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## Increasing Value and Flow in the Marine Bio- discovery Pipeline

*Deliverable 6.8: MGR Workshops report with analyses and recommendations.*

SEVENTH FRAMEWORK PROGRAMME  
COLLABORATION PROGRAMME



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## Deliverable 6.8: MGR Workshops report with analyses and recommendations.

Due date: M52, 31.1.2017    Dissemination level: Public

Actual date: M54 (final MGR workshop not until M53, after the due date)

### Objective of PharmaSea's MGR Workshops

This report is the outcome of T6.4 of PharmaSea: "Organisation of two multi-stakeholder Workshops on identified policy/legal barriers to the access and sustainable use of MGR for in marine biodiscovery activities". The purpose of the Workshops was to discuss key legal and policy constraints related to the access and use of MGR (Marine Genetic Resources) and the formulation and validation of ways to address them. The team involved in organizing, supporting and reporting on the workshops was composed of Partners 5, 6 & 23 (eCoast, BioBridge and IUCN-ELC, the Environmental Law Centre of the International Union for the Conservation of Nature).

In the event, the activities of WP6 generated extreme interest amongst policy-makers concerned with the Nagoya Protocol of the CBD (Convention on Biological Diversity), and the topics of Access and Benefit-Sharing (ABS) for MGR in areas within and beyond national jurisdiction. Also, the project was extended from 48 months' duration to 54 months. The MGR Workshop 1 took place in Leuven, Belgium in May 2014, M21, and was coordinated by IUCN-ELC. The MGR Workshop 2 took place in M53, February 2017, and was coordinated by eCoast. These workshops and the 4 meetings of PharmaSea's Advisory Panel of Policy and Legal Experts APPLE together constituted a contribution to ABS and ABNJ discussions wider than the original anticipated activity for PharmaSea.

Each Workshop brought together the main European stakeholders including representatives of the European Commission's DGs and practitioners of ABS and related issues with representatives from relevant international entities and environmental and IPR lawyers, to exchange views on issues relating to the conservation and sustainable use of marine biological diversity. Attendees also included members of the PharmaSea APPLE. The discussions and outputs of each Workshop were closely linked to ongoing efforts and developments e.g. in the framework of the Ad Hoc Open-ended Informal Working Group of UNCLoS and the Prep Coms of CBD, with the aim of providing a lasting impetus to develop pragmatic solutions.

**Appendix 1** gives the lists of attendees for each Workshop. **Appendix 2** provides the programme for each Workshop. **Appendix 3** is the background paper for Workshop 1; **Appendix 4** is the discussion paper for Workshop 2.

## PharmaSea's MGR Workshop 1

The *MGR Workshop 1* was held in Leuven on 7-8 May 2014 to consider '*Options for an Access and Benefit-Sharing (ABS) Regime for Marine Genetic Resources (MGR) from Areas Beyond National Jurisdiction (ABNJ)*'. A background document (**Appendix 3**) was developed and circulated by eCoast, which aimed to provide a non-exhaustive list of preliminary ideas, questions, problems and potential solutions for a future ABS regime and thereby to provide a basis for discussions at the workshop. The primary objective of the workshop was to build on the existing UNCLOS framework (rather than amending UNCLOS provisions) in such a way that the continuation of R&D on MGR from ABNJ could be assured. The workshop discussions were structured around three sessions, to consider options for non-monetary benefit-sharing, options for monetary benefit-sharing, and issues related to compliance and monitoring. The discussions considered current practices and future options, from the perspective of the scientific community engaged in R&D on MGR and from legal experts and policy makers. The report has been published<sup>1</sup>.

It was originally planned that the proposals presented and elaborated at the workshop would then be submitted to and presented at the UN *Ad Hoc* Open-ended Informal Working Group meeting in June 2014 in order to support the decision-making process within the UN General Assembly. However, in considering the options proposed by WP6 for a potential future ABS regime for MGR from ABNJ, the participants agreed that it was too early in the process of the BBNJ working group for such a detailed regime to be presented and advised that a more acceptable approach would be the development and coordination of current practices in sampling and curation of MGR, data-sharing and integration which had been identified during the workshop and which could form the basis of a future regime. Such an approach would limit the introduction of additional administrative burden for the marine scientific community. The discussions also highlighted areas where a potential future regime could support and enable sustainable and environmentally responsible marine scientific research.

Whilst MGR sourced from ABNJ fall outside of the scope of the Nagoya Protocol, the entry into force of the Protocol will have implications for how researchers utilize all (M)GR in their R&D. Research institutions will have to adapt their procedures to deal with these new measures. This will, however, pave the way for any potential future ABS regime for MGR from ABNJ. It will be important to ensure that an imbalance is not created in regards to obligations on researchers between sampling within or beyond national jurisdiction.

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<sup>1</sup> McMeel O, Greiber T, Vanagt T and Jaspars M (2014) Report of the PharmaSea WP6 Stakeholder Workshop on '*Options for an Access and Benefit-Sharing Regime for Marine Genetic Resources from Areas Beyond National Jurisdiction*' PharmaSea-eCOAST-6.8a Ostend, Belgium

MGR from ABNJ are often collected and deposited in *ex-situ* collections via basic marine scientific research activities. Any future regime on ABS of MGR from ABNJ would have a first impact on the activities of the basic marine scientific research community. One conclusion of this Workshop was that, since their work contributes to the protection and preservation of the marine environment but also directly or indirectly facilitates the entry of MGR into the value chain, their needs and concerns must be considered. The scientific community engaged in basic and applied research on MGR must also be encouraged not to remain silent in these discussions. Their input at an early stage in the process could help ensure that a potential future Implementing Agreement would enable rather than impede marine scientific research. Finally, with respect to ABS of MGR from ABNJ, future practices must be considered, including the collection of MGR via means other than marine scientific research, for example via environmental impact assessments for deep sea mining.

## PharmaSea's MGR Workshop 2

The *MGR Workshop 2* was held in Leuven in February 2017, as a follow-on of the 4<sup>th</sup> PharmaSea APPLE meeting<sup>2</sup>. It focused on the current efforts from key stakeholders including the European Commission to create a pan-European approach on the access, benefits sharing and IPR of MGR and harmonization of relevant policies and legal instruments. It brought together international experts with the main stakeholders in Europe, the European Commission and EU Member State experts and representatives, including Belgium, Estonia, Germany, Malta, and UK. MGR from different regimes (i) within the EU; (ii) within non-EU States; and (iii) in areas beyond national jurisdiction were considered. The system of ABS, as provided under the umbrella of the CBD, is much more advanced in other countries than in the EU, particularly in biodiversity-rich countries such as Australia, New Zealand and South Africa, which for example has had a legal regime since 2012. Consortium partners and members of the PharmaSea APPLE with experience in this provided vital inputs. In view of the current public consultation on the ratification of the Nagoya Protocol on ABS organised by the EC, and the dynamic nature of the landscape, this workshop was strongly geared to contribute to the actual policy agenda then under elaboration. The MGR Workshop also included presentation and discussion of PharmaSea's *Mare Geneticum* draft paper (see **Appendix 4**) and discussion of the evolution in policies and recommendations at EU and international levels (IUCN, UNCLOS and CBD/NP).

Charlotte Salpin of UNCLOS reviewed the recent developments of the UN processes focusing on Biodiversity of Areas beyond National Jurisdiction (BBNJ). John Brincat, of the European Commission DG MARE, gave the EU's Perspective on the continued negotiations.

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<sup>2</sup> The APPLE meeting is reported on in PharmaSea D6.2 *Report of APPLE Meeting 4 and overview of work to date*

Geoff Burton, of the United Nations University's Institute for the Advanced Study of Sustainability, who had advised the Australian Government on bioprospecting and ABS, discussed issues arising in balancing the interests of States, Academy and Private Sector in the BBNJ framework, and Hiroko Muraki Gottlieb of IUCN described the diplomatic and technical developments on MGR in ABNJ at IUCN.

The 2011 package that introduced ABNJ, Marine Protected Areas, and capacity-building by transfer of technologies was dealt with in the first PrepCom. There is now a new Chair of PrepCom. It has been useful to agree on a definition of MGR, as this is one of the areas of convergence. During discussion, some reference was made to the Plant Treaty multilateral system as a model for a MGR system. Because ABNJ includes oceanic waters, there needs to be a clear understanding of whether the framework applied in the concept of Freedom of the High Seas applies to BBNJ. In addition, a differentiation is needed between fish and other marine life as a commodity (ie from fisheries activity) and fish as a GR, and sorting out the wording to allow this to happen is important in developing the MGR definition. The concept of Benefit-sharing is more difficult to work out, for BBNJ. Direct contribution to CBD could be one option; the ISA might be a vehicle for collecting and distributing monetary benefits; a trust fund or clearing house mechanism might be workable. One suggestion is that the biodiversity from samples from ABNJ taken under ISA rules should be deposited in a national collection somewhere for use in R&D and commercialisation. It might become attractive to nations such as many small island states, which don't have large-scale research capacity, to establish such collections and other nations could provide capacity-building, training and equipment as part of non-monetary benefits. The question of digital data and in silico genetic resources still needs discussion. In considering intellectual property, there might be traditional knowledge associated with some lifeforms from the open seas, and it may be that an international body such as WIPO could be asked to help develop a patenting framework that specifically recognises the issues of BBNJ.

There has been a change in the process since 2009 that has made EU more enthusiastic about it – there had been polarisation between the existing concept of Freedom of the High Seas and supporters of a more multilateral system, and a need to position MGR aspects alongside the principle of Common Heritage of Mankind or common concern of mankind as mentioned by IUCN. In 2011, the meeting allowed a greater mutual understanding, with 5 elements including a definition of MGR, the approach to technology transfer, and ABS options. The USA, Japan, and Canada were working towards a solution to find a balance, whereas Russia did not seem enthusiastic, and Iceland was understandably keen to protect fisheries, although it did not oppose the aspects concerning MGR. One challenge of ABS negotiations is that the views and positions of all the organisations such as ISA need to be incorporated into decision-making. The position of the African Union, that it is important that the agreement operationalises what UNCLOS has established on mineral resources, also revealed the difference between the actual value of minerals and the “potential” value of MGR.

The questions still to decide are what the mechanism will be and who the competent authority will be. So far, no-one has been brave enough to suggest any actual mechanism for benefits, some are asking for percentages of royalties, others for derogations from the usual IPR rules so that, effectively, use of GRs in certain territories would be royalty-free. Though non-monetary benefits are useful, capacity building in the ABNJ context is hard to define. A number of horizontal issues would need to be considered, including making sure that definitions were consistent between an ABNJ regime, CBD and the Nagoya Protocol, and that any mechanism that is agreed does not hamper marine scientific research. One specific problem in deciding the competent authority is that, if states were to agree to give ISA the management of MGR whether from the Area or from the water column, the legal competences of ISA would alter.

Although it would be good to have certainty in a short period of time, there is more chance of a greater number of states engaging more and committing to a system if it takes longer to discuss, negotiate and agree. UNCLOS took 10 years, and this will also take a long time, and it would not be surprising if the US doesn't join an ABNJ system. They are pushing at the moment not for a COPMOP meeting but for a general UN meeting; in this way, the US would have a right to decide the outcomes but not have the obligation to sign up to them. However, even if the US is not a party, the scientists in the US might follow the international agreement, as happens with CBD and the Nagoya Protocol. Note that for US-based companies to participate in international markets, they are obliged to meet the rules and requirements of all the markets, including the NP and EU Regulation 511/2014. In any case, even if specific negotiations on ABNJ do not go anywhere, application of Article 10 of the NP should lead to global multilateral mechanism in BBNJ<sup>3</sup>.

In discussing and negotiating aspects of dealing with BBNJ between States, there is clear divergent thinking between some of them. Some countries, through either caution (such as Japan or Russia) or an excessively firm viewpoint (such as Venezuela) are holding up the process of gaining consensus. Non-littoral states want the same access to benefits as littoral and island states. Some countries don't have a wide grasp of the issues and the background to MGR, perhaps because their fisheries agencies are the only source of information and provide the delegates, and there is confusion between fish as a traded commodity and fish as MGR, with concerns that a regime to manage MGR in ABNJ will adversely affect fishing on the high seas.

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<sup>3</sup> Article 10 of the Nagoya Protocol states: "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 utilization 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."

There is a limited understanding of derivatives, data, GR as information, in silico and synthetic biology. Consequently, developing countries and small island states are concerned about the possibility that other states might force them into situations they don't want. The national interests of developing states need to be considered, for instance Fiji would want collaboration to support their own marine science with activities within and outside their EEZ. Concepts of capacity building and technology and knowledge transfer include access to research vessels and participation in scientific collaborations. There is a growing interest in Marine Protected Areas. On the other hand, the perceived agendas of national interests of developed states is that their own marine science shouldn't be inhibited, their own biotech industry is supported, there is no impingement of any ABNJ regime on freedom of high seas, there is maximum freedom to operate, and there are no additional financial and resource burdens. The US, for example, wants obligations to continue beyond living MGR only as far as gene sequences.

Activities that may help include avoidance of conflict between Freedom of the High Seas and Common Heritage of Mankind by using UN Resolution 69/292 of 2015 as the reference point/umbrella; requirements for disclosure of source in patent applications; and science community initiatives such as the World Federation of Culture Collections Catalogue of Microorganisms, which has 34 countries participating. In terms of speaking to delegations, side events could be a solution - attendance in New York has been good so far, better than at CBD. There are problems: often there is a change of delegates from 1 meeting to another – there is a challenge in continuity of knowledge when educated delegates are changed and new ones need to be educated over again; and NGOs are active and efficient in informative sessions, but some States are reluctant or cautious of perceived “NGO driven” events.

There has been progress towards reaching consensus on BBNJ within the framework of the UN Resolution 69/292 of 2015; but there is still discussion on the common heritage of mankind (definition and principles) vs fair and equitable sharing of benefits. What is needed are a clear set of rules on access fees, a transparent scheme for access and use of MGRs and procedures consistent with the CBD. However, simply adding ‘marine’ to definitions in the CBD is not enough. Although ‘derivatives’ is a term used, it has been overtaken by the general term ‘utilisation’, which could then include RNA, DNA, secondary metabolites and data arising from R&D and exploitation. Actually, if you don't know what to do with DNA and RNA, it doesn't have a value. It's the derivatives that create value; but to talk meaningfully about benefit-sharing, some value does need to be put on what can be utilised.

Marcel Jaspars (University of Aberdeen and PharmaSea's Scientific Coordinator), Arianna Broggiato (eCoast) and Thomas Vanagt (eCoast) presented different aspects of the paper *Mare Geneticum*, which incorporates PharmaSea's view of the issues involved in utilising BBNJ and recommendations for a framework. The floor was opened for a general discussion of the paper. The paper was revised in response to the outcomes of discussion and the text, as submitted for publication, is given in **Appendix 4**.



*Mare Geneticum* - Foundations (A Broggiato): The historical inspiration is Grotius's *Mare Liberum* of 1609 – the world's oceans were to be freely accessible to all and shared amongst nations. The premises for fair and equitable sharing of benefits arising from the use of MGR are to connect those countries having the knowledge, MGR and technologies with those that don't, but want to utilise them; this poses problems for dealing with MGR from ABNJ.

However, there is not much evidence of systematic commercial development of ABNJ MGR<sup>4</sup> and the debate needs to not confuse the potential of ABNJ with the actual exploitation of MGR which have almost all come from EEZs. Therefore, we still need a study of the potential of ABNJ and a review of the full spectrum of monetary and non-monetary benefits that could be derived from ABNJ MGR exploitation. This is especially in the light of the statement in the UN's First Global Integrated Marine Assessment, that it is current uneven research capabilities between nations that is the primary source of inequity, not disparities in access to MGRs in situ.

*Mare Geneticum* - the Science (M Jaspars): The concepts in *Mare Geneticum* are based on the known hyper-biodiversity of the oceans and the impossibility of determining which legal regime (territorial sea, EEZ, High Seas (Areas beyond national jurisdiction ABNJ)) a marine organism has come from. We need to take account of the conflict between marine organisms as commodities (typically fish) and as GRs; and the state of current regulatory regimes that suggests that reporting GRs from ABNJ will need a new international organisation. Good Practice for research cruises and sampling needs standardising; tracking material from origin to exploitation needs better databases and traceability systems such as NAPIS/OpenNAPIS – in published papers and patents, mistakes have been made on origin and species that negate IP.

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<sup>4</sup> See Leary D and Juniper SK (2013) Ch 34 *Addressing the Marine Genetic Resources Issue: Is the debate heading in the wrong direction?* In *The Limits of Maritime Jurisdiction* ed. Schofield C, Lee S and Kwon M-S, pp 769-785 Martinus Nijhoff/Brill Academic ISBN 9789004262584

## Appendix 1: Attendees at the PharmaSea MGR Workshops

### The PharmaSea MGR Workshop 1

PharmaSea Project Partners	Affiliation
Marcel Jaspars	University of Aberdeen, Scotland (PharmaSea Project Leader)
Alex Crawford	KU Leuven, Belgium
Camilla Esguerra	KU Leuven, Belgium (PharmaSea Coordinator)
Thomas Greiber	IUCN Environmental Law Centre, Germany
Isabelle Huys	KU Leuven, Belgium
Laura Lallier	eCOAST Belgium
Meredith Lloyd-Evans	BioBridge Ltd, UK
Oonagh McMeel	eCOAST Belgium
Thomas Vanagt	eCOAST, Belgium
External Participants	Affiliation
Marie-Cécile Barras	Novamen, France, representing the SeaBioTech Project
John Brincat	European Commission, DG MARE, Belgium
Arianna Broggiato	Catholique University Louvain, Belgium, representing the MicroB3 Project
Geoff Burton	United Nations University Institute of Advanced Studies, Australia
Jan-Bart Calewaert	EMODnet Secretariat, Belgium
Kjersti Lie Gabrielsen	MarBank, Norway
Kathryn Garforth	Secretariat of the Convention on Biological Diversity, Canada
Laura Giuliano	Mediterranean Science Commission (CIESM), Monaco
Lyle Glowka	Secretariat of the Convention on Migratory Species, United Arab Emirates
Alicja Kozłowska	European Commission DG ENV, Belgium
Kate Larkin	European Marine Board, Belgium
Charlotte Salpin	United Nations Division for Ocean Affairs and Law of the Sea, USA
Hugo Schally	European Commission DG ENV, Belgium
Johanna Wesnigk	EMPA, Germany, representing the MicroB3 Project

## The PharmaSea MGR Workshop 2

PharmaSea Project Partners	Affiliation
Marcel Jaspars	University of Aberdeen, Scotland (PharmaSea Project Leader)
Arianna Broggiato	eCOAST, Belgium
Peter De Witte	KU Leuven, Belgium
Isabelle Huys	KU Leuven, Belgium
Laura Lallier	eCOAST, Belgium
Meredith Lloyd-Evans	BioBridge Ltd, UK
Ays Sirakaya	eCOAST, Belgium
Monika Ślęzak	KU Leuven, Belgium
Lydia Slobodian	IUCN Environmental Law Centre, Germany
Thomas Vanagt	eCOAST, Belgium
External Participants	Affiliation
Susann Agius	COMAR, Malta
Katie Beckett	ABS project manager, Dept for Business, Energy & Industrial Strategy, UK
John Brincat	European Commission DG MARE, Belgium
Geoff Burton	Institute for the Advanced Study of Sustainability, United Nations University, Tokyo, Japan
Fien De Raedemaeker	VLIZ, Belgium
Lowri Mai Griffiths	Head of the Maritime Policy Unit, Foreign & Commonwealth Office, UK
Julian Jackson	Pew Charitable Trusts, UK
Salima Kempnaer	National Focal Point FPS Health, Food Chain Security & Environment, Belgium
Leo Matthias Maier	European Commission DG Environment, Belgium
Sophie Mirgaux	Department of Marine Environment, Belgium
Dominique Muyldermans	ABS-int, Belgium
Hiroko Muraki	IUCN, New York USA
Charlotte Salpin	UN Division for Ocean Affairs and Law of the Sea, New York USA
Kabri Tubi	Ministry of the Environment, Estonia
Marliese von den Driesch	Information & Coordination Centre for Biological Diversity, Federal Ministry of Food & Agriculture, Germany

## Appendix 2: Programmes of the PharmaSea MGR Workshops

*The PharmaSea MGR Workshop 1 & APPLE meeting 2, Leuven, Belgium, 7<sup>th</sup>-8<sup>th</sup> May 2014*

<b>Day 1 MGR Workshop 1</b>
Welcome, tour de table and introduction to PharmaSea (Marcel Jaspars – UniAberdeen, PharmaSea Coordinator)
Options for an Access and Benefit---Sharing Regime for Areas Beyond National Jurisdiction – Setting the context for the workshop (Thomas Greiber – IUCN Environmental Law Centre)
<b><i>Session 1: Options for Non-Monetary Benefit-Sharing</i></b>
Discussion points: <ul style="list-style-type: none"> <li>• Different types of access</li> <li>• Creating a network of different pools (biorepositories, data banks, patent pools, etc.)</li> <li>• Exchange of information</li> <li>• Collaboration &amp; cooperation</li> <li>• Capacity---building</li> </ul>
<b><i>Session 2: Options for Monetary Benefit-Sharing</i></b>
Discussion points: <ul style="list-style-type: none"> <li>• Payment at different stages in chain of access &amp; utilization of genetic resources</li> <li>• Providing financial resources for conservation/sustainable use activities</li> <li>• Providing financial resources to support global research and capacity-building undertakings</li> </ul>
Wrap-up of sessions 1 & 2
<b>Day 2 MGR Workshop 1 &amp; APPLE</b>
<b><i>Session 3: Issues of Compliance</i></b>
Discussion points: <ul style="list-style-type: none"> <li>• Right to protect research results or to waive protection</li> <li>• Obligation to “feed” multilateral system (samples, data)</li> <li>• Monitoring and enforcement</li> </ul>
Wrap-up of Session 3 and close of MGR Workshop 2
<b><i>APPLE Meeting No 2</i></b>

The PharmaSea MGR Workshop 2 & APPLE meeting 4, Leuven, Belgium 1<sup>st</sup>-2<sup>nd</sup> February 2017

<b>Day 1 ABS Case Studies – APPLE</b>
Welcome and update on the PharmaSea project (Marcel Jaspars – UniAberdeen, PharmaSea Co-ordinator and APPLE Chair)
Overview of PharmaSea WP6 activities and achievement to date (Thomas Vanagt – eCoast, WP6 WP Leader)
Case Study - ‘Piggybacking’- use of samples from other activities for marine bioprospecting – fishery, mining-prospecting, oceanography etc (Ays Sirakaya – eCOAST)
Case Study - Traceability of MGRs and genomic tech/synthetic biology (Lydia Slobodian – IUCN ELC)
Case Study – Realistic monetary benefit-sharing (Meredith Lloyd-Evans – BioBridge)
ABS Perspective from the Private Sector (Dominique Muyldermans – ABS-int)
Case Study - Non-monetary Benefit-sharing (Lydia Slobodian – IUCN)
Case Study - Legacy issue in ABS of MGR - How to deal with ownership of materials after a project finishes, the termination and transfer rules, the destruction or retention of samples etc, (Arianna Broggiato – eCOAST)
Case Study - The impact of the Nagoya protocol on access to marine genetic resources for R&D purposes, and the role of biorepositories Case Study (Lydia Slobodian – IUCN)
ABS experiences from a national perspective: the UK (Katie Beckett - The Department for Business, Energy and Industrial Strategy, UK)
<b>Day 1 Marine Genetic Resources in ABNJ – MGR Workshop</b>
Recent Developments of the BBNJ Process at the UN (Charlotte Salpin – UNCLOS)
Closing discussion
<b>Day 2 Marine Genetic Resources in ABNJ – MGR Workshop</b>
Welcome by (Thomas Vanagt – eCoast)
European Union’s Perspective on the Negotiation (John Brincat – European Commission DG MARE)
Balancing the interests of States, Academy and Private Sector in the BBNJ framework (Geoff Burton – United Nations University)
Diplomatic and Technical developments of IUCN on MGR in ABNJ (Hiroko Muraki Gottlieb - IUCN)
<b>“Mare Geneticum”</b>
The Scientific context (Marcel Jaspars, PharmaSea Coordinator)
Foundations (Arianna Broggiato)
Building Blocks (Thomas Vanagt)
Open discussion on “Mare Geneticum”
How to maximize the influence of PharmaSea’s proposal? (Thomas Vanagt – eCOAST)
Future of the APPLE Panel and Approval of Recommendations for the GA of PharmaSea (Marcel Jaspars - PharmaSea Coordinator)
Closing discussion

## Appendix 3: Background Paper for MGR Workshop 1: *Options for an Access and Benefit-Sharing Regime for Areas Beyond National Jurisdiction: Possible Ideas on How to Address ABS for MGR in ABNJ*

Thomas Greiber, IUCN-ELC Bonn

### Background

Before the end of the 69<sup>th</sup> session of the UN General Assembly in 2015, States were required to take a decision whether to start the negotiation of an international instrument on the conservation and sustainable use of biodiversity in areas beyond national jurisdiction (ABNJ)<sup>5</sup>. As agreed in 2011 by the UN Ad Hoc Open-ended Informal Working Group set up to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction, the scope of such an international instrument for ABNJ would include *'marine genetic resources, including questions on the sharing of benefits, measures such as area-based management tools, including marine protected areas, and environmental impact assessments, capacity-building and the transfer of marine technology'* together and as a whole in a single package (so called 'package deal')<sup>6</sup>.

In order to avoid a new international legal framework hampering future research and development (R&D) on marine genetic resources (MGR) from ABNJ, the scientific community has to inform policy-makers about the feasibility and modalities of scientific activities undertaken, and the already advanced practices in place within the scientific community, especially regarding sharing of non-monetary benefits. Furthermore, the scientific community should use the opportunity to become proactive, influence the UN debate at an early stage, and propose concrete ideas, concepts and options with regard to a potential access and benefit-sharing (ABS) regime for MGR from ABNJ.

The objective of this PharmaSea MGR workshop is to further develop ideas and concepts with regard to a potential ABS regime for MGR from ABNJ by bringing together marine biodiscovery practitioners with legal experts (in the fields of ABS, IPR and law of the sea), policy-makers and other relevant stakeholders. The proposals will then be submitted to and presented at the UN Working Group meeting in June 2014 in order support the decision-making process within the UN General Assembly.

The following text is intended as a basis for discussion. It aims at providing a non-exhaustive list of preliminary ideas, questions, problems and potential solutions for a future ABS regime with the objective to:

- Promote international R&D on MGR from ABNJ instead of creating obstacles; and
- Build on the existing UNCLOS framework instead of amending UNCLOS provisions (in particular the freedom of marine scientific research (MSR) and the relevant UNCLOS requirements including international cooperation in MSR, the creation of favourable conditions for the conduct of MSR, the publication and dissemination of information and knowledge resulting from MSR, and the promotion of data and information flow and transfer of knowledge).

Furthermore, it is important to note that the issues addressed below are envisaged as and as part of an overall international instrument for ABNJ rather than a stand-alone ABS regime for ABNJ.

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<sup>5</sup> UNGA resolution 66/288. *'The future we want.'* UN doc. A/RES/66/288, of 11 September 2012. Para 162; UNGA resolution 67/78. *'Oceans and the law of the sea.'* UN doc. A/RES/67/78, of 11 December 2012. Para 181; UNGA resolution 68/70. *'Oceans and the law of the sea.'* UN doc. A/RES/68/70, of 9 December 2013. Para 197.

<sup>6</sup> UNGA resolution 66/231. *'Oceans and the law of the sea.'* UN doc. A/RES/66/231, of 24 December 2011. Paragraph 167.

## I. Objectives of an ABS Regime for ABNJ

- Creation of a multilateral system that facilitates greater access to MGR from ABNJ and ensures equitable and fair sharing of benefits from their utilization
  - Recognizing that facilitated access is a critical non-monetary benefit for ALL stakeholders involved in R&D related to MGR, i.e. a global benefit for MGR stakeholders in developing as well as developed countries (including land-locked states)
  - Aware that the results of successful R&D will be a benefit for all humankind
  - Acknowledging Para 5 of the UNCLOS Preamble referring to the *'[...] realization of a just and equitable international economic order which takes into account the interests and needs of mankind as a whole and, in particular, the special interests and needs of developing countries [...]'*.
- Striking an appropriate balance between on the one hand efficient dissemination of materials (i.e. collected samples), associated knowledge (i.e. data and research results) and capacities (i.e. technologies and biotech know-how) to global science communities and other users, and on the other hand appropriate intellectual property rights (IPR) protection and management (including the right to apply for patents and copyrights)
  - Acknowledging the UNCLOS obligations regarding MSR
  - Acknowledging also an uneven distribution of technologies and expertise amongst international researchers
  - At the same time recognizing high investment costs of R&D on MGR from ABNJ, as well as the interests and practices of researchers in publishing and protecting their research results and inventions.
- Enhancing and complementing existing international ABS regimes
  - Recognizing the existing regulatory ABS gap in ABNJ under UNCLOS, and the need to close the ABS gap left by the CBD and its Nagoya Protocol without expanding their geographical scope.
- Conservation and sustainable use of MGR from ABNJ for the benefit of present and future generations
  - Recognizing existing UNCLOS obligations to protect and preserve the marine environment (Art. 192) and *'[...] rare or fragile ecosystems as well as the habitat of depleted, threatened or endangered species and other forms of marine life'* (Art. 194.5)
  - Reflecting that ABS is one part of the 'package deal' comprising amongst others also area-based management tools (including marine protected areas) and Environmental Impact Assessment (EIA).

## II. Definition of Terms

- Building on terms used/defined in the CBD and its Nagoya Protocol<sup>7</sup>
  - Leading to more clarity, consistency and compatibility of existing and new ABS regimes
  - Important to have a common ABS understanding under different regimes in order to ensure efficient and effective implementation and avoid potential loopholes.
- Need to consider the development of a new definition for associated knowledge (i.e. data and research results related to R&D on MGR from ABNJ)
  - CBD and its Nagoya Protocol only address traditional knowledge of indigenous and local communities associated with genetic resources

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<sup>7</sup> Genetic material: *'any material of plant, animal, microbial or other origin containing functional units of heredity'*; Genetic resources: *'genetic material of actual or potential value'*; Utilization of genetic resources: *'to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology'*; Biotechnology: *'any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use'*; Derivatives: *'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'*

- Knowledge related to R&D on MGR from ABNJ lies mostly with researchers
- Knowledge-sharing under a new ABS regime as a potential key benefit for the scientific community.
- No need to distinguish between commercial and non-commercial R&D, as definition of utilization under Nagoya Protocol covers both
  - In practice distinction is difficult (if not impossible), as samples taken and utilized for basic research may subsequently be used for commercial purposes
  - However some distinction (IPR protection vs. open access) could kick in leading to differentiated benefit-sharing obligations depending on whether materials and associated knowledge are protected or made publicly available (see example of ITPGRFA<sup>8</sup>).

### III. Scope of an ABS Regime for ABNJ

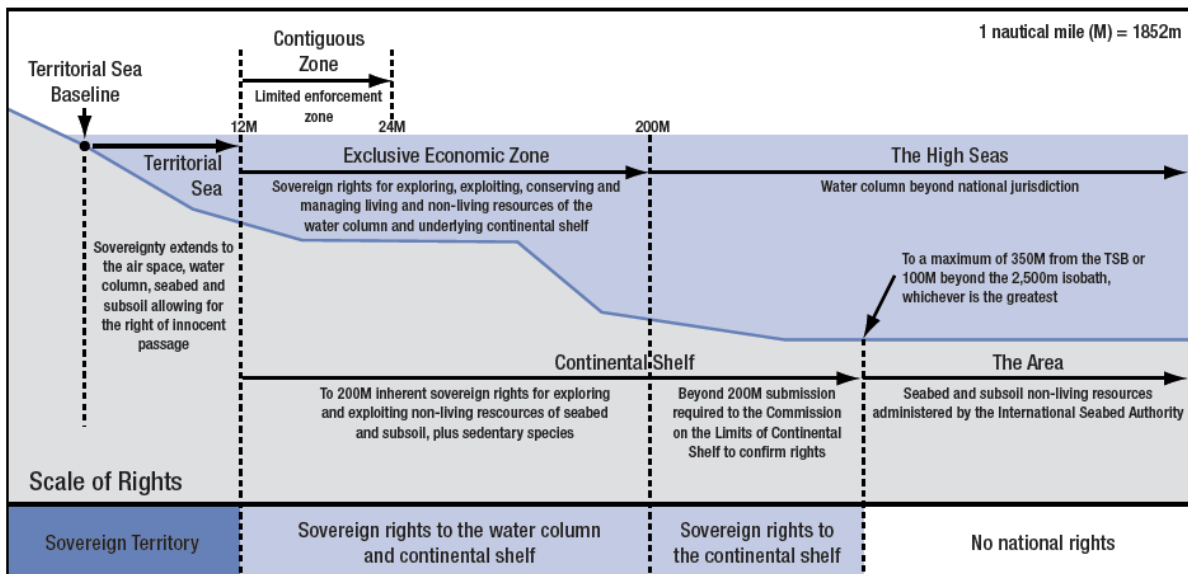
1. Geographical scope (i.e. maritime zones covered by the regime): ABNJ regime should cover both maritime zones, the Area as well as the water column beyond national jurisdiction – see **Figure 1** on the next page.
  - Sampling of MGR takes place in both (see also different sampling techniques)
  - Would solve the problem of samples moving between/found in both ecosystems.
2. Substantive scope (i.e. actual resources and activities regulated by the regime):
  - ABNJ regime should cover materials (samples of MGR from ABNJ), associated knowledge (data and research results) and capacities (technologies and biotech know-how)
  - ABNJ regime should address access as well as benefit-sharing
    - Access to *in situ* MGR from ABNJ should continue to fall under the freedom of MSR (see below)
    - Access to *ex situ* MGR from ABNJ and access to associated knowledge as well as capacities should be addressed as part of benefit-sharing under a multilateral system (see below).
3. Temporal scope:
  - No retroactivity
  - **Potential problem:** How to deal with existing collections containing MGR, i.e. distinguishing between ‘old’ and ‘new’ resources
    - MGR from ABNJ collected in the future as well as associated knowledge could be marked to identify their origin
    - Biorepositories and databanks could also be invited to include ALL MGR samples and associated knowledge within the multilateral system (i.e. pre- as well as post-regime, and those from ABNJ and within national jurisdiction) on a voluntary basis, which in fact could be easier to manage
    - **Potential problem:** Assuming a biorepository/databank decides to include all MGR/associated knowledge (i.e. from ABNJ as well as within national jurisdiction) in the multilateral system, what if a country of origin has given its PIC and granted MAT to do R&D on its resources and store the samples and knowledge, but third party transfer has not been approved?

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<sup>8</sup> Art. 13.1 (d)(ii) of the ITPGRFA regulates that ‘[...] a recipient who commercializes a product [...] that incorporates material accessed from the Multilateral System, shall pay to the mechanism [...], 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 who commercializes shall be encouraged to make such payment.’



Figure 1: Geographic scope of marine areas



Source: Arctic Council, *Arctic Marine Shipping Assessment 2009 Report* (Tromsø, Norway: 2009), p. 52, available at [www.pame.is/images/stories/PDF\\_Files/AMSA\\_2009\\_Report\\_2nd\\_print.pdf](http://www.pame.is/images/stories/PDF_Files/AMSA_2009_Report_2nd_print.pdf).

#### IV. Relationship with Other International Agreements and Instruments

- Part of an Implementing Agreement under UNCLOS
  - Nothing in the Implementing Agreement should prejudice the rights, jurisdiction and duties of states under UNCLOS; Implementing Agreement to be interpreted and applied in the context of and in a manner consistent with UNCLOS (see Art. 4 of the UN Fish Stocks Agreement)
  - Important to secure freedom of MSR, but also related obligations.
- Implementing Agreement should not affect rights and obligations of any Party deriving from any existing international agreement.
- Implementing Agreement should be implemented in mutually supportive manner with other relevant international instruments
  - Referring to the need to avoid conflicts with and rather complement the implementation of the CBD and its Nagoya Protocol (i.e. closing the existing gap and taking advantage of institutional structures created, such as ABS checkpoints).

#### V. Access

1. Access to (sampling of) *in situ* MGR should be subject to the principle of the freedom of MSR
  - Important aspect to get global support for an ABNJ ABS regime
  - Does not mean unlimited freedom, but freedom subject to
    - Environmental considerations (sustainability), and
    - MSR obligations<sup>9</sup>
  - Sustainability considerations could be addressed through EIA processes
    - EIA is another issue covered by the 'package deal'
    - EIAs conducted by flag states (in line with international standards) could mean less bureaucracy, more efficient processes and therefore limited burden for R&D

<sup>9</sup> Promoting international cooperation in MSR (Art. 242 & 143.3(a)); making knowledge resulting from MSR available by publication and dissemination (Art. 244.1 & 143.3(c)); promoting data & information flow & transfer of knowledge (Art. 244.2 & 144.2).

- Q: To what extent are EIAs already carried out? What is feasible keeping in mind that EIAs need a baseline while most of the *in situ* access/sampling is discovery (so there is no baseline)?
  - MSR obligations would be reflected under fair and equitable benefit-sharing
  - Sampling could be registered in Global Clearing House.
2. Access to *ex situ* MGR, associated knowledge (data and research results) and capacities (technologies and biotech know-how) would be addressed as part of the multilateral benefit-sharing system).

## VI. Fair and Equitable Benefit-sharing

1. Fair and equitable benefit-sharing could be achieved through a multilateral system which sets up a framework for the sharing of both
  - Non-monetary benefits arising from the utilization of MGR from ABNJ: Through the development of rules for efficient, effective, transparent and coherent implementation of the already existing MSR provisions under UNCLOS with regard to MGR from ABNJ
  - Monetary benefits arising from the utilization of MGR from ABNJ: Thereby promoting the 'realization of a just and equitable international economic order which takes into account the interests and needs of mankind as a whole and, in particular, the special interests and needs of developing countries' (Para 5 of the UNCLOS Preamble) and building a compromise to get global support for an ABNJ ABS regime.
2. Non-monetary benefits would include: Facilitated access to collected samples (*ex situ* MGR), associated knowledge (data and research results for *in silico* analysis) and related capacities (research infrastructure, including technologies and biotech know-how)
  - Objective: create global benefits, i.e. benefits for both developing and developed countries
  - Facilitation of different types of access could lead to more R&D opportunities; increased access by multiple actors to an initial resource, data or research infrastructure could increase the number of potential leads developed.
- 2.1 Access to/exchange of samples (*ex situ* MGR)
  - Examples of current practices:
    - Sample materials collected during drilling operations under the International Ocean Discovery Program
    - European Marine Biological Resource Centre
    - World Federation of Culture Collections.
  - Potential problems:
    - Sampling activities and storage vary depending on end usage/planned research
    - Correct curation, transport, etc. necessary to maintain samples
    - Integration/linkage of samples with associated environmental and metadata required
    - Samples of macroorganisms are finite (biomass might be exhausted/not sufficient for future research)
    - 90% of microbial strains cannot currently be cultured; interesting metabolic processes often linked to *in situ* environmental stimuli (which are difficult/impossible to replicate)
    - Q: If synthesized genes (based on data) can be placed in easy to grow microorganisms for expression of useful products, does this at least partly solve the problem(s)? I.e. can such practical limitations of physical access to MGR be mitigated through appropriate access to/exchange of associated knowledge?

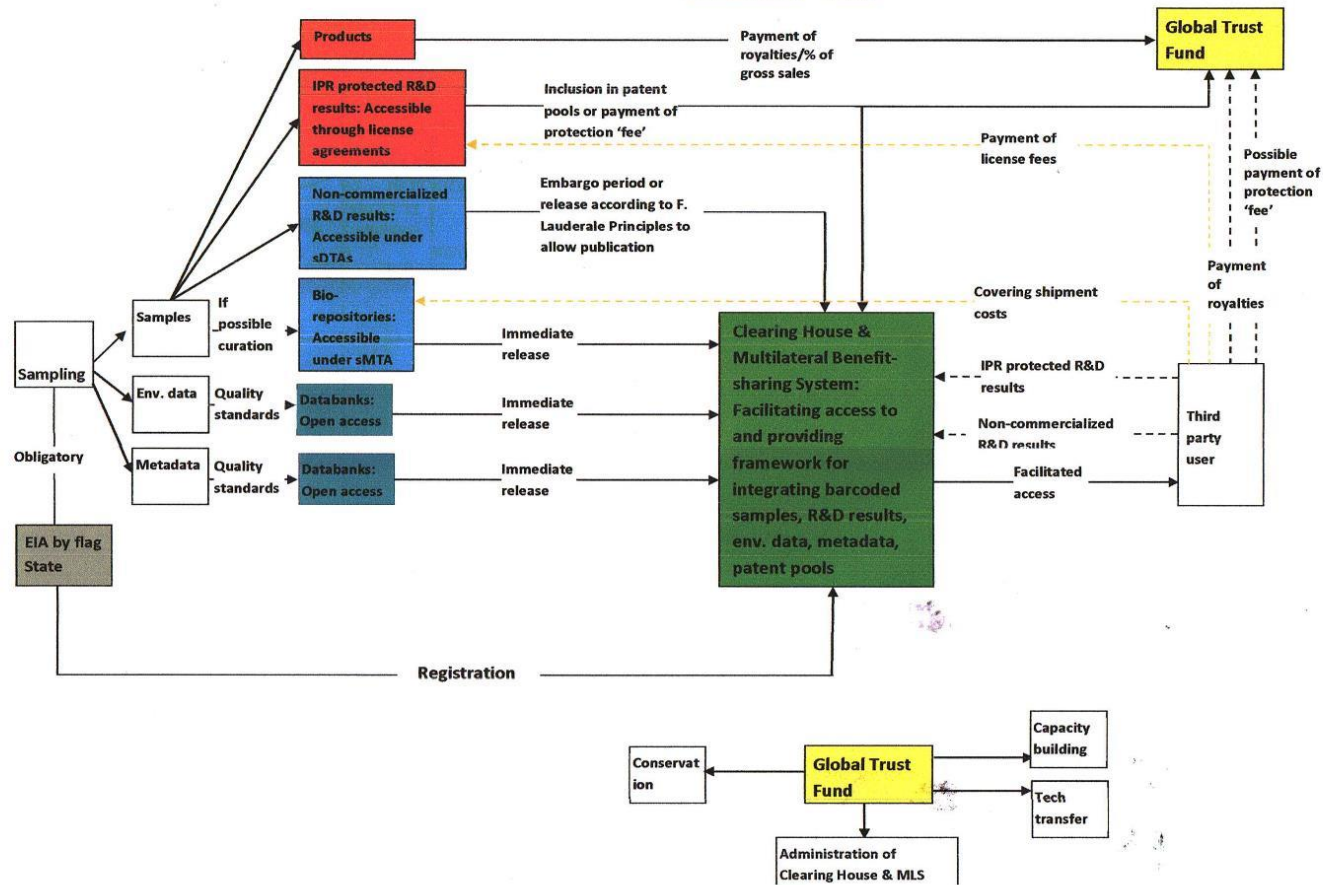


Figure 2: Visualization of a possible ABS regime for ABNJ<sup>10</sup>

<sup>10</sup> Inspired by Marcel Jaspars and Oonagh McMeel, 'The Marine Biodiscovery Pipeline' advanced draft; and Caroline von Kries, Graphs visualizing the MICROB3 Ocean Sampling Day Research Pipeline.

2. Non-monetary benefits would include: Facilitated access to collected samples (*ex situ* MGR), associated knowledge (data and research results for *in silico* analysis) and related capacities (research infrastructure, including technologies and biotech know-how)
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  - Potential structure:
    - Multilateral system would not consist of one single biorepository, but a network of biorepositories and/or virtual repository
    - **Q: What would be needed to establish such a network? Could a Global Clearing House plus a framework of standards and data integration be feasible and sufficient?**
      - Collections under management and control of a state (e.g. funded with public resources) and/or in the public domain could be obliged to join the multilateral system
      - Other (purely private) collections could be invited and encouraged to join the multilateral system.
    - No change of ownership in transactions, but only temporary transfer/loan
    - If material was finite:
      - **Q: Could there be a requirement to ensure a quantity of finite samples are stored in such a way to ensure nucleic acids can be extracted in the future (i.e. a form of conservation)**
      - **Q: Would it make sense and be feasible to give preferential physical access to researchers from or consortia including developing countries lacking capacities? If so, how could these countries and researchers be identified?**

- Q: Otherwise could samples become part of a virtual repository: e.g. chemical data-bank in Strathclyde's drug discovery portal<sup>11</sup>.
  - Global standards for curation, storage and transport to ensure sufficient quality
    - Q: Is it possible to curate and store samples in a way that they can be used for all types of research work in the future?
    - Q: Could this be considered to be a form of conservation bearing in mind that many samples cannot be cultured or viable tissue maintained ex situ.
  - Global standards for necessary associated environmental and metadata to ensure sufficient quality
  - Standard Material Transfer Agreement(s) (sMTA) regulating utilization of samples and sharing of associated knowledge resulting from R&D on the samples, potential third Party transfer and protection of IPR, costs of shipping and handling, etc.
    - To facilitate access/exchange click-wrap and shrink-wrap approaches could be considered<sup>12</sup>.
- 2.2 Access to/exchange of data
- Examples of current practices:
    - International Nucleotide Sequence Databases (INSD)<sup>13</sup>
    - InterRidge
    - Ocean Biogeographic Information System (OBIS)
    - Bermuda and Ft Lauderdale Principles<sup>14</sup>
    - Micro B3's Ocean Sampling Day (OSD) Programme
    - GSC's MixS standard
    - Strathclyde's drug discovery portal.
  - Potential problems:
    - Integration/compatibility of different data-sets
      - Q: Would it be possible to broaden INSD to include other genetic sequence databases? Would it be possible to transfer the INSD approach to other databanks, if any? Would INSD already provide the infrastructure needed, or to build on?

<sup>11</sup> Strathclyde's drug discovery portal is an example of a matchmaking service which runs virtual screens at users 'request. Users will be asked to sign an online user agreement as part of the registration process which will protect IPR. If hits are identified users are informed a match has occurred so that they have the opportunity to initiate a new collaborative project.

<sup>12</sup> Software manufacturers generally attach license agreements inside the packaging of their products, which bind the consumer to the terms of the agreement upon removal of the shrink-wrap (cellophane wrapping that seals boxes of mass marketed software). Click-wrap licenses are another form of creating an electronic agreement, except that the license is included on the computer screen before installation rather than on the box. By clicking on a button that says 'I agree' or 'I accept,' the licensee agrees to the terms of use of the contract. An important difference between click-wrap agreements and shrink-wrap agreements is that with click-wrap the user actually has an opportunity to read the contract before using or installing the program.

<sup>13</sup> Developed and maintained collaboratively between DNA Data Bank of Japan (DDBJ), European Nucleotide Archive (ENA), and GenBank for over 18 years.

<sup>14</sup> Bermuda Principles from 1996 ensured that the human genetic sequence was made available immediately in public databases with no terms or conditions on its use. Fort Lauderdale Principles entitle the data producers to make the first presentation and publish the first genome-wide analysis of the data. The data can be used freely for studies of individual genes or other individual features of these sequences.

- Q: Would it be possible to build on data integration work undertaken by projects like MICRO B3 or others?<sup>15</sup>
  - Potential embargo before release of data to the public
    - Q: Would immediate release as soon as sequenced be acceptable?<sup>16</sup>
    - Q: Would application of Bermuda or Fort Lauderdale Principles be acceptable?
  - Differentiation between precompetitive and competitive data
  - Cost implications of open source
    - Q: Will putting data in the public domain have considerable cost implications? Putting publications in open source might be costly.
    - Q: Is there a need to distinguish between data and literature publication (example of Tara Ocean).
  - Potential structure:
    - Funders could make it a requirement that associated knowledge is submitted to virtual repositories in order to make publicly available and share.
  - However, a researcher could still decide to protect research results (file a patent) which then trigger payment of a 'protection fee' (see monetary benefit-sharing below)
    - Access could be granted to all researchers (also from non- Parties), but exchange of data could take place according to standard Data Transfer Agreements (sDTA) regulating: use and reuse of data under viral license clause, IPR and benefit-sharing, quality standards
      - Q: Could sDTAs follow the creative commons license approach?
    - Associated knowledge developed through accessed data would need to be put in the public domain again (see approach taken under ITPGRFA); IPR protection would again trigger a payment of a 'protection fee'
    - Implementing Agreement could lead to the development/updating and adoption of standards for metadata and environmental data (contextual information) to make information as comprehensive and uniform as possible to aid different analysis pipelines
      - Q: Would standards for other data be needed, e.g. sequence data?
    - Custom-made software and other knowledge discovery tools to be developed to integrate different data sets and facilitate data-mining.
- 2.3 Access to/exchange of technology: expensive infrastructure (e.g. ocean vessels and ROVs) requiring sharing of ship time
- Examples of current practices:
    - Experiences from transnational initiatives (e.g. EUROLLEETS, Ocean Facilities Exchange Group, European Marine Biological Resource Centre)]
    - Experiences from bids to national agencies
    - Experiences from public-private partnerships (e.g. SERPENT project)
      - Q: Do we know about any specific problems of these existing practices? And if so, what are they?
      - Q: Could such national and regional initiatives be up-scaled to the global level?
- 2.4 Capacity-building
- Examples of current practices:
    - International Seabed Authority
    - Global Environment Facility

<sup>15</sup> Under MICRO B3 work is undertaken to provide an integrated view of microbial diversity and function in the marine environment; to develop innovative software approaches allowing users from biotechnology as well as ecosystems research to exploit information on microbial communities; and to support users in effectively managing, analysing, and sharing genomic and metagenomic data.

<sup>16</sup> See Ocean Sampling Day data policy.

- Regional projects, such as MICROB3 and others
    - Q: Do we know about any specific problems of these existing practices? And if so, what are they?
    - Q: What would be needed to scale up such national and regional capacity-building initiatives?
  - Potential structure:
    - Parties could be required to encourage their funding agencies to promote international collaboration in relevant R&D projects
    - Framework for developing international capacity-building programs (including infrastructure, tech and know-how transfer) could be set up with a special focus on researchers from developing countries
    - Framework for establishing data analysis working groups
      - Type of transparent collaboration where interested parties declare how they would like to contribute to the data analysis, which might help maximize the efforts of the scientific community and build the strongest possible interpretation of the data.
    - Establishment of a Scientific Coordination Council.
3. Monetary
- 3.1 Payments at outset of R&D (before access to in situ resources)
    - Usually only applied where clear commercial intent
    - **Problem:** Objective of sampling cruises mostly hybrid.
  - 3.2 Payments at milestones
    - When accessing ex situ resources, associated knowledge and technology
      - Q: Could a small amount be charged to those accessing the networks? Funds could be used by databanks to maintain/administer the system, or even to reward the ones who shared (creating an incentive to join).
    - When protecting research results (file for IPR)
      - 'General rule' could be that research results are put in the public domain
        - Reflecting Art. 241 UNCLOS '*Marine scientific research activities shall not constitute the legal basis for any claim to any part of the marine environment or its resources.*'
      - But if IPR is filed to protect research results, which is normal practice in current R&D, the IPR holder could be required to choose between
        - Either paying a 'Protection fee' (to be collected by a Global Trust Fund)
        - Or joining a patent pool (which could bring financial returns through license fees)
    - Same obligations would apply to third party that accesses data through the multilateral system and protects R&D results incorporating resources/associated knowledge accessed through the networks.
  - 3.3 Payments after commercialization
    - Royalties (share of income from gross sales of products)
      - Standard percentage (see ITPGRFA as an example)
        - Q: Would it make sense to establish different percentage rates for different sector products (to reflect the need for hire upfront investments in different sectors)?
      - To avoid unnecessary administrative burden, a global tax could be introduced
      - Funds to be collected and managed by a Global Trust Fund.
  - 3.4 Access to patent pools
    - Reflecting Art. 241 UNCLOS
    - IPR protected R&D results could be shared through different sector patent pools
      - Multiple patent holders agree to license their protected research results as a package to anyone willing to pay license fees, which are distributed among the patent owners

- Pool members license all patents in one package and avoid spending time to research the relevant patents and separately negotiate all licenses
- Sectoral approach as patent pools usually share IP with some commonalities in terms of innovation
- Objective of patent pools would be to support further innovation
  - In situations where a manufacturer has to license a number of patents from multiple patent holders, the price of the product shoots up; negotiating such patent thickets pose serious challenges (in particular for developing countries); licenses may be available but the transaction costs in dealing with the patent thickets are prohibitive.
- Development of non-exclusive licenses<sup>17</sup>
  - Inclusion of so-called virus effect provision/viral clause: When the protected work is being redistributed, the new distributor has to redistribute the work under the same or an equivalent license, even if the work has been modified
  - **Q: Could we also argue that joining a patent pool also potentially increases the chances of financial returns (holding a patent does not necessarily lead to placing a product on the market; however, through licenses patent holders have an effective way to share their innovations and may be compensated by a fair royalty).**

## **VII. Monitoring and Compliance**

### 1. Monitoring

- **Potential problem:** MGR found in horizontal transboundary situation (water columns within vs. beyond national jurisdiction)
  - Issue to be solved through proper recording: records are normally kept what kind of sample is taken and from where
  - Codes of conduct for researchers could advise not to sample within a certain distance from the boundary in order to avoid confusion/lack of clarity.
- **Potential problem:** MGR found in vertical transboundary situation (water column beyond national jurisdiction which is in ABNJ vs. extended continental shelf of coastal states which is within the scope of the CBD and its Nagoya Protocol)
  - Issue to be solved through proper recording: records are usually kept what kind of sample is taken and from where
  - MGR from water column beyond national jurisdiction and from non-sedentary species from the extended continental shelf (not covered by Art. 77 UNCLOS) would fall under ABNJ ABS regime
  - MGR from sedentary species would not be covered by ABNJ ABS regime, i.e. only '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' (Art. 77.4 UNCLOS).
- **Potential problem:** Could forum shopping become a problem? (ie Would researchers find themselves in the position that they chose cruise paths to avoid what they consider to be burdensome administrative procedures?)
  - Cruise paths are recorded and sampling is logged carefully (by national agencies and international organizations).

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<sup>17</sup> Under a non-exclusive license the licensor grants a right to use the intellectual property (or product) to more than one licensee simultaneously. That is to say, unlike exclusive licenses, non-exclusive licenses can be granted to several users at the same time. It is important to note that the sale of non-exclusive licenses provides the opportunity to increase the earnings of a product, while the owner also maintains a certain level of control.



- **Potential problem:** Distinction between samples and associated knowledge from ABNJ (covered by the regime) and those from within national jurisdiction (covered by the CBD and its Nagoya Protocol) stored in the same biorepository/databank
    - Unique identifiers could be used to help distinguish (see for example practices under the MOSAICC Code of Conduct<sup>18</sup>).
  - **Potential problem:** Distinction between MGR in public and private biorepositories/databanks
    - Biorepositories/databanks under management and control of a state (e.g. funded with public resources) and/or in the public domain could be obliged to join the multilateral system
    - **Q: Is the assumption correct that in practice most R&D is at least partly funded by the public? This would put the problem into perspective**
    - Other (purely private) biorepositories/databanks could be invited and encouraged to join the multilateral system (see example of ITPGRFA<sup>19</sup>).
  - **Q: How could utilization of samples and data be monitored?**
    - Unique identifiers for collected samples and data?
    - Reporting to Global Clearing House
    - Checkpoints at national level.
2. Compliance
- **Q: What incentives could promote non-monetary benefit-sharing?**
    - Access to networks could generally be restricted to Parties
    - Parties to follow or expand the EU approach of “trusted collections” to “trusted research institutions”: Those willing to share receive a special status which will allow access to the networks.
  - **Q: How to deal with non-Parties?**
    - Researchers from non-Parties could be invited to join on a voluntary basis (see also example from ITPGRFA), but need to fulfil certain compliance criteria
    - Benefit would be that they get access to the networks.
  - **Q: Would free-riding be a potential problem?**
    - Or could this be avoided through registration processes?
  - **Q: What sanctions could be envisaged?** Being an international legal instrument, an Implementing Agreement can only set obligations for States, not for non-State actors (such as individuals, institutions)! At the same time, sanctions should not be addressed to the State as a whole, but only individuals and institutions in non-compliance should be held liable in the end. States could be obliged to take measures against individuals/institutions in non-compliance, such as
    - Fines
    - Restriction of access to future public research funding
    - Following or expanding the EU approach of “trusted collections” to “trusted research institutions”: Those in non-compliance could lose their status and face restriction of access to the networks.

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<sup>18</sup> The Micro-organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC) developed by the World Federation of Culture Collections foresees that members register their culture collections through a unique acronym and numerical identifier, and catalogue their microbiological resources. The culture collection acronym and its unique number facilitate access to data for multiple purposes: scientific, technical, administrative, etc.

<sup>19</sup> Under the ITPGRFA, if a collection is managed without direct Government control, it is not prima facie covered. Instead, the collection is only included in the Multilateral System with the consent of the institution concerned. However, Parties agree to take appropriate measures to encourage natural and legal persons within their jurisdiction who hold GR listed in Annex I of the ITPGRFA to include such resources in the Multilateral System.

***VIII. Other Issues to Consider***

- Financial resources to administer the multilateral system
  - Perhaps at least partly through Global Trust fund
- Contribution to conservation, sustainable use and promotion of future R&D
  - Perhaps at least partly through Global Trust Fund
- Transboundary cooperation
- Codes of conduct/guidelines/standards
- Awareness-raising.

## Appendix 4: Discussion Paper for MGR Workshop 2: *Mare Geneticum*: Balancing Governance of Marine Genetic Resources In International Waters<sup>20</sup> \*

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### Abstract

A fair and effective regime regulating benefit-sharing of marine genetic resources (MGR) in areas beyond national jurisdiction (ABNJ) must consider inclusivity of developing states, as well as support scientific research and safeguard investments of the private sector. The present innovative proposal ensures a delicate balance through an approach based on open access, albeit with limitations. Access to MGR in ABNJ is facilitated, but conditional to the public release of the collected samples and raw data. The adoption of the principle of open access guarantees a powerful form of non-monetary benefit-sharing. The balance is maintained by the option for an extended embargo period, allowing samples and data to be kept confidential for a certain period, against payment to a biodiversity contribution fund. Monetary benefit-sharing, as a sector-negotiated percentage on revenue, could be imposed at the point of product commercialization, and would offer a tangible payment system with a low transaction cost.

### Key Words

Marine genetic resources; areas beyond national jurisdiction; biodiversity, Law of the Sea; benefit-sharing; research; open access.

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## Introduction

*Mare Liberum*. Freedom of the seas. When Hugo Grotius wrote this piece in 1609,<sup>21</sup> one of the foundations of contemporary maritime legal doctrine, the seas of this world had been a *de facto* synonym of freedom for centuries already. In his view the world's oceans were to be freely accessible to all and shared amongst nations. This was not globally accepted then, and his work was a direct response to the Portuguese maritime policy claiming exclusivity of traffic to the East Indies for trade purposes.<sup>22</sup> From the English point of view, John Selden's *Mare Clausum* was also claiming a monopoly over fishing rights in the North Sea.<sup>23</sup>

Nevertheless, Grotius's *Mare Liberum* left us with a heritage of thoughts tending towards the consideration of the oceans as a common space and common resource to be "free and open to all".<sup>24</sup> And even though coastal States' creeping jurisdiction into the ocean has continuously increased over the 20<sup>th</sup> century,<sup>25</sup> there is still 40%<sup>26</sup> of this planet's surface (64% of the surface of the oceans) that is in the international areas of the High Seas<sup>27</sup> and the Area,<sup>28</sup> commonly referred to as areas beyond national jurisdiction (ABNJ).

The Freedom of the High Seas that all sailors of this world already knew and cherished slowly began to become a "relative" freedom as the international community was cooperating to regulate certain activities that occur in ABNJ. The 1958 Geneva Convention on the High Seas<sup>29</sup> addresses what can and cannot be controlled in international waters, e.g. piracy, pollution, and the discretion of warships.

In 1982, with the adoption of the United Nations Convention on the Law of the Sea (LOS),<sup>30</sup> the jurisdiction of coastal States was further extended. The freedom of the High Seas, though recognised as a principle, was further restricted. In the Area for example the exploitation of minerals became regulated as the Common Heritage of Mankind.<sup>31</sup>

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<sup>21</sup> H Grotius *Freedom of the Seas, or, the right which belongs to the Dutch to take part in the East Indian trade* (Oxford University Press, New York, 1916).

<sup>22</sup> MB Vieira, 'Mare Liberum vs. Mare Clausum: Grotius, Freitas, and Selden's debate on dominion over the seas' (2003) 64(3) *Journal of the History of Ideas* 361-377, at p. 361.

<sup>23</sup> *Ibid.*, at p. 362.

<sup>24</sup> H Grotius (1916), at p. 32.

<sup>25</sup> E Franckx, 'The 200-Mile Limit: Between Creeping Jurisdiction and Creeping Common Heritage? Some Law of the Sea Considerations from Professor Louis Sohn's Former LL.M. Student' (2007) 39(3) *The George Washington International Law Review* 467-498, at p. 469 et seq.

<sup>26</sup> See the Global Environmental Facility, available at <http://www.thegef.org/topics/areas-beyond-national-jurisdiction>; accessed 18 January 2017.

<sup>27</sup> United Nations Convention on the Law of the Sea (Montego Bay, 10 December 1982, in force 16 November 1994), 1833 UNTS 396, Art. 87.

<sup>28</sup> *Ibid.*, Art. 1(1).

<sup>29</sup> Convention on the High Seas (Geneva, 29 April 1958, in force 30 September 1962), 450 UNTS 11.

<sup>30</sup> LOSC (n 7).

<sup>31</sup> *Ibid.*, Art. 136.

Despite appearances, however, Grotius’s heritage has not been slowly erased but rather operationalized. The pillar of his argument for freedom relied on the idea of sharing a common thing: the sea.<sup>32</sup> The current tendency to regulate these traditionally lawless areas is not occurring in a *mare clausum* type of policy, but rather following the recognition that there is a further need for sharing the resources provided by our planet. This comes with realising the need for international cooperation and regulation to put the adequate frameworks in place within which such sharing can happen.

It is in the context of this ideology of global sharing that the international community is today in the process of negotiating a new international legally-binding instrument (ILBI) under LOSC. Launched by the UN General Assembly in 2004,<sup>33</sup> the purpose of the “biodiversity beyond national jurisdiction” (BBNJ) process was to assess the status of conservation and sustainable use of marine biodiversity in ABNJ and to investigate the potential need for further international cooperation. The BBNJ process led the General Assembly to launch the development of the aforementioned ILBI in 2015, establishing a Preparatory Committee for the purpose of providing recommendations on the elaboration of a draft text, to be delivered by the end of 2017.<sup>34</sup>

The Preparatory Committee “shall address the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction, in particular, together and as a whole, marine genetic resources, including questions on the sharing of benefits [...]”.<sup>35</sup>

When considering the question of marine genetic resources (MGR) and the sharing of benefits in this BBNJ context, the international community has come a long way from Hugo Grotius’s conception – but not that long. Grotius had a spatial approach to the freedom of the seas, arguing that access and navigation was the right of all for “the sea is common to all”.<sup>36</sup> The international community has moved from sharing the ocean space freely to sharing its natural resources in an organised and regulated fashion, in particular commodities like fisheries and minerals.

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<sup>32</sup> Grotius (1916), at p. 22 *et seq.*

<sup>33</sup> UNGA Res. 59/24, UN Doc. A/RES/59/24, 17 November 2004, para. 73

<sup>34</sup> UNGA Res. 69/292, UN Doc. A/Res/69.292, 6 July 2015, para. 1(a).

<sup>35</sup> *Ibid.*, para. 2.

<sup>36</sup> Grotius (1916), at p. 28.

Centuries later, the BBNJ process is now trying to govern and regulate the less tangible but nevertheless valuable biodiversity, with the aim of enhancing access for scientific research on MGR in ABNJ and for the sharing of benefits arising from their utilisation.<sup>37</sup> This enhanced access to MGR can of course not be regarded independently from the overarching objectives of sustainable use and conservation of marine biodiversity in ABNJ. In its modern and evolved version, the *Mare Liberum* of the 17<sup>th</sup> century thus finds its echo in the *Mare Geneticum* of the 21<sup>st</sup> century.

In recent years, many comprehensive doctrinal studies have been written on the topic of MGR in ABNJ, analysing international cooperation issues, identifying legal gaps and illustrating possible interpretations. Hence, the present article will not introduce the history and diplomacy behind the BBNJ process,<sup>38</sup> neither will it analyse in depth the legal issues surrounding the discussion. Enshrined in the *Mare Geneticum* approach of shared access and utilization, this article provides a pragmatic approach to the MGR in ABNJ component of the new ILBI, aiming to inform and inspire the BBNJ negotiations during and after the work of the Preparatory Committee. The analysis will cover all three pillars of an access and benefit-sharing (ABS) regime: access; benefit-sharing; and compliance.

This article first gives an overview of the building blocks of the proposed governance regime. It then lays out the scientific and technical foundations forming the rationale of our proposal. This includes findings based on recent technical analyses on the market value of MGR in ABNJ and the gaps in research capabilities of States, and indications where relevant data is not available and further studies might be needed. In addition, the experiences gained from ABS regimes under the Convention on Biological Diversity (CBD) and its Nagoya Protocol are also referred to.<sup>39</sup>

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<sup>37</sup> For a comprehensive description of access to marine genetic resources within national jurisdiction of coastal States, see LE Lallier, O McMeel, T Greiber, T Vanagt, AD Dobson and M Jaspars, 'Access to and use of marine genetic resources: understanding the legal framework' (2014) 31(5) *Natural Products Reports* 612-616; and LE Lallier, A Broggiato, D Muyltermans and T Vanagt, 'Marine Genetic Resources and the Access and Benefit-Sharing Legal Framework' in LJ Stal and MS Cretoiu (eds.), *The Marine Microbiome - An Untapped Source of Biodiversity and Biotechnological Potential* (Springer International Publishing, Switzerland, 2016) 453-472.

<sup>38</sup> A Broggiato, S Arnaud-Haond, C Chiarolla, and T Greiber, 'Fair and equitable sharing of benefits from the utilization of marine genetic resources in areas beyond national jurisdiction: Bridging the gaps between science and policy' (2014) 49 *Marine Policy* 176-185, at p. 179-181.

<sup>39</sup> Convention on Biological Diversity (Rio de Janeiro, 5 June 1992, in force 29 December 1993), 1760 UNTS 79; Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the 1992 Convention on Biological Diversity (Nagoya, 29 October 2010, in force 12 October 2014), UNEP/CBD/COP/DEC/X/1.

The core of this article further develops each building-block of the proposed governance regime for MGR in ABNJ. This is followed by illustration of how the scientific community is implementing in practice the concept of open access to data and samples as applicable to marine scientific research (MSR) in ABNJ, as we are proposing with this article. The final section illustrates a potential centralized compliance system, before summing up the whole proposed governance regime.

### Overview and scope of the proposed building blocks

The proposed governance regime can be divided in three steps that build on the CBD and the Nagoya Protocol, access, benefit-sharing, and compliance, as shown on the vertical axis of Figure 1. However, it is not the ambition or purpose of this paper to provide with detailed or final solutions, in particular with regards to enforcement or implementation measures. Rather, *Mare Geneticum* seeks to propose sound basic principles for the establishment of a realistic and functioning MGR regime in ABNJ.

In this regime, *in situ* access to MGR in ABNJ is facilitated through a simple notification step: the Obligatory Prior Electronic Notification (OPEN). The online notifications submitted by (prospective) users should be managed by the international organisation that will likely be established or mandated by the ILBI. However, the user must accept certain conditions for the OPEN to be recorded: the obligation to share non-monetary and monetary (when applicable) benefits arising from the utilization of the MGR.

The main non-monetary benefit is based on the open access (OA) principle: releasing samples and raw data (metadata and, if applicable, sequence data and biochemical data) to the public domain through openly accessible biorepositories and databases. Connecting various collections around the globe will strengthen existing and newly created networks of biorepositories, or “common pools” of MGR.<sup>40</sup> Their coordination coupled with the OA approach will make *ex situ* access consequently as facilitated as *in situ* sampling through the same OPEN system.

To safeguard the interests of scientists and of commercial users, limitations to the OA principle can be awarded *via* an embargo period that will allow a user to keep material and data privately for a certain period, e.g. to safeguard confidentiality while publishing the first results of a research or while applying for a patent. When needed, the embargo could be extended, triggering the payment of an exclusivity fee as a counterpart.

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<sup>40</sup> Broggiato *et al* (2014), at p. 181; T Greiber, ‘Common pools for marine genetic resources: a possible instrument for a future multilateral agreement addressing marine biodiversity in areas beyond national jurisdiction’, in EC Kamau and G Winter (eds.), *Common Pools of Genetic Resources – Equity and Innovation in International Biodiversity Law* (Routledge, London and New York, 2013), 399-414, at p. 407-411; G Wright, J Rochette and T Greiber, ‘Sustainable Development of the Oceans: Closing the Gaps in the International Legal Framework’ in V Mauerhofer (ed.), *Legal Aspects of Sustainable Development* (Springer International Publishing, Switzerland, 2016) 549-564, at p. 556.



This will allow users to further advance their research and to safeguard their investments. However, as will be further explained, it should be noted that in practice, the likelihood of confidentiality needs due to major discoveries is fairly limited. Small up-front payments for short-term exclusivity represent a better chance of revenues to feed in an international fund put in place by the ILBI. Considering the low proportion of real lucrative outcomes from blue biodiscovery and hence the unlikelihood of sufficient revenue to be redistributed directly to State parties, as further explain below, it is advisable to set up a contribution fund for monetary benefits. Such a fund should be dedicated to the functioning of an international organisation, if any is to be mandated by the ILBI: for the regular implementation and management of the relevant MGR provisions: as well as to contribute to the conservation efforts of the three other building blocks of the BBNJ package, namely environmental impact assessments, marine protected areas and technology transfer. The *Mare Geneticum* approach thus offers three possibilities to users:

- Open Access to MGR and data;
- Embargo period (relatively short);
- Exclusivity against payment.

If monetary benefits, additional to the exclusivity fee, would be requested in the ILBI, we suggest these to be linked to the commercialization of a product derived from MGR coming from ABNJ, and not to the R&D. To reduce the transaction cost and to maximize predictability to attract investments from the private sector, a fixed percentage could be fixed per sector.

Compliance will be ensured through the centralized system of the OPEN registry whereby reports and additional conditions arising during the lifespan of MGR and data utilisation will kept and tied to it, enabling easy tracking and tracing.

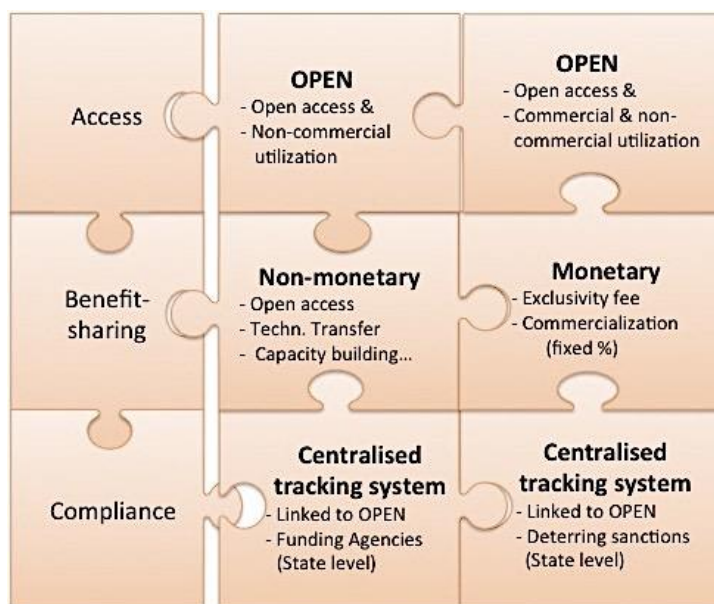


Figure 1: The matrix of *Mare Geneticum*

## Rationale for *Mare Geneticum*

### Premises

The premises of the present proposal are based on the need for a multilateral system to regulate MGR from ABNJ and the importance of sustaining scientific research undertaken by both public and private users.

This article acknowledges that ensuring the sustainable use of MGR from ABNJ together with the fair and equitable sharing of the benefits arising from their utilization is possible only by bridging the gap between those countries that hold knowledge, MGR and technologies, and those that do not,<sup>41</sup> in order to achieve a more “[...] equitable and efficient utilization of their (seas and oceans) resources” as stated in the fourth paragraph of the Preamble to the LOSC.

Given the absence of national jurisdiction in the geographical area concerned, any regime regulating ABS of MGR needs to be multilateral in order to be effective. Moreover, access should be granted upon pre-defined conditions, as the case-by-case negotiation of terms would increase the costs, lengthen the administrative procedure and, most importantly, impair legal certainty for the users. The ILBI must provide legal certainty and stability both for the scientific community and for the private sector. Indeed, being able to assess (financial) risks at the onset of research and development (R&D) would provide companies with the stable environment in which they can make the necessary investments.

A multilateral approach also ensures consistency by not differentiating between the water column (High Seas) and the seabed (Area) in ABNJ as neither science nor the definition of MGR justifies such a differentiation.<sup>42</sup> Support for this overarching approach lies in the UN General Assembly decision on the development of an ILBI, which while requiring action under the framework of LOSC:

“...2. Also decides that negotiations shall address the topics identified in the package agreed in 2011, namely the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction, in particular, together and as a whole, marine genetic resources, including questions on the sharing of benefits, measures such as area-based management tools, including marine protected areas, environmental impact assessments and capacity-building and the transfer of marine technology;”<sup>43</sup>

<sup>41</sup> Broggiato *et al* (2014), at p. 183.

<sup>42</sup> Conservation and Sustainable Use of Marine Biological Diversity of Areas beyond National Jurisdiction: Preparing for the PrepCom, Report of the BBNJ Workshop of the Centre for International Law, National University of Singapore, February 2016, available at <http://cil.nus.edu.sg/wp/wp-content/uploads/2015/10/CIL-report-of-BBNJ-workshop-21-March-2016-final-2.pdf>; accessed 18 January 2017.

<sup>43</sup> UNGA Res. 69/292 (2015), para. 2.

MSR is crucial to advance knowledge of marine biodiversity, ecology and ecosystem processes, and for its role in the provision of ecosystem services and the maintenance of ocean health for the benefit of humankind. Advancing our knowledge of the marine environment brings many environmental, social and economic benefits<sup>44</sup>, contributing to food security, conserving and managing the marine environment and resources, helping to understand, predict and respond to natural events and to human impacts and processes, eradicating poverty and contributing to sustainable development.<sup>45</sup> Besides, scientific research on MGR leads to applications in biotechnology. Therefore, the strategic purpose of an ILBI should be to promote MSR and further downstream research directed to advancing scientific knowledge and understanding of the oceans for the wider long-term benefit of humanity.<sup>46</sup>

Advances in science require the availability of research material, samples and data, together with advanced technologies and research capabilities. To facilitate access to MGR in ABNJ, the governance mechanism should be based on a principle of OA by coupling light -touch procedures with the obligation to share the raw data and to deposit samples in publicly accessible biorepositories (see *infra*). OA refers to research outputs that are free of all restrictions on access (e.g. access tolls). Quite importantly though, it does not necessarily mean free utilisation as some restrictions or conditions of use may be attached to the accessed material or data. For example, some databases of images available online currently associate certain copyright and license restrictions on the use of such images (e.g. forbidden sales, limited modifications...), without restricting access as such.

To ensure that regulations arising out of ILBI are not overly burdensome or even inapplicable in practice,<sup>47</sup> an excellent understanding of the MSR process is an absolute necessity. The involvement of the marine scientific community is therefore of paramount importance: we echo the need to bridge the gaps between science and policy.<sup>48</sup>

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<sup>44</sup> H Harden-Davies, 'The regulation of marine scientific research: addressing challenges, advancing knowledge' in RM Warner and SB Kaye (eds.), *Routledge Handbook of Maritime Regulation and Enforcement* (Routledge, Abingdon, 2016) 212-230, at p. 216.

<sup>45</sup> UN Report of the Secretary-General UNGAOR, UN Doc. A/64/66/Add.2, 19 October 2009, para. 15.

<sup>46</sup> Harden-Davies (2016), at p. 228; P Oldham, S Hall, C Barnes, C Oldham, AM Cutter, N Burns, and L Kindness, 'Valuing the Deep: Marine Genetic Resources in Areas Beyond National Jurisdiction' (Defra, London, 2014) 1-241, at p. 18.

<sup>47</sup> A Broggiato, 'Exchange of information on research programs regarding marine biodiversity in areas beyond national jurisdiction' in IUCN information papers for the intersessional workshop on marine genetic resources in ABNJ (IUCN Environmental Law Center, Bonn, 2013) 55-62, at p. 55; Harden-Davies (2016), at p. 218. Available at <http://www.un.org/depts/los/biodiversityworkinggroup/documents/IUCN%20Information%20Papers%20for%20BBNJ%20Intersessional%20Workshop%20on%20MGR.pdf>; accessed 18 January 2017.

<sup>48</sup> Broggiato *et al* (2014), at p. 176.

## Scientific and technical baseline

### Commercial value of MGR in ABNJ

Prior to discussing potential benefit-sharing arrangements related to MGR in ABNJ, their actual commercial value should be assessed. Are the expectations of large financial gains from the utilisation of MGR in ABNJ realistic?

Uncertainty has been raised about the actual likelihood of commercialisation following R&D on MGR,<sup>49</sup> and too much emphasis has generally been placed on monetary benefit streams. Indeed, there is currently little evidence of systematic commercial-scale development of MGR from ABNJ.<sup>50</sup> Furthermore, it is important not to conflate the potential of MGR in ABNJ with the more prolific commercialization of marine biodiversity products from shallower waters, primarily within coastal States' jurisdiction.<sup>51</sup> In theory, marine biodiversity has enormous potential. Biochemists are often effusively enthusiastic about the diversity of biomolecules produced by marine organisms compared to their terrestrial counterparts. However, to date, the realization of this potential in relation to ABNJ has been slow compared to national jurisdictions.<sup>52</sup> Therefore, while the potential for development has been widely stated,<sup>53</sup> its appreciation still requires further study. Moreover, a comprehensive study reviewing the full spectrum of monetary and non-monetary benefits that could be derived from MGR in ABNJ would also be invaluable, as there appears to be none at this stage.<sup>54</sup>

That there is evidence of commercial interest can be seen from evidence that there are currently a number of patents and pending applications based on MGR in ABNJ, from both the Area and the high seas.<sup>55</sup> Nevertheless, the existence of such patents does not indicate the eventual development of marketable products. Moreover there is an increasing evidence of academia seeking patents to protect their IPs, even without true commercial intent.

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<sup>49</sup> DK Leary and SK Juniper, 'Addressing the Marine genetic resources issue: Is the debate heading in the wrong direction?' in C Schofield, S Lee and MS Kwon (eds) *The Limits of Maritime Jurisdiction* (Martinus Nijhoff Publishers, Leiden, 2014) 769-785, at p. 773; and D Leary, M Vierros, G Hamon, S Arico, and C Monagle, 'Marine Genetic Resources: A Review of Scientific and Commercial Interest' (2009) 33 *Marine Policy* 183-194, at p. 187.

<sup>50</sup> Leary and Juniper (2014), at p. 773; SK Juniper, 'Technological, Environmental, Social and Economic Aspects of Marine Genetic Resources' in IUCN information papers for the intersessional workshop on marine genetic resources in ABNJ (IUCN Environmental Law Center, Bonn, 2013) 15-21, at p. 20-21.

<sup>51</sup> Oldham *et al* (2014), at p. 197.

<sup>52</sup> Juniper (2013), at p. 19.

<sup>53</sup> *Ibid.*; and Oldham *et al* (2014), at p. 182.

<sup>54</sup> L Glowka, 'Evolving Perspectives on the International Seabed Area's Genetic Resources: Fifteen Years after the Deepest of Ironies' in D Vidas (ed.) *Law, Technology and Science for Oceans in Globalisation* (Martinus Nijhoff Publishers/Brill, Leiden/Boston, 2010) 397-419, at p. 415.

<sup>55</sup> M Vierros, C Salpin, C Chiarolla and SM Arico 'Emerging and unresolved issues: The example of seabed and open ocean genetic resources in areas beyond national jurisdiction' in SM Arico (ed.), *Ocean sustainability in the 21st century* (Cambridge University Press, Cambridge, 2015) 198-232, at p. 212.

Finally, distinguishing new MGR discoveries within national jurisdictions from those in ABNJ should be encouraged in a more systematic manner. To this end, the UNESCO Intergovernmental Oceanographic Commission added the option “areas beyond national jurisdiction” for geographical search in the new version of the Ocean Biogeographic Information System (OBIS) platform. OBIS is a global data sharing platform and clearing house for marine biodiversity (biogeographic and biometric) data in all oceans, hosted by the International Oceanographic Data and Information Exchange (IODE). MarinLit, the Royal Society of Chemistry database, is also of interest as it gives the location, when available, of organisms from which compounds were derived, clearly showing that most are derived from the EEZ.<sup>56</sup>

### Gaps in research capabilities of States

In order to propose the widest acceptable options for the ILBI governance system, one must identify the areas where the inequalities between States are most pronounced. The analysis should focus on the actual availability of MGR from ABNJ and the capacities needed to study and exploit them.<sup>57</sup> Genetic resources can be accessed in different ways: *in situ*, *ex situ*, and *in silico*. Access to *in-situ* resources means collecting samples of marine organisms (containing genetic material) within their natural surroundings. Access to *ex situ* MGR occurs when the resources are accessed away from their natural surroundings such as from culture collections, museums and research institutions; while *in silico* normally describes directly accessing genetic data such as whole genomes or isolated gene sequences, with or without functional annotations, or biochemical data on gene products such as proteins, peptides and metabolites.

Recent technical analyses showed uneven levels of access to MGR between a small group of developed countries and the rest of the world, mostly for the following reasons:

1. The cost of technology to sample in international waters and the deep-sea, and the cost of its maintenance;<sup>58</sup>
2. The scientific skills to undertake research on marine biodiversity;<sup>59</sup>
3. The cost and scientific skills to undertake molecular screening and biodiversity assessment;<sup>60</sup>
4. The scientific skills to analyse the data thereby produced.<sup>61</sup>

<sup>56</sup> MarinLit is a database dedicated to marine natural products research. <http://pubs.rsc.org/marinlit/>

<sup>57</sup> Glowka (2010), at p. 411-412.

<sup>58</sup> Broggiato *et al* (2014), at p. 177; Juniper, (2013) at p. 15-17; Juniper ‘Use of Marine Genetic Resources’ in M Banks, C Bissada, PE Araghi (eds) *The First Global Integrated Marine Assessment World Ocean Assessment I under the auspices of the United Nations General Assembly and its Regular Process for Global Reporting and Assessment of the State of the Marine Environment, including Socioeconomic Aspects* (UN, 2016), Chapter 29, at p. 6.

<sup>59</sup> Juniper (2016), at p. 9; Juniper (2013), at p. 16-17.

<sup>60</sup> Broggiato *et al* (2014), at p. 179.

<sup>61</sup> Juniper (2016), at p. 7; G Shimmiel, ‘Extent and Types of Research, Uses and Applications’ in *IUCN information papers for the intersessional workshop on marine genetic resources in ABNJ* (IUCN Environmental Law Center, Bonn, 2013), 7-15, at p. 13.

In 1995, only six countries had the technological, financial and human resources to directly access MGR *in situ* in ABNJ (Finland, France, the United Kingdom, Japan, Russia and the United States of America).<sup>62</sup> In 2012, twenty-nine countries, both developed and developing, had access to MGR from hydrothermal vents as members of InterRidge, (the International Cooperation in Ridge-Crest Studies),<sup>63</sup> a cooperation organisation, and of the Pacific Islands Applied Geoscience Commission.<sup>64</sup> However, notwithstanding the wider access to deep-sea sampling technologies, disparity remains.<sup>65</sup>

Another important capability to derive value from marine biodiversity is the specialist scientific skills required to identify species, both known species and those new to science.<sup>66</sup> Marine biodiversity specialists are mostly trained in developed countries with a long history of botanical and zoological scholarship in universities and museums. A recent review of the literature revealed that the majority of publications in the field of marine biodiversity come from relatively few developed countries.<sup>67</sup> These specialists are experts in the morphological identification of specimens (classical taxonomy) and, increasingly, the interpretation of DNA sequence information to identify marine plants, animals and microbes (molecular taxonomy). There is a global scarcity of taxonomists able to identify marine flora and fauna. This problem is particularly acute for a range of marine invertebrate phyla.<sup>68</sup>

Various scientific approaches to undertake molecular screening and analyse the acquired data, such as microbial metagenomics, also require sophisticated bioinformatics tools and training which are most accessible in developed countries.<sup>69</sup> Nevertheless some capabilities in bioinformatics and genomics exist in developing countries, particularly in the health and agricultural science sectors, and these skills could be adapted and applied to the exploitation of MGR.<sup>70</sup> Moreover, there are capacity building initiatives aiming at lowering this disparity. The UK's Wellcome Trust for example provides training in genetic data analysis (mainly on human genome and human pathogens) to developing countries, as does Japan's National Institute of Technology and Evaluation.

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<sup>62</sup> Glowka (2010), at p. 412.

<sup>63</sup> Available at [www.interridge.org](http://www.interridge.org); accessed 18 January 2017.

<sup>64</sup> Glowka (2010), at p. 412.

<sup>65</sup> Broggiato *et al.* (2014), at p. 179; Juniper (2013) at p. 15-16; Juniper (2016), at p. 6.

<sup>66</sup> I E Hendriks and CM Duarte, 'Allocation of effort and imbalances in biodiversity research' (2008) 360(1) *Journal of Experimental Marine Biology and Ecology* 15–20, at p. 17; Juniper (2016), at p. 7.

<sup>67</sup> *Ibid.* Hendriks and Duarte, at p. 18.

<sup>68</sup> Available at [www.publications.parliament.uk/pa/ld200708/ldselect/ldsctech/162/162.pdf](http://www.publications.parliament.uk/pa/ld200708/ldselect/ldsctech/162/162.pdf); accessed 18 January 2017.

<sup>69</sup> Juniper (2016), at p. 8; Shimmield (2013), at p. 13.

<sup>70</sup> Juniper (2013), at p. 17; Juniper (2016), at p. 8; Shimmield (2013), at p. 17.

Technological advances are now radically changing life sciences:<sup>71</sup> the cost of sequencing has decreased significantly and new technologies have emerged, such as bioinformatics. OA bioinformatics databases are essential for the success of genetics as they allow the discovery of new genes unexplored by the depositor of the data and their comparison to large sets of genes and sequences deposited by others in the databases. The ability to mine public domain and OA databases containing genomic and proteomic data, and to subsequently use such data, could become as important as physical access to organisms or their genetic material.<sup>72</sup> This practice has led the genetics community to enthusiastically adopt the OA database model (see *infra*). As Glowka points out, “in theory, all that would be needed is internet access, appropriate software and skilled researchers”,<sup>73</sup> allowing further engagement of developing countries’ scientists.

To sum up, as underlined by the First Assessment of the Ocean made by the United Nations, the current uneven research capabilities across the globe are the primary source of inequity amongst States,<sup>74</sup> *more than disparities in accessing the resources in situ (authors’ emphasis)*. This requires efforts in capacity development related to MSR so that a greater number of countries can participate in the exploitation of MGR.<sup>75</sup> Therefore, after ensuring OA to samples and data as one of the main ways of benefit-sharing (see *infra*), the ILBI should promote and strengthen capacity building.

### **Mare Geneticum balancing open access and commercial interests**

#### **Facilitated but conditional access**

The UNGA Resolution defines the subject of the ILBI negotiation in the 2011 package as “the conservation and sustainable use of marine biological diversity of ABNJ, in particular, together and as a whole, *marine genetic resources, including questions on the sharing of benefits...*”<sup>76</sup> without specifically mentioning the question of access to MGR. Notwithstanding the fact that access is a prerequisite to enforce subsequent benefit-sharing, *Mare Geneticum* proposes facilitated access procedure should subject to notification rather than authorization.

*In situ* access to MGR is generally done without commercial intent.<sup>77</sup> Indeed, most deep-sea and high seas expeditions are publicly funded, rendering MGR sampling cruises in ABNJ non-commercial in character, or at least with intents that are not solely or primarily commercial.<sup>78</sup>

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<sup>71</sup> Glowka (2010), at p. 408; Juniper (2013), at p. 22; Leary and Juniper (2014), at p. 777.

<sup>72</sup> Glowka (2010), at p. 415.

<sup>73</sup> *Ibid.*

<sup>74</sup> Juniper (2016), at p. 8.

<sup>75</sup> Juniper (2013), at p. 21.

<sup>76</sup> UN 69/65, UN Doc A/69/L.65, 11 May 2015, para. 3.

<sup>77</sup> Juniper (2013), at p. 18.

<sup>78</sup> Wright *et al* (2016), at p. 557.

Moreover, most publicly-funded institutions require the deposit of taxonomic and genetic discoveries in public collections and databases, usually within one year of the completion of a project. It should be noted however that extracts of marine samples collected for non-commercial purposes might be deposited in collections with a drug discovery objective, or be subsequently used for R&D purposes. Indeed, the majority of biodiscovery ventures with a commercial interest begin with *ex situ* or *in silico* access rather than *in situ*.

As strongly advocated by the scientific community,<sup>79</sup> in designing and implementing any ABS measures for MGR in ABNJ it is important to avoid excessive bureaucratic burdens that could hamper MSR. Within the present proposal all the different ways to access MGR coming from ABNJ are facilitated.

**Notification procedure: Obligatory Prior Electronic Notification (OPEN)**

The facilitated procedure to access MGR from ABNJ *in situ* consists of an Obligatory Prior Electronic Notification (OPEN) step, submitted electronically via a registration platform that will be publicly accessible in an online registry. The OPEN will require a minimum dataset of information to be recorded: it is important to underline that most of this data are already collected by scientists and there will be no extra burden on them. The dataset includes:

- Information about the collector and the corresponding contact point;
- Geographical area(s) of sampling;
- Period of sampling;
- Complete description of the research project and participating research entities. This may be based on the cruise plan that is often provided with funding applications;
- Expected nature of what will be collected – this should be done by sample type, for instance pelagic vertebrate, benthic invertebrate, sediment, core sample, plankton, water, etc;
- Description of the targeted MGR when possible;
- The commitment to release the collected samples or data in an openly accessible biorepository, with or without exceptional conditions depending on the intent of use (see *infra*);
- The commitment to update the OPEN information at certain milestones. This is critical to ensure compliance and monitoring.

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<sup>79</sup> Deep-sea marine scientific research and genetic resources in areas beyond national jurisdiction: DOSI submission to the Second Preparatory Committee - 22 March 2016. Deep Ocean Stewardship Initiative (DOSI) is a union of experts from across disciplines and sectors formed to develop new ideas for sustainable use and management of deep-ocean resources.



Any OPEN will contain OA conditions and benefit-sharing obligations associated with the collected material, whether those are monetary or not. The lifetime of the samples and extracted data will be punctuated with milestones corresponding to the identification of samples, to the deposit of samples and/or duplicates in a collection, and to the transfer to users and change of intent for utilisation, as will be defined in the ILBI and for which any agreement on conditions of utilisation and benefit-sharing should be linked or annexed to the OPEN. It is advisable to link the OPEN platform to the CBD Clearing House database,<sup>80</sup> in order to ensure that all accessions of genetic resources are captured in the CBD Clearing House.

A unique alphanumeric identifier will be associated with each OPEN and will keep track of the cruise information and the samples thereby collected. Each code associated with these samples throughout their lifetime should reflect this identifier, allowing subsequent determination of the provenance and hence securing legal certainty and compliance (see *infra*). This system is needed to harmonise MSR practice and will generate a valuable database on global marine biodiversity.

A chosen institution should manage the secure internet tool capable of collecting this information through a centralized mechanism, or coordinate a decentralized system. Whether a new organisation is established by the ILBI or whether an existing institution is mandated for this purpose will have to be determined by the international community's negotiations on the ILBI terms.

When MGR from ABNJ are accessed *ex situ* in a collection, a notification should be registered on the same online registry and linked to the existing OPEN, which may be amended with additional information or conditions of utilisation. In case of a commercial intent, the user will be required to accept and be bound by monetary benefit-sharing obligations in addition to the already existing non-monetary benefits, entailing a subsequent payment to the contribution fund upon commercialization of any product as described further below. These conditions can be easily encoded into the material transfer agreement signed with the collections with the access agreement, and which should be annexed to the OPEN to ensure traceability.

In cases of *in silico* access a notification in the OPEN registry should be done when the geographical origin of the MGR generating the data is known. Access to *in silico* data is quite challenging to track and trace, as is shown by the examples occurring within national jurisdictions under the CBD and Nagoya Protocol system.

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<sup>80</sup> Available at <https://absch.cbd.int/>; accessed 18 January 2017.

The Global Catalogue of Microorganisms (GCM)<sup>81</sup>, a global OA bioinformatics database, is working on ensuring ABS compliance by means of linking the unique identifier of each strain of microorganism to the internationally recognized certificate of compliance (IRCC)<sup>82</sup> of the CBD Clearing House. The GCM provides authenticated access and material information and could accommodate all OPEN data or Nagoya Protocol IRCC. The GCM software, using the strain identifiers that have been submitted to it and thanks to OA to certain information, searches published patent records for the same identifiers and can provide reports on these, therefore it potentially allows anyone to trace any use of the material and identify any patents taken out or licenses granted under patent, contributing to providing legal certainty. The requirement to include the OPEN identifier in any record/publication/patent could enable the system to run automatic searches and accrue records, as is being done by the GCM to some extent.

In the field of *in silico* access, GenBank<sup>83</sup> operates under the INSDC policy<sup>84</sup> which advocates full OA and prohibits restrictions or licensing requirements. *A contrario*, *Mare Geneticum's* approach includes exceptions that will allow future commercial ventures and investments that would be otherwise repelled. The ABS compliance of INSDC in linking gene sequences with eventual ABS strings attached might become an issue of discussion within the framework of the Nagoya Protocol. In this case, if this compliance can be ensured with the collaboration of the INSDC, a similar project as the one run between the GCM and the ABS CH could be run between GenBank and the CBD Clearing House in order to link the sequence data to the original material, its ABS conditions and to the OPEN registry. This would enable users to easily be aware of their obligation to share the benefits when utilizing sequence data of MGR from ABNJ.

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<sup>81</sup> WFCC Global Catalogue of Microorganisms (GCM) is a system to help culture collections to manage, disseminate and share the information related to their holdings. <http://gcm.wfcc.info/> Accessed 17 March 2017.

<sup>82</sup> The internationally recognized certificate of compliance (IRCC) originates from the permit or its equivalent issued by State Parties to the Nagoya Protocol at the time of access as evidence that access to genetic resources was based on prior informed consent and that mutually agreed terms were established. When this permit is communicated to the ABS Clearing house of the Nagoya Protocol it becomes the IRCC.

<sup>83</sup> GenBank<sup>®</sup> is the NIH genetic sequence database, an annotated collection of all publicly available DNA sequences. GenBank is part of the International Nucleotide Sequence Database Collaboration (INSDC), which comprises the DNA DataBank of Japan (DDBJ), the European Nucleotide Archive (ENA), and GenBank at NCBI. These three organizations exchange data on a daily basis. Available at <https://www.ncbi.nlm.nih.gov/genbank/> Accessed 17 March 2017.

<sup>84</sup> Available at <https://www.insdc.org/policy> Accessed 17 March 2017.

### Authorization procedure in case of Environmental Impact Assessment

Sampling at sea does not usually produce significant environmental disturbance, therefore no environmental impact assessment (EIA) should be required prior to the activity. However, there should be a screening stage that could trigger the need for EIA, for instance when the sampling will occur in marine protected areas or in vulnerable marine ecosystems such as hydrothermal vents, or when destructive devices will be used. It must be stressed that the obligation to put the samples in openly accessible biorepositories should eventually minimise the need for subsequent sampling for the same MGR or in the same area, implementing the principle of avoidance of double sampling enshrined in the InterRidge Code of Conduct<sup>85</sup> and the ABS CIESM Charter.<sup>86</sup> One limitation however, may be the fact that different types of research sometimes require different types of collecting methods and storage. To this end, the effective coordination of the OPENS and of biorepositories will be required to ensure the dissemination of information about samples and their availability amongst the scientific community.

Another trigger for EIA could be the harvest of species that can, following interesting discoveries on their genetic material, be deemed necessary for the development of a product. For instance, Chris Battershill and his New Zealand colleagues collected several tons of the *Lissodendoryx* sponge after a careful environmental survey in order to provide the US National Cancer Institute with sufficient supplies of the bioactive compound halichondrin B for clinical testing against cancer. This research eventually led to a simplified synthetic analogue of halichondrin B, eribulin, which is approved for clinical use as an anticancer agent. A case like this should trigger not only an authorization process through the EIA requirement, but also the addition of an access fee to the OPEN process, considering the administration needed for an EIA.

### Facilitating research while securing ventures: sharing conditions and exceptions

Bearing in mind the main disparity between countries as previously explained, it must be stressed that promoting or facilitating access to *ex situ* and *in silico* MGR for researchers worldwide provides a significant and public benefit. Free or 'at cost' access to *in situ* resources is to be conditional to the creation or strengthening of already existing "common pools"<sup>87</sup> of MGR coming from ABNJ and the associated raw data.<sup>88</sup> Facilitated *in situ* access coupled with the sharing of *ex situ* MGR and *in silico* data ensure equal levels of opportunity in research to the scientific community worldwide, overcoming one of the main gaps in research capability between countries.

<sup>85</sup> Available at <https://www.interridge.org/node/16908> Accessed 17 March 2017.

<sup>86</sup> Available at <http://www.ciesm.org/forums/index.php?post/2013/03/14/CIESM-Charter-on-ABS> Accessed 17 March 2017.

<sup>87</sup> Broggiato *et al.* (2014), at p. 181; Greiber (2013), at p. 407-411; Wright *et al.* (2016) at p. 556.

<sup>88</sup> This would have to be delocalised as no single collection can do this. Using a virtual system can collate all the available data and perhaps even lead to reduction in the oversampling of certain deep-sea areas such as the Mariana Trench.

To this end, one must differentiate access from utilisation: access, the acquisition of samples or data, does not constitute utilization. There is no direct and immediate commercial value at the access point, hence there should be no need for authorization, and no discrimination, in this facilitated access procedure. No procedural distinction should be made between public and private entity, nor between basic research and commercially driven research, as long as the users respect the set of conditions based on the OA principle and on benefit-sharing.

In practice these conditions will need to be encoded into legal obligations: at the moment of the OPEN notification the users sign clickwrap terms containing the obligations to share the raw data in public databases, such as GenBank, according to the principle of OA, and to deposit any existing duplicates of the samples in public biorepositories. The terms also should contain an obligation to contribute to the contribution fund in case of commercialization of a later derived product from the accessed resources, as well as the obligation to make a payment of an exclusivity fee in return for an embargo on the release of the samples and data into the public domain, for a period to be determined, potentially renewable for payment of a further fee, in order to secure R&D or potential commercial intent, whether such intent is known upstream or arises later in the process.

As a limitation to the obligation to share raw data and accessed materials, the grant of an initial embargo period should be left as an option for the users to allow them to capitalise on their research material. The embargo period should be reasonable but fairly short, considering that only the raw data is to be released and not the detailed research results. It will nevertheless be possible to extend the embargo period by payment of an exclusivity fee. These possibilities should be clearly stated at the time of granting the OPEN. The embargo period should secure biodiscovery investments and thereby ventures and new discoveries, but should not in any case free the user from its benefit-sharing obligations: the ultimate release of samples and raw data to the public domain, and the payment of monetary contributions when a product is eventually commercialised.

## Benefit-sharing obligations

The first benefit to be shared under *Mare Geneticum* is enabling and facilitating access to MGR and associated data, thus empowering humankind to make the best of the last frontier that is the ABNJ. Scientific research produces benefits *per se*, including the better understanding of marine ecology and the oceanic system, or the improvement of the sustainable use of the oceans and its resources. Hence MSR represents a benefit for all humankind that goes beyond the availability of any products made from MGR,<sup>89</sup> even though some of these may make important contributions to public health, bioremediation or food security and also produce global benefits.<sup>90</sup>

There is, however, no guarantee of monetary benefits arising out of the utilization of MGR.<sup>91</sup> In fact, only seven pharmaceutical products derived from marine organism are currently on the market. Five of them are small molecule drugs discovered before 1990, all of which took more than fifteen years to develop into clinical products. By 1990, 5,800 small molecules of marine origin had been reported, meaning that just one compound for every 1,160 led to a commercial product. Given the long development timelines for pharmaceuticals, no compound discovered after the adoption of the CBD has reached the market yet. At the moment, twenty-eight marine natural products are in clinical trials and a further 250 are undergoing preclinical investigation.<sup>92</sup> In addition, it must be stressed that, of the seven marine-derived products in use, six come from organisms found in the EEZs of coastal states. The seventh one, a highly purified polyunsaturated fatty acid (22<sup>®</sup>/Lovaza<sup>®</sup>) used in those patients at risk of heart attack, is derived from a range of fish species appearing both within and beyond national jurisdiction. While the other products are developed by chemical or biochemical processes, Omacor/Lovaza requires harvesting fish to produce the product. One of the seven, eribulin (trade name Halaven<sup>®</sup>, produced by Eisai) required 25 years of development before reaching significant sales, Y29.3 billion in 2014, or USD \$282 million at the current conversion rate.<sup>93</sup>

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<sup>89</sup> T Greiber 'Types of benefits and benefit sharing' in *IUCN information papers for the intersessional workshop on marine genetic resources in ABNJ* (IUCN Environmental Law Center, Bonn, 2013) 29-37, at p. 29.

<sup>90</sup> FO Glöckner, LJ Stal, RA Sandaa, JM Gasol, F O'Gara, F Hernandez, M Labrenz, E Stoica, MM Varela, A Bordalo, and P Pitta, 'Marine Microbial Diversity and its role in Ecosystem Functioning and Environmental Change' in JB Calewaert and N McDonough (eds) *Marine Microbial Diversity and its role in Ecosystem Functioning and Environmental Change*, Marine Board Position Paper 17 (Marine Board-ESF, Ostend, Belgium 2012) 17-41, at p. 25.

<sup>91</sup> Greiber (2013), at p. 32; Juniper (2013), at p. 19-20.

<sup>92</sup> Available at <http://marinepharmacology.midwestern.edu/>; accessed 18 January 2017.

<sup>93</sup> Eisai Annual Report 2014, available at <http://www.eisai.com/pdf/eannual/epdf2014an.pdf>; accessed 18 January 2017.

Given the above, non-monetary benefits are considered the most practical and immediately valuable aspect of ABS, in particular because the chances of developing a commercial product are relatively slim. For this, OA databases are crucial. However, strengthening “common pools” not only requires the release of material, but also implies the need for global coordination, management, and institutional arrangements.

Even though the LOSC does not specifically provide for an ABS regime with regard to MGR in ABNJ, which will be eventually the role of the ILBI, non-monetary benefit-sharing obligations applying to MSR in ABNJ are inherent in the Convention.<sup>94</sup> As a matter of fact, the scientific community already implements them as best practice (*vide infra*). Accordingly this aspect of our proposal is not inconsistent with LOSC.

#### **Non-monetary benefits: the OA principle as the core benefit**

Considering the above, non-monetary benefits will create direct, quasi-immediate benefits compared to monetary benefit-sharing. Moreover they contribute to building capacity, creating opportunities, and promoting R&D in all countries.<sup>95</sup> They include training of scientists, transfer of research results and scientific information, transfer of technology, or access to *ex situ* collections and *in silico* data. As most of these advantages emanate from research practice, the scientific community is one of the main stakeholders to be listened to when drafting a benefit-sharing regime for MGR in ABNJ.<sup>96</sup>

Part XIII of the LOSC deals with fundamental and applied MSR<sup>97</sup> occurring within national jurisdiction as well as in ABNJ.<sup>98</sup> Part XIII contains clear obligations on non-monetary benefit-sharing arising from scientific research.<sup>99</sup> In essence, it promotes international cooperation, and publication and dissemination of information and knowledge, especially in favour of developing countries.<sup>100</sup> Article 244(1) provides for the obligation to publish and disseminate marine scientific information and knowledge with a view to promoting openness and transparency, while articles 143(3) and 244(2) aim at strengthening autonomous MSR capabilities of less technologically well-developed States rather than the mere transfer of technologies.<sup>101</sup>

<sup>94</sup> Broggiato, *et al.* (2014), at p; 181. Greiber (2013), at p. 44.

<sup>95</sup> Glowka (2010), at p. 9; Greiber (2013), at p. 32

<sup>96</sup> Vierros *et al* (2015), at p. 212; Oldham (2014), at p. 2.

<sup>97</sup> Wright *et al* (2016), at p. 556.

<sup>98</sup> Greiber (2013), at p. 35.

<sup>99</sup> Broggiato *et al.* (2014), 176-185, at p. 182; Greiber (n 70), at p. 35.

<sup>100</sup> Article 242-244 LOSC.

<sup>101</sup> A Broggiato, T Dedeurwaerdere, F Batur and B Coolsaet ‘Introduction. Access and Benefit-Sharing and the Nagoya Protocol: the Confluence of Abiding Legal Doctrines’ in B Coolsaet, F Batur, A Broggiato, J Pitseys, T Dedeurwaerdere (eds) *Implementing the Nagoya Protocol - Comparing Access and Benefit-sharing Regimes in Europe* (Brill/Martinus Nijhoff Publishers, 2015) 1-29, at p. 11.

The UN analysis of State practice indicates that data obtained through MSR, particularly from ABNJ, is effectively shared via international data repositories such as OBIS as well as via publication in international journals.<sup>102</sup>

These provisions constitute the legal basis for further developing a comprehensive and coherent non-monetary benefit-sharing scheme for MGR in ABNJ. To this extent, the OA principle at the basis of the *Mare Geneticum* governance is consistent with both these LOSC obligations and the current scientific practice and values.

Many scientific codes of conduct and guidelines<sup>103</sup> are already raising awareness and building up best practice in the MSR community in terms of sharing samples, data and research results, as well as strengthening capacity building and training in developing countries.<sup>104</sup> Various examples are the already existing gene banks, digital databanks, scientific journals and patent pools,<sup>105</sup> but also the common practice of joint research programmes. For instance, the Intergovernmental Oceanographic Commission of UNESCO (IOC-UNESCO)<sup>106</sup> widely promotes international cooperation in MSR, capacity building, technology transfer and data-sharing. The IOC collects, analyses and publishes information from States on practices in MSR and technology transfer.<sup>107</sup> It has published guidelines for States on the transfer of marine technology,<sup>108</sup> and has established a capacity-building development programme to strengthen MSR. It plays a role in international cooperation projects such as the International Oceanographic Data and Information Exchange (IODE), which facilitates international cooperation on data format standards to harmonise the use of data between States.

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<sup>102</sup> United Nations Division for Ocean Affairs and the Law of the Sea Office of Legal Affairs, *Marine Scientific Research: A Revised Guide to the Implementation of the Relevant Provisions of the United Nations Convention on the Law of the Sea* (United Nations, 2010) para 116.

<sup>103</sup> InterRidge Code of Conduct and the ABS CIESM Charter.

<sup>104</sup> Broggiato *et al.*, (2014), 176-185.

<sup>105</sup> Patent pools which are consortia of entities agreeing to cross-license patents relating to a particular technology in order to save time and money, to mitigate patent-related risks, and to create collective benefits.

<sup>106</sup> IOC is a competent international organization under the UN Convention on the Law of the Sea for Marine Scientific Research under Part XIII and Capacity Development (CD) and Transfer of Marine Technology (TMT) under Part XIV. The IOC is the primary international organization responsible for marine science in the UN system, as also recognized by LOSC (Annex 8 article 2).

<sup>107</sup> Elizabeth J Tirpak, *Practices of States in the Fields of Marine Scientific Research and Transfer of Marine Technology: An Update of the 2005 Analysis of Member State Responses to Questionnaire No. 3*, UN Doc. IOC/ABE-LOS VIII/8 (19 March 2008).

<sup>108</sup> Intergovernmental Oceanographic Commission, *IOC Criteria and Guidelines on the Transfer of Marine Technology*, IOC Information Document, 1203 (UNESCO, 2005).

In 1996, the leaders of the scientific community advocated the immediate release of DNA sequence data in public databases in the Bermuda Principles.<sup>109</sup> In 2007, the Organisation for Economic Cooperation and Development (OECD) recommended wider and open sharing of data from public funding,<sup>110</sup> followed by the European Commission's policy instructions to Member States to "promote the broad dissemination of knowledge created with public funds, by taking steps to encourage open access to research results, while enabling, where appropriate, the related intellectual property to be protected".<sup>111</sup> From there national policies blossom around the globe, in particular in the host countries of the main funding agencies that currently finance ABNJ research: the European Union (EU), the United States (US), China and Germany.<sup>112</sup>

What all these countries' and regions' data policies have in common is the implementation of the open access approach, though to different extents. The National Science Foundation of the US adopted the Sample and Data Policy of the Division of Ocean Sciences in 2011<sup>113</sup>. This requires the Principal Investigator working under its funding "to submit at no more than incremental cost and within a reasonable time frame (but no later than two (2) years after the data are collected), the primary data, samples, physical collections and other supporting materials created or gathered in the course of work under NSF/OCE grants". It further requires submission of sequence data to a publicly accessible data repository. The EU published a Recommendation on access to and preservation of scientific information in 2012<sup>114</sup> encouraging all EU Member States to put publicly-funded research results in the public domain in order to strengthen science and the knowledge-based economy.

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<sup>109</sup> For a summary of the principles agreed at the first international strategy meeting on human genome sequencing (commonly referred to as Bermuda Principles of 1996), see [http://www.ornl.gov/sci/techresources/Human\\_Genome/research/bermuda.shtml](http://www.ornl.gov/sci/techresources/Human_Genome/research/bermuda.shtml) Accessed 17 March 2017. For a historical analysis of the principles, see Eliot Marshall, 'Bermuda Rules: Community Spirit, With Teeth', *Science*, Vol. 291, Issue 5507, 1192.

<sup>110</sup> OECD, OECD Principles and Guidelines for Access to Research Data from Public Funding, <http://www.oecd.org/science/scienceandtechnologypolicy/38500813.pdf> Accessed 17 March 2017.

<sup>111</sup> EC recommendation C/2008/1329 of 10 April 2008, <http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008H0416:EN:NOT>; COMMISSION RECOMMENDATION of 17 July 2012 on access to and preservation of scientific information (2012/417/EU) Official Journal of the European Union L 194/39 21/07/2012

<sup>112</sup> Oldham *et al* (2014)

<sup>113</sup> Available at <https://www.nsf.gov/pubs/2011/nsf11060/nsf11060.pdf> Accessed 17 March 2017.

<sup>114</sup> Commission Recommendation of 17.7.2012 on access to and preservation of scientific information. C(2012) 4890 final. Available at [https://ec.europa.eu/research/science-society/document\\_library/pdf\\_06/recommendation-access-and-preservation-scientific-information\\_en.pdf](https://ec.europa.eu/research/science-society/document_library/pdf_06/recommendation-access-and-preservation-scientific-information_en.pdf) Accessed 17 March 2017.



In 2014 the National Natural Science Foundation of China (NSFC), one of the country's major basic-science funding agencies, and the Chinese Academy of Sciences (CAS) announced that researchers they support should deposit their papers into online repositories and make them publicly accessible within 12 months of publication. The Deutsche Forschungsgemeinschaft (DFG) adopted in 2015 Guidelines on the Handling of Research Data, calling for the long-term archiving of research data and open access to it<sup>115</sup>.

While OA to sample material is less advanced, there is a global movement towards enabling the long-term maintenance of valuable biological, chemical and other materials resulting from research activities. In the field of deep-sea research, the scientific community advocates increased sharing of such samples, and for research grants to include a budget for curating and long-term care. Samples arising from MSR carried out in ABNJ can often be accessed through international networks of collections. For example, the InterRidge statement of commitment to responsible research practice notes that the network is building open databases on available biological samples preserved in laboratories and museums around the globe, as an available resource and to minimise repeated sampling.<sup>116</sup>

In addition, many journals currently require making available unique material included in publications. The journal Nature's policy states that:

“A condition of publication in a Nature journal is that authors are required to make unique materials promptly available to others without undue qualifications. It is acceptable to request reasonable payment to cover costs of distribution and reagents may be made available via commercial or non-commercial third party providers.”<sup>117</sup>

Such a strong statement from a top international peer-reviewed journal sends a message that sharing of materials is essential for a productive global research enterprise, although compliance with this requirement may still need to improve.<sup>118</sup> From this trend has emerged best practice in open science, technological advances and the ever-growing practice of digitalisation of genetic data and other information, which has enabled more global accessibility than ever before.<sup>119</sup> Therefore, enabling and increasing access to relevant scientific data, publications and software to analyse this data is undoubtedly an important component of non-monetary benefit sharing.<sup>120</sup>

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<sup>115</sup> Available at [http://www.dfg.de/download/pdf/foerderung/antragstellung/forschungsdaten/guidelines\\_research\\_data.pdf](http://www.dfg.de/download/pdf/foerderung/antragstellung/forschungsdaten/guidelines_research_data.pdf) Accessed 17 March 2017.

<sup>116</sup> Available at <https://www.interridge.org/IRStatement> ; accessed 18 January 2017.

<sup>117</sup> Available at <http://www.nature.com/authors/policies/availability.html> ; accessed 18 January 2017.

<sup>118</sup> D Cyranoski, 'Research materials: Share and share alike?' (2002) 420 *Nature* 602-604, at p. 604.

<sup>119</sup> G.M. Garrity, L.M. Thompson, D.W. Ussery, N. Paskin, D. Baker, P. Desmeth, D.E. Schindel and P.S. Ong, *Study on the Identification, Tracking and Monitoring of Genetic Resources*, UN doc. UNEP/CBD/WG-ABS/7/INF/2, of 2 March 2009, p. 19.

<sup>120</sup> Greiber (2013), at p. 35.

However, the moderate optimism brought by new opportunities thereby created cannot obscure the reality of some researchers and users from developing countries, whose institutions do not always have the necessary license to journals, nor the necessary internet access and bandwidth. In this respect, the contribution fund to be established by the ILBI could assist those in need of better access.

### *Monetary benefit-sharing*

The present section deals with the obligation to require monetary payments at different stages of the research pipeline. There could be two milestones at which monetary payments could be due.

1. The OPEN entails the payment of an exclusivity fee early in the biodiscovery process, when the user wants to extend the embargo period on releasing the MGR collected in ABNJ to the public domain. When the exclusivity option is exercised, payment of the exclusivity fee is compulsory and should be transferred to the contribution fund to be established by the ILBI. The exclusivity fee's amount should be determined by a sliding scale, depending on various factors: the duration of the extension period, the MGR object(s) of the embargo, the level of research funding employed to date, and the user's capacity.
2. In case the ILBI would require monetary benefits linked to the utilization of the genetic resource as such, we suggest this second payment step to be triggered by the commercialization of a product developed on the basis of MGR from ABNJ. This form of royalty should be paid to the same international fund set up by the ILBI to manage exclusivity fees. The percentage of revenue to be shared should be predetermined per sector (e.g. pharmaceuticals, cosmetics, food industry...), possibly by consultation with representative organisations and stakeholders of the said sector, in order to provide for legal certainty, predictability and equity amongst players. It should also be consistent with the market levels payable under ABS systems already in place within national jurisdictions (eg Brazil) and under development at regional levels, to avoid creating any perverse incentives.

Considering that it may take over 20 years to release a product onto the market, having the possibility to pay an exclusivity fee at an early stage of the research not only guarantees continuous investments in blue biodiscovery, but also secures early incoming monetary resources into the ILBI contribution fund.

With these governance principles, *Mare Geneticum* seeks to secure the fair and equitable sharing of the benefits arising out of the utilisation of MGR coming from ABNJ, and to enhance MSR and enable biodiscovery worldwide for the benefit of humankind. However, promoting fundamental research through OA whilst allowing users to take research results to the level of application and commercialisation of the biodiscovery pipeline will be a difficult balance to achieve.

### Enforcement and compliance: centralised tracking system

Ensuring compliance and enforcement of benefit-sharing obligations is not an easy task, especially within a multilateral context. To this end, the OPEN registry would provide a centralized system where monitoring can be based on reporting and updating obligations. At the end of a non-commercial research project or at the moment of commercialization of a product developed on the basis of MGR coming from ABNJ, a second OPEN notification could be envisaged and would need to be linked to the first one. An alternative could be additional information and potentially additional conditions (e.g. exclusivity) to be annexed to the pre-existing OPEN.

Effective compliance starts with the obligation to report activities to the institution that will be mandated or established by the ILBI for managing access to MGR and the OPEN registry, similarly to the International Seabed Authority's reporting requirements imposed on seabed mining contractors.<sup>121</sup> There would be an obligation to update, either be on a regular basis (e.g. annually) or at certain milestones in the MGR lifetime, but should at the very least occur at every permanent subsequent transfer to collections or to different users, and when the type or the intent of the utilisation changes (eg when commercial intent arises). Using the OPEN as the central tracking system will ensure the smooth and effective monitoring of MGR utilisation. While the obligation to update or report will firstly be imposed upon the responsible person of a research project accessing MGR *in situ*, when signing the OPEN clickwrap agreement, it should also be binding for any subsequent user accessing MGR *ex situ*, or data *in silico* when possible. In other words, because it is quite often that multiple users conduct research on the same MGR and that third party transfer is common practice in biodiscovery ventures,<sup>122</sup> the obligation should be tied to the MGR through the OPEN and its unique identifier, and not to the primary user only. Subsequent users can easily become subject to the OPEN conditions applicable when signing a material transfer agreement with peers or with a biorepository.

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<sup>121</sup> LOSC, Annex III, article 17(1)(b).

<sup>122</sup> M Jaspars, D De Pascale, JH Andersen, F Reyes, AD Crawford and A Ianora 'The Marine Biodiscovery Pipeline and Ocean Medicines of Tomorrow' (2016) 96(1) *Journal of the Marine Biological Association of the United Kingdom* 151–158.

Low impact cost-effective monitoring is advisable. Trust should be placed in researchers to report sample collection along with findings and transfers. Ocean scientists are generally meticulous about recording when and where samples are collected *in situ*, notwithstanding that it is often a part of research methodology and protocol, hence it is unlikely to put an additional burden on researchers.<sup>123</sup> Moreover, as previously mentioned, most funding agencies and scientific journal editors require researchers to deposit genetic and proteomic data in publicly accessible archives where they are openly accessible. Quite importantly, reporting standards should be simple, consistent and interoperable.

Further down the research chain, potential R&D users of MGR coming from ABNJ should submit a new notification when a commercially oriented project begins, considering that such a change of intent might trigger the need for additional conditions of use other than just an embargo period on the public release of said MGR and associated data. In particular, there might be intellectual property rights to take into account as well as payment requirements arising from the monetary benefit-sharing provisions of the ILBI. This new notification could either be in the form of an annex to the MGR's OPEN, or as a second OPEN that should be linked to the first one.

With today's powerful tools such as computer programmes and the Internet, setting up a centralized tracking system is not only possible but also relatively simple to put into effect and to operate. This tracking format has been established by the 2015 Brazilian legislation on access to and use of its genetic resources,<sup>124</sup> whereby users have to submit similar information to an ABS registry. However, its effectiveness cannot be evaluated, as it is not operational yet.

The IOC-UNESCO could easily support the ILBI's implementation, such as the OPEN mechanism, by providing:

- (i) A global data sharing platform and data clearing house mechanism for marine biodiversity data in all ocean basins, including ABNJ;
- (ii) A mechanism for international cooperation in MSR, coordination in global ocean observation, and development of standards, manual and guidelines and codes of conduct in MSR and data sharing protocols;
- (iii) And a global network of regional centres to enhance capacity, by training the next generation of scientists and area managers in applying international standards and best practices.<sup>125</sup>

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<sup>123</sup> Vierros *et al* (2015), at p. 212.

<sup>124</sup> Brazilian Biodiversity Law, Federal Act No. 13.123/2015, May 20, 2015; Decree No. 8.772/2016, 11 May 2016.

<sup>125</sup> IOC-UNESCO 'IOC Potential Contribution To A New International Instrument Under UNCLOS On The Conservation And Sustainable Use Of Marine Biological Diversity Of Areas Beyond National Jurisdiction', Information Document IOC/INF-1338, Paris, 17 May 2016. Available at [http://ioc-unesco.org/index.php?option=com\\_oe&task=viewDocumentRecord&docID=17286](http://ioc-unesco.org/index.php?option=com_oe&task=viewDocumentRecord&docID=17286); accessed 18 January 2017.

While States are responsible for the implementation of international treaties, the centralised system for OPENs would alleviate the legislative and administrative means to be deployed in order to ensure compliance. Indeed, instead of managing ABNJ material and data through national registries to be coordinated at a global level, States would merely have to ensure that users comply with adequate and effective reporting. The failure to report or comply with the OPEN conditions, when observed by the mandated international organisation, or by funding agencies when possible, should be notified to the relevant State, and be subject to sufficiently and proportionally discouraging penalties in order to ensure the equal compliance of public and private research organisations. Compliance mechanisms will be the responsibility of State parties to the ILBI, and should serve as incentives to respect the *Mare Geneticum* governance established by it. Any international organisation put in place by the ILBI should coordinate and manage the OPEN mechanism with State parties, while leaving enforcement to the States. To this end, there will be an important need to set globally accepted, and harmonised, minimum standards of compliance. It is thus within the hands of States, both international law makers and subjects, to draft an ILBI reflecting the balanced regime necessary to efficiently share the benefits of MGR without impeding or slowing down fundamental as well as applied research.

### **Towards an implementing agreement**

The governing principles and implementing mechanisms put forward in this article are intended to lay the basis for a new governance regime in the high and the deep seas that are, by nature and by law, international. Based on the idea that the utilisation of MGR should benefit humankind as a whole, notwithstanding the intellectual property rights that may arise from associated discoveries, *Mare Geneticum's* approach is about adequate regulating for better sharing, in distant echo of Grotius:

“Now, as there are some things which every man enjoys in common with all other men, and there are other things which are distinctly his and belong to no one else, just so has nature willed that some of the things which she has created for the use of mankind remain common to all, and that others through the industry and labor of each man become his own.”<sup>126</sup>

While the international community has engaged in the process of developing an implementing agreement to the LOSC in ABNJ, the ILBI, it is going to be their task to draft a realistic and balanced system based on sound foundations. During the Preparatory Committee's sessions for an ILBI, several States have called for open access to research data, samples and knowledge, as well as the need for a data sharing and clearing house facility.

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<sup>126</sup> Grotius (1916), at p.2.

Although a number of databases and biorepositories already exist, what will be needed is a coordinated tracking system such as the unique identifier of an OPEN record for MGR samples and data from ABNJ.

The new ILBI should adopt a simplified monetary benefit-sharing system in order to promote biodiscovery ventures rather than to deter them, and to avoid implementation struggles as may be seen with the LOSC Part XI regime on seabed mining.<sup>127</sup> Above all, the ILBI should emphasize and strengthen non-monetary benefit-sharing for the advancement of science and nature conservation through, *inter alia*:

- Open access to raw data and samples;
- Enhanced international research coordination and cooperation;
- Targeted training and sharing of expertise, methodology, guidelines and best practices;
- Standardised data management, taxonomy and species identification;
- Marine spatial planning in ABNJ, including protected areas;
- Ecosystem-based management;
- Development of marine conservation policies.

Indeed, because *Mare Geneticum* is not a standalone approach but part of a four-component package, sharing the benefits arising out of MGR in ABNJ should also mean attributing such benefits to the designation and management of marine protected areas, the systematisation of environmental impact assessment processes, and the transfer of technology. Notwithstanding the fact that humankind has a lot to gain from healthy and sustainably managed oceans, the LOSC preamble is here to recall that the spirit and purpose of the Convention as a whole is to “promote the peaceful uses of the seas and oceans, the equitable and efficient utilization of their resources, the conservation of their living resources, and the study, protection and preservation of the marine environment”.

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<sup>127</sup> J-S Fritz ‘Deep Sea Anarchy: Mining at the Frontiers of International Law’ (2015) 30 *The International Journal of Marine and Coastal Law* 445-476.