genetic resources in ABNJ will become part of the MLS within this treaty system (as explained in the first section of this report). However, the MLS of the FAO Treaty does provide many interesting aspects and lessons learned (as was expected by the Ministry of EL&I when designing the research question for this report), which is taken into account in the evaluation of the options. In the subsection on 'Evaluation of the Options' the two politically and legally most viable options are evaluated in more detail. The section concludes with a recommendation for a preferred option, as well as legal questions for further discussion.

First, an overview is given of the theoretical options, partly based on those presented by Arico and Salpin, to consider the governance of marine genetic resources in ABNJ, including their implications and disadvantages:¹⁰⁵

¹⁰⁵ Arico and Salpin, *supra* note 58, pp. 58–61.

- Retaining the *status quo*:
 - Marine genetic resources in ABNJ remain unregulated with respect to access and benefit-sharing;
 - The responsibility to adopt measures to regulate activities carried out in the Area or in the high seas rests with flag States.
- Adoption of guidelines by the United Nations General Assembly:
 - Focus on organizing cooperation and coordination between flag States;
 - Non-legally binding (interim solution?);
 - Guidelines do not allow for a great level of detail (should be complemented by a code of conduct).
- Using the framework of the CBD:
 - Only applies to processes and activities carried out under the jurisdiction or control of States;
 - Only regulates activities in so far as they have or are likely to have a significant adverse impact on the (marine) environment;
 - The institutional framework of the CBD would need adjustments in order to address issues of access and benefit in ABNJ;
 - Bringing activities and processes in ABNJ under the CBD would require amendments to the CBD, or the adoption of a Protocol (Article 28 CBD), particularly if a specific institutional framework to grant access authorization and negotiate benefit-sharing arrangements is envisioned;
 - No explicit inclusion of genetic resources from marine ABNJ in the Nagoya Protocol, which reflects an intentional choice not to bring genetic resources originating from ABNJ under this new access and benefit-sharing regime within a CBD context.
- Applying the regime of the Area:
 - The international community is divided on the question whether or not the principle of common heritage of mankind also applies to living resources on the deep seabed. If these resources were to fall under this regime the following general principles would be relevant:
 - (1) deep seabed genetic resources would not be subject to appropriation by States or private entities;
 - (2) deep seabed genetic resources may only be used for peaceful purposes;

- (3) the access to deep seabed genetic resources for commercial purposes would require an international regulatory framework;
 - (4) benefits ensuing from the utilization of deep seabed genetic resources should be shared with mankind as a whole;
 - In any case, at present the detailed regime of the Area only applies to non-living resources. Bringing living resources within the scope of the Area's regime and the ISA's mandate would require either:
 - (1) amending the LOSC;
 - (2) adopting a Protocol;
 - (3) developing an implementing agreement; or
 - (4) adopting an agreed interpretation of the LOSC by States Parties, stating that genetic resources found in the Area fall under the regime of either Part XI (the Area) or Part VII (high seas), and clarifying the relation between marine scientific research and (bio) prospecting;
- If an expanded mandate were to be given to the ISA, considerable reform of its structure would be needed.

- A new implementing agreement to the LOSC on the governance of ABNJ, covering issues on access to and benefit-sharing of marine genetic resources, and possibly also on marine protected areas and environmental impact assessments
 - It will be a long and costly process, because many interests are at stake;
 - Risk of re-opening discussion on the LOSC itself;
 - Risk that the process will be deadlocked on the discussion about applying the principle of the common heritage of mankind or the rules on the freedom of the high seas;
 - Advantage that the question whether Part XI of the LOSC applies or not, may remain an open question at the start of the discussion.¹⁰⁶

The last option, an implementation agreement to the LOSC, would have the advantage that a comprehensive, tailor-made agreement could be established specifically for the governance of ABNJ. The Implementing Agreement of Part XI to the LOSC¹⁰⁷ and the Implementing Agreement on Straddling Fish

¹⁰⁶ Arico and Salpin, *supra* note 58, p. 58.

¹⁰⁷ Agreement Relating to the Implementation of Part XI of the United Nations Convention on the Law of the Sea of 10 December 1982, done in New York, 28 July 1994, in force 28 July 1996 (1994) 33 ILM 1309.

Stocks and Highly Migratory Fish Stocks to the LOSC¹⁰⁸ (Fish Stocks Agreement) are similar instruments within the context of the the LOSC.

However, the option of an implementation agreement to the LOSC with respect to the development of a multilateral system for marine genetic resources in ABNJ, did not seem to be politically feasible during the period in which this report was being prepared. For that reason the researchers were asked to examine the alternative options. It must be noted that the negotiations during the most recent meeting of the BBNJ Working Group in May/June 2011 have resulted in an opening to further elaborate on the option of an implementation agreement in future international discussions. The Working Group recommended by consensus to the General Assembly to initiate a process on the legal framework for the conservation and sustainable use of ABNJ, by identifying gaps and ways forward, including through the implementation of existing instruments and the possible development of a multilateral agreement under the LOSC. Such a process should address the conservation and sustainable use of ABNJ together and as a whole, including issues on marine genetic resources (and benefit-sharing), marine protected areas and environmental impact assessments.¹⁰⁹ The analysis in this report in any case is also relevant in that context.

The ‘do-nothing option’ and non-legally binding options, such as a resolution by the General Assembly, are not considered as desirable solutions and are not evaluated further in this report. The legal framework of the CBD, as well as the common heritage regime of the Area within the context of the LOSC, are evaluated for their suitability and implications in the subsections below.

Evaluation of the Options

The arguments in favour of the respective legal frameworks are, as far as applicable, followed by a reference to the corresponding Article(s). The drawbacks of the legal frameworks are followed by one or more suggestions to overcome these drawbacks. Finally, for each framework some additional considerations are included with respect to the institutional aspects involved.

¹⁰⁸ Agreement for the Implementation of the Provisions of the United Nations Convention on the Law of the Sea of 10 December 1982 Relating to the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks, done in New York, 4 August 1995, in force 11 December 2001, 2167 UNTS 3.

¹⁰⁹ IISD, Summary of the Fourth Meeting of the Working Group on Marine Biodiversity Beyond Areas of National Jurisdiction: 31 May–3 June 2011, (2011) 25(70) *Earth Negotiations Bulletin*, MBWG 4 final, 1 and 6.

Convention on Biological Diversity

Arguments Pro

1. The main objectives of the CBD (conservation of biodiversity, sustainable use of its components, fair and equitable sharing of benefits arising out of utilization of genetic resources) could be used to justify the accommodation of a MLS for access and benefit-sharing.

Article 1 CBD

2. The governance principles of the CBD, such as the ecosystem approach, sustainable use and protection of the environment, are also applicable to the management of ABNJ generally.

Articles 2, 6, 8, 10 CBD, etc.

3. The access and benefit-sharing system of the CBD has already been elaborated for areas within national jurisdiction by the adoption of the Bonn Guidelines and the Nagoya Protocol.

Articles 3, 4, and 5 Nagoya Protocol; Part I Bonn Guidelines

4. The CBD provides two concepts for decision making on access and benefit-sharing, namely prior informed consent (PIC) and mutually agreed terms (MAT).

Articles 15(4), 15(5) and 15(7) CBD

5. The CBD provides that parties provide or facilitate access for and transfer of technologies to developing States under fair and most favourable terms.

Article 16(2) CBD

6. The CBD provides that parties shall cooperate to ensure that intellectual property rights are supportive of the CBD's objectives.

Article 16(5) CBD

7. The CBD offers a forum with expertise relevant to organizing access to and benefit-sharing of genetic resources worldwide.

Arguments Contra

1. Regarding ABNJ, the CBD only applies to processes and activities carried out under the jurisdiction or control of States. See Article 4(b) CBD.

The CBD does not apply to components of biodiversity in ABNJ. See Article 4(a) CBD.

Develop a Protocol on access and benefit-sharing for the utilization of marine genetic resources originating from ABNJ, which is possible under Article 28 CBD.

Another option is to explore to what extent bioprospecting activities in ABNJ are already covered by Article 4(b) CBD.

2. Marine ABNJ are not included in the scope of the Nagoya Protocol on access and benefit-sharing.

Develop a Protocol on access and benefit-sharing for the utilization of marine genetic resources originating from ABNJ.

3. The provisions on access and benefit-sharing regulate the interests of the owner Parties *vis-à-vis* the user Parties, as for example in Article 15(1) CBD.

Development of a framework on access and benefit-sharing, designed specifically for ABNJ to reflect the applicable legal frameworks.

4. The PIC and MAT processes for access and benefit-sharing can be delayed by opponents.

Do not provide a veto right in the decision-making processes.

5. The lack of a specific institutional framework to grant access authorization and negotiate benefit-sharing arrangements in ABNJ.

Establishment of an institutional framework for access and benefit-sharing by the adoption of a Protocol (Article 28 CBD).

6. The already existing concerns about the CBD¹¹⁰ and national access and benefit-sharing legislation, such as:

- lack of clarity concerning access rules;
- bureaucracy and unreasonable transaction costs;
- lack of understanding of the role of business by regulators and institutions providing access;¹¹¹
- lack of monitoring and enforcement.¹¹²

When developing a Protocol for marine genetic resources in ABNJ, compliance with the existing system should be improved simultaneously.

Attention should be paid to how to deal with existing concerns about the CBD specifically in the context of ABNJ, which would seem to raise specific problems.

7. Contracts can provide legal certainty and clarify the rights and duties of the contracting parties only where the contract terms are unambiguous and mutually agreed, which is not the case in the access and benefit-sharing context.

¹¹⁰ Although the Nagoya Protocol addresses some of these concerns and might overcome them.

¹¹¹ K ten Kate and SA Laird, *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing* (Earthscan, London, 1999) at 297.

¹¹² *Ibid.*, p. 300.

Provide clear model contracts on access and benefit-sharing. This is also encouraged by Article 15 of the Nagoya Protocol.

8. Few States have adopted workable systems for the identification of ownership of genetic resources.¹¹³

Provide clear guidance on the implementation of access and benefit-sharing. This is also encouraged by Article 16 of the Nagoya Protocol.

9. Most users consider that access and benefit-sharing responsibilities apply only where the user specifically obtained the resource from the source State directly. Users appear to consider that if the material is acquired from another collector, it is not covered by access and benefit-sharing requirements.¹¹⁴

Provide clear guidance on access and benefit-sharing responsibilities in practice, for users as well as for providers of marine genetic resources. This is also encouraged by Article 17 (awareness-raising) of the Nagoya Protocol.

Enhance access and benefit-sharing responsibilities for material acquired from ex situ collections and, if applicable, from ABNJ.

10. TRIPS does not contain a disclosure of origin obligation regarding the place where species were collected. Disclosure of origin is necessary for access and benefit-sharing for: royalties/trust fund, disclosure of resources of common interest (for example, the Budapest Treaty).

Review the relationship between the CBD and TRIPS.

11. Disclosure of origin positions in the WTO TRIPS Council are extremely divergent. Disclosure is relevant and important so that the material can be qualified and treated for benefit-sharing according to its origin.

If the disclosure of origin becomes a requirement in TRIPS, it is recommended to reform the CBD's access and benefit-sharing principle and include it in the TRIPS in a way that access to genetic resources would be balanced by appropriate sharing of benefits. For genetic resources in ABNJ this could be done by means of a new protocol.

12. The United States of America is not a Party to the CBD.

Assess whether participation of the United States in (the development of) a regime on access and benefit-sharing for marine genetic resources in ABNJ is feasible and/or necessary.

¹¹³ S Bhatti, S Carrizosa, P McGuire, T Young (eds.), *Contracting for ABS: The Legal and Scientific Implications of Bioprospecting Contracts*. ABS Series No. 4. IUCN Environmental Policy and Law Paper No. 67/14 (IUCN, Bonn, 2009) at 12.

¹¹⁴ *Ibid.*, p. 13.

Further Comments on Institutional Aspects

If a system of authorization is favoured, a structure with the authority to grant access to genetic resources in ABNJ would be needed. The frequency of the CBD COP meetings does not seem to be appropriate for consideration of access applications. With regard to benefit-sharing, a small permanent structure may be desirable in order to negotiate arrangements with bioprospectors and act as a mechanism for the distribution of such benefits. Such a structure could be a new subsidiary body.¹¹⁵

Regime of the Area within the LOSC Arguments Pro

1. If the common heritage of mankind applies:
 - deep seabed genetic resources would not be subject to private appropriation;
 - would justify/require management by an international institution;
 - benefits ensuing from the utilization of these resources should also be shared with mankind as a whole.

Article 136 LOSC;

Article 137; Article 137(2); Article 140 LOSC

2. If a new separate framework for marine genetic resources in ABNJ were to be developed, it might conflict with the existing regime of the Area, since mineral and genetic resources may coexist on the same sites.
3. Entrusting the ISA with administering marine genetic resources would avoid fragmentation of the regime of ABNJ and derive benefit from the ISA's expertise.

Arguments Contra

1. Views differ as to whether the living resources of or at the seabed of ABNJ should be covered by the regime contained in Part VII of the LOSC or the regime contained in its Part XI. Some States could argue that Part XI is only applicable to mineral resources as it stands.

Expand the scope of Part XI to include living resources situated partly in the water column and partly in and on the seabed. Or consider the divergent views as a given, as they will be difficult to resolve. Instead of continuing

¹¹⁵ Arico and Salpin, *supra* note 58, pp. 59–60.

negotiations on this issue of principle for years, it is recommended to search for a solution without settling a fundamental divergence of views.

2. The mandate of the ISA is limited to mineral resources.
Expansion of the mandate of the ISA or the creation of a separate entity to deal with marine genetic resources.
3. The structure of the ISA is based on the regulation of the mining industry, which might not be suitable for the regulation of the biotechnology industry.
Expansion of the mandate of the ISA or the creation of a separate entity to deal with marine genetic resources.
4. The current system for the management of the Area by the ISA has not been really been tested in practice so far. This is not problematic, because the actual mining activities are in a pioneering phase. However, bioprospecting activities are developed a bit further and thus in a greater need of legal certainty.
Take into account that, if bioprospecting were to fall under the mandate of ISA, it will take a long time before the new system will work in practice. Development of best practices and model working guidelines, etc. takes time. Any new regime will in any case take time to develop and this is not specific to the framework of the LOSC.
5. Part XI does not incorporate modern concepts of environmental law.
The ISA has incorporated modern concepts of environmental law in elaborating the regime for mining the mineral resources of the Area. The development of a specific regime for marine genetic resources in ABNJ could be used to give these principles an explicit treaty basis.

Further Comments on Institutional Aspects

States which refer to Part XI as a model for the governance of marine genetic resources, do not intend necessarily to broaden the powers of the ISA and to apply the detailed regime for mineral resources of the Area to genetic resources. Their objective is to ensure that a new regime would be based on the common heritage of mankind and its key notion of benefit-sharing.

States which reject the applicability of the common heritage principle rely on an interpretation of the LOSC according to which marine genetic resources, not being minerals, do not fall under the regime of the Area and the principle of the common heritage of mankind. According to these States, the rules on the freedom of the high seas should apply. This would basically imply free access to the genetic resources and the application of rules for the protection of intellectual property to processes and substances developed on the basis of

these resources. The States supporting this position are not in a hurry to engage in negotiations. Their concern is that such negotiations might produce an expansion of the common heritage idea and might lead to obstacles and burdens for private enterprise by the creation of new institutions or the expansion of the existing ones with added costs.

The existing structure of the ISA (the composition of the members of the Council) and in particular the balance of various interest groups, may not be appropriate when different interests are at stake. The ISA is a body designed to regulate a deep-sea mining industry. Its current structure reflects the interests of producer and consumer States of minerals. These interests are different from those of the biotechnology industry and the scientific community. Furthermore, at present the ISA does not have expertise to deal with benefit-sharing and deep-sea genetic resources, in particular in the area of patents associated with biotechnology. Also, the process of development of biotechnology from the deep-sea's genetic resources is complicated and lengthy. The reward for those who engage in such activities is the monopoly on exploitation that comes with the grant of a patent and the associated profit which flows from its exploitation.¹¹⁶

The Way Forward

Preferred Option

On the basis of the assessment in this report, and in particular the previous subsections, it can be concluded that if there is a political will internationally to create an access and benefit-sharing system for genetic resources in ABNJ, all legal, technical and institutional obstacles can theoretically be solved.

This leaves us with two scenarios with corresponding questions. In the first scenario, where enough political will exists to establish an access and benefit-sharing system, the question is which legal framework is the most suitable to accommodate such a system for marine genetic resources in ABNJ. It must be noted that alternatively this political will could be reached by making the issue of marine genetic resources part of a package deal, for example a broad framework for the governance of ABNJ. However, the attempts by, *inter alia*, the EU and the BBNJ Working Group to combine the debate on marine genetic resources with the debates on marine protected areas and environmental impact assessments, did not seem to be very promising until recently (see the remarks on the latest developments in the subsection on 'Introduction to the options'). In the second scenario, where there is no consensus on the

¹¹⁶ Leary, *supra* note 55, pp. 222–223.

applicability of the common heritage regime, the question is how the governance gap, as perceived by a part of the world, can be practicably solved nevertheless.

Regarding the first scenario, the development of a protocol within the framework of the CBD seems to be the most appropriate option, considering, *inter alia*, the CBD's objectives and its stage of development. Such a protocol should take into account the specific characteristics of (marine genetic resources in) ABNJ. Unfortunately, the most likely scenario is the one where there is no consensus on the applicability of the common heritage regime. In order to reach a practical solution in this case, it is necessary to recognize first that there is an 'agreement to disagree', as is done with respect to the Antarctic Treaty Area.

Starting from that position, it is recommended that the Netherlands and the EU, as proponents of a generally acceptable and effective regime for marine genetic resources in ABNJ, assess the options for establishing a multilateral access and benefit-sharing system. In addition, the shared particular interests of the EU Member States must be clarified. Is the main interest obtaining legal certainty on access to marine genetic resources in ABNJ, including the *ex situ* collections, and is the issue of monetary benefit-sharing of less importance for the EU Member States themselves? A clear picture on this could help maintain the correct focus, when developing a proposal and during negotiations, for a practical solution for a generally acceptable and effective regime for marine genetic resources in ABNJ coherent with the EU's view on the status of marine genetic resources in ABNJ.

Questions for Discussion

Uncertainty on the appropriate regime for the governance of marine genetic resources in ABNJ and the possibilities to establish an access and benefit-sharing regime are partly caused by the lack of definitions or unclear definitions in the LOSC. Although it is recommended in this report to follow a solution-oriented approach and to avoid long discussions on the interpretation of terminology used by the LOSC, it might be desirable to consider the following questions:

1. Should a definition of "marine genetic resources" be developed? If so:
 - Should this definition make a distinction between genetic resources in or on the seabed in ABNJ and/or in the water column of the high seas?
 - If a distinction were to be made between genetic resources in or on the seabed in ABNJ and in the water column, would the definition of

sedentary species,¹¹⁷ as employed in the context of the regime of the continental shelf, provide a useful model?

- Should this definition also clarify the division between the Area and the water column of ABNJ? For instance what elements of a hydro-thermal vent system would be part of the Area?
- 2. Should the regime applicable to marine genetic resources be developed within the LOSC or are other instruments more appropriate?
- 3. Should it be considered more important to ensure access to genetic resources originating from ABNJ or to ensure the equal sharing of the benefits resulting from their exploitation?
- 4. Should it be required to pay a fee for access to the *ex situ* collections of genetic resources originating from ABNJ? And should this fee be deposited into a common fund or paid to the party who collected the samples *in situ*? Or should free access be guaranteed for the whole of mankind?
- 5. Should an institutional system be developed for the *ex situ* collections of marine genetic resources comparable to the IARCs under the FAO Treaty? Or should all samples collected be deposited in one common receptacle?
- 6. Should a (dynamic) limitative list be developed for those genetic resources originating from ABNJ that will be part of the multilateral access and benefit-sharing system to be established?

¹¹⁷ Sedentary species as defined in Article 77(4) of the LOSC: “organisms which, at the harvestable stage, either are immobile on or under the sea-bed or are unable to move except in constant physical contact with the sea-bed or the subsoil”.

