

Inclusive innovation: Enhancing global participation in and benefit sharing linked to the utilization of marine genetic resources from areas beyond national jurisdiction

Jane Eva Collins^{a,b,*}, Harriet Harden-Davies^c, Marcel Jaspers^d, Torsten Thiele^{e,f}, Thomas Vanagt^b, Isabelle Huys^a

^a Department of Pharmaceutical and Pharmacological Sciences, University of Leuven, Leuven, Belgium

^b ABSint, Vaardijkstraat 19D, 8200, Bruges, Belgium

^c Australian National Centre for Ocean Resources and Security (ANCORS), University of Wollongong, Australia

^d Marine Biodiscovery Centre, Department of Chemistry, University of Aberdeen, Old Aberdeen, AB24 3UE, Scotland, UK

^e Global Ocean Trust, Germany

^f London School of Economics, Institute of Global Affairs, London, UK

ABSTRACT

Negotiations for a new international legally binding instrument under the United Nations Convention on the Law of the Sea for the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction (ABNJ) have commenced. For the new agreement to be fair and effective, it is vital that all States are able to participate in the long-term sustainable use and conservation of the ocean beyond national jurisdiction. This includes participation in marine scientific research and the utilization of marine genetic resources (MGR) through subsequent innovation processes. Open access to MGR, such as data, coupled with capacity building, can promote the equitable sharing of benefits associated with MGR. In this paper, it is hypothesized that an 'inclusive innovation' approach may facilitate participation and promote enhanced engagement in the conservation and sustainable use of biodiversity beyond national jurisdiction. A number of existing genetic resource initiatives provide examples of efforts to foster inclusivity in the innovation process, including BioBricks, Open Source Drug Discovery, GenBank and the Global Genome Biodiversity Network. An analysis of these examples enables clear identification of common elements that are adopted by such initiatives, whereby inclusive innovation either develops naturally or is promoted actively through measures for open access, capacity building, and collaboration. By empowering more States and stakeholders to participate in research and innovation processes, global potential in terms of enhanced scientific knowledge and opportunities associated with biodiversity of ABNJ can be promoted and the overall objective of the conservation and sustainable use can be best pursued.

1. Introduction

No internationally agreed or legal definition for marine genetic resources (MGR) yet exists. However, a definition can be inferred by considering the terms 'genetic material' and 'genetic resource' as defined in the 1992 Convention on Biological Diversity [1]. According to Article 2 of the CBD, genetic material is 'any material of plant, animal, microbial, or other origin containing functional units of heredity'. In addition, 'genetic resources' are defined as 'genetic material of actual or potential value' (CBD, Article 2). MGR, therefore, could be considered as the marine equivalent of these definitions.¹ In addition, the President's aid to negotiations (2019) provides a number of potential definitions for MGR. MGR represent a source of materials with as-yet largely untapped potential, with the capacity to produce high value products. Examples of

marketed pharmaceutical products derived from marine bioactive compounds are listed in Table 1. Due to the rapid progress in technological fields of marine exploration and laboratory testing, there is significant opportunity for discovery of new and possibly valuable genetic resources with applications in a number of sectors, ranging from the pharmaceutical industry to cosmetics, agriculture, nutraceuticals and energy [5,6]. As a result, utilization of MGR has the potential to provide benefits to many users. The degree to which this potential is realized will depend largely on the manner in which discovery is guided and benefits are shared. Other factors to consider include technology, levels of scientific development and commercial viability.

In 2015, after almost a decade of discussions by informal working groups on marine areas beyond national jurisdiction, the United Nations General Assembly decided to develop a new international legally

* Corresponding author. Department of Pharmaceutical and Pharmacological Sciences, University of Leuven, Leuven, Belgium.

E-mail address: jane.collins@abs-int.eu (J.E. Collins).

¹ <https://www.wipo.int/about-ip/en/>.

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Table 1

Marketed pharmaceutical drugs derived from marine bioactive compounds extracted from marine organisms (adapted from Refs. [2–4] ^a).

Marine organism/species	Bioactive compound	Application/indication	Commercial name
Sponge/ <i>Tethya crypta</i>	Cytarabine	Treatment of leukemia	Cytosar-U®
Sponge/ <i>Tethya crypta</i>	Cytarabine liposomal	Treatment of lymphomatous meningitis	Depocyt®
Sponge/ <i>Tethya crypta</i>	Vidarabine	Antiviral	Vira-A®
Snail/ <i>Conus magus</i>	Ziconotide	Antiviral	Prialt®
Sea squirt/ <i>Ecteinascidia turbinata</i>	Trabectedin	Antitumoral	Yondelis®
Sponge/ <i>Halichondria okadae</i>	Eribulin mesylate	Antitumoral	Halaven®

^a <https://www.eisai.com/news/news201610.html>.

binding instrument (ILBI) on biodiversity beyond national jurisdiction under the Law of the Sea Convention [7]. A preparatory committee began working on this in 2016, and provisions for the agreement were reported back to the General Assembly in 2017 [6,8,9]. Formal United Nations negotiations for a new ILBI under UNCLOS for the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction (BBNJ) have now commenced. The first session of the Intergovernmental Conference (IGC) convened from 4 to 17 September 2018, the second from 25 March to 5 April 2019 and the third from 19 to 30 August 2019. The fourth session is planned to take place in the first half of 2020. Negotiations address a ‘package’ of four elements (MGR, including questions on the sharing of benefits; measures such as area-based management tools (ABMT), including marine protected areas (MPAs); environmental impact assessments (EIA), and; capacity-building and the transfer of marine technology) and cross-cutting issues, as agreed during preparatory committee meetings in 2011 (UNGA Res. 69/292, UN Doc. A/Res/69.292, 6 July 2015, para. 2.).

It has been recognized that in order for the new agreement to be fair and effective, it is vital that all States and stakeholders are able to participate in the long-term sustainable use, management and protection of ocean areas beyond national jurisdiction [12]. This includes participation in the utilization of MGR as well as the sharing of potential derived benefits. To promote global participation in the utilization of (as well as scientific knowledge and opportunities derived from) MGR from areas beyond national jurisdiction (ABNJ), a growing body of literature suggests that approaches should aim to open up and combine resources, as well as create a level playing field in terms of research capabilities [10–12].

The negotiations for the new agreement present an opportunity to aim to address governance of MGR. Open access to marine biological samples and data linked to scientific research has been suggested as a positive and effective approach to sharing benefits within the context of the ILBI. Open access can be defined as ‘releasing samples and data to the public domain through openly accessible biorepositories and databases’ [10]. However, this does not necessarily mean free utilization, since some restrictions may still apply. Capacity building, encompassing scientific training and access to resources, research infrastructure and technology, could also be a tool through which benefits can be shared [11,41]. Open access and capacity building, therefore, represent two important approaches for the equitable sharing of potential benefits associated with utilization of MGR. The adoption of open access and capacity building measures could offer several advantages [10,11] and also lay the foundation for ‘inclusive innovation’ (Fig. 1).

2. Generating and sharing benefits through inclusive innovation

In this paper, the term inclusive innovation is intended to encompass the definition of open innovation together with a focus on inclusivity. Open innovation describes the notion that entities should look for ways of ‘tapping into and harnessing the ideas that lie beyond their formal boundaries’ in order to benefit from access to a vastly greater pool of knowledge, creativity and opportunities [13]. This approach may help to accelerate the innovation process. By building on open innovation with a focus on inclusivity, the term inclusive innovation can be defined as promoting the participation of all relevant stakeholders (including developed and developing states, public and private sectors) in innovation processes. With regards to ABNJ, an inclusive innovation approach could therefore provide a useful lens to focus efforts, with an overarching aim of reducing global inequality in terms of capability to participate in the utilization of MGR from ABNJ, as well as associated and subsequent innovation processes. Two concepts which could lead to inclusive innovation include open access and capacity building.

An ‘inclusive innovation’ approach can represent an effective avenue to facilitate and promote enhanced engagement of all stakeholders in aspects associated with use of BBNJ. For example, engaging stakeholders with a wide variety of expertise during the innovation process could generate a feedback loop whereby progressively more benefits are generated and shared, more data become openly accessible and capacity grows at local and global scales (Fig. 1). This could in turn support efforts to remove barriers (such as access to MGR data, lab facilities, research equipment and specific training) that currently prevent or limit many developed and most developing States from utilizing MGR from ABNJ. In addition, improving marine biodiversity-related knowledge from ABNJ would support conservation and sustainable use, maximizing opportunities for potential benefits in the form of scientific knowledge and innovation opportunities linked to the utilization of MGR from ABNJ.

This paper examines how open access to MGR data, capacity building and inclusive innovation can be adopted as important components of scientific research and development. Discussions regarding the scope and definition of the term ‘MGR data’ are ongoing, and it is not the aim of this paper to suggest what this definition should be. For the sake of the current paper, MGR data will refer only to raw genetic data and rapidly/automatically generated data [10]. Whilst it is appreciated that both MGR samples and data may both be considered as part of ILBI discussions, a detailed examination of MGR sample material is out of the scope of the current paper. In this paper inclusive innovation encompasses the meaningful participation of (and collaboration with) all relevant States and stakeholders, including those who may not necessarily or ordinarily have the capacity (i.e. financial resources, knowledge, skills, infrastructure, technology etc.), to participate in utilization of MGR from ABNJ and subsequent innovation processes.

Lessons and common elements will be drawn from examples of initiatives that foster inclusivity in the innovation process, including BioBricks, Open Source Drug Discovery, GenBank and the Global Genome Biodiversity Network. In addition, analysis of supporting elements within existing genetic resource initiatives will shed light on possible ways in which the ILBI could facilitate maximum global engagement in, and potential from, utilization of MGR from ABNJ through efforts linked to benefit-sharing (Fig. 2). It is not the purpose of the paper to provide detailed solutions, rather to propose practical elements of an approach for the utilization of MGR in ABNJ to foster open access and capacity building, thereby laying the foundation for inclusive innovation through the development of the ILBI. In this paper, the focus will be on access to and sharing of MGR data.

Intellectual Property (IP) refers to ‘creations of the mind, such as inventions; literary works; designs; and symbols, names and images used

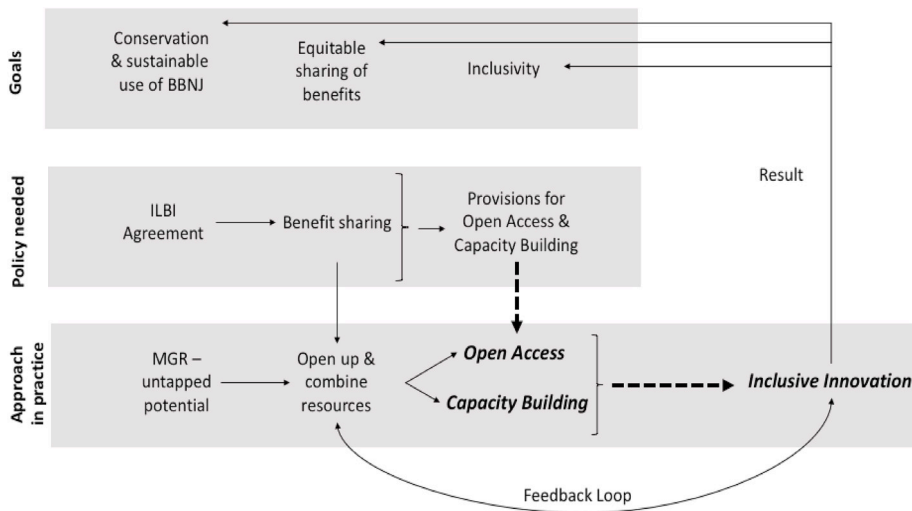


Fig. 1. Representation of how open access to MGR data together with capacity building could pave the way for inclusive innovation in terms of associated policy and practice. The top bar indicates the high-level, policy requirements to be considered during negotiations for the new agreement. The overarching objective of the new agreement will be the ‘conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction’. A key element (as part of a ‘package’ of elements to be considered) within the agreement encompasses ‘MGR, including questions on the sharing of benefits’. Global potential from MGR from ABNJ could be facilitated through efforts linked to benefit-sharing. Open access and capacity building represent two important tools through which benefits could be shared. The bottom bar indicates how the policy could be implemented and put into practice.

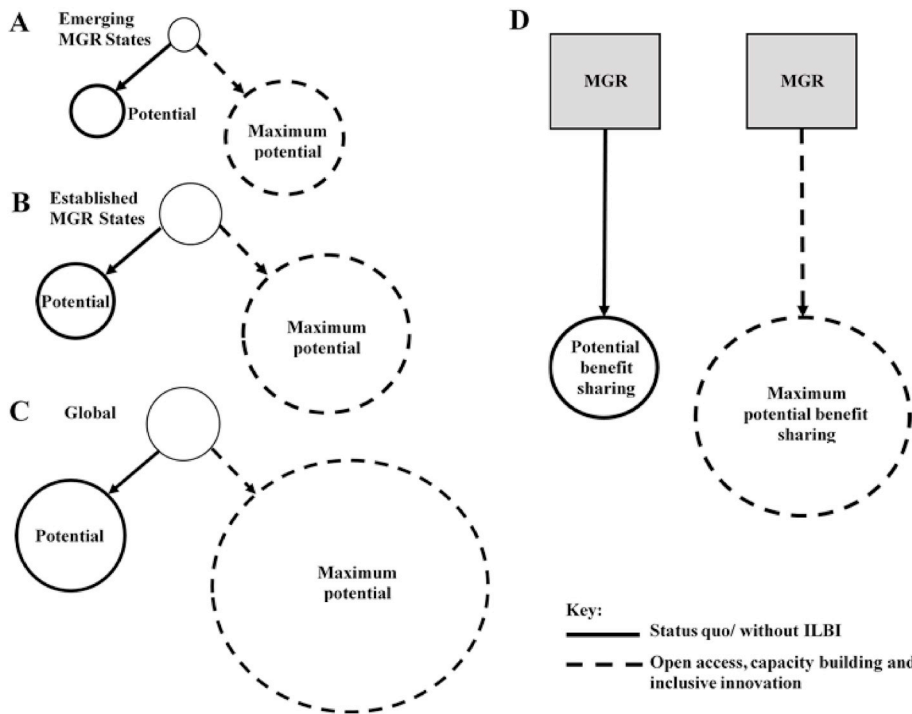


Fig. 2. **A and B)** Two possible approaches (indicated by the dashed and solid lines) could be taken for generating scientific knowledge, opportunities and wealth from MGR from ABNJ, by **A)** emerging, and **B)** established MGR States. The size of the middle circles represents current capability to utilize MGR from ABNJ, as well as knowledge and overall capacity for conservation and sustainable use of BBNJ. **Bold, solid line: status quo/without ILBI** – does not encourage inclusive innovation. Emerging and established MGR States grow slightly in terms of capability to utilize MGR from ABNJ, scientific knowledge, opportunities and wealth. **Bold, dashed line: open access, capacity building and inclusive innovation** – maximum potential growth in capability for both emerging and established States, as well as knowledge and capacity. All stakeholders/States have the opportunity to benefit. **C)** Two possible approaches for generating global (emerging plus established MGR States) scientific knowledge, opportunities and wealth from MGR from ABNJ. **Bold, solid line: status quo/without ILBI** – does not encourage inclusive innovation. Emerging and established MGR States grow slightly in capability. Global potential increases slightly. **Bold, dashed line: open access, capacity building and inclusive innovation** – maximum possible growth in capability for both emerging and established MGR States (in terms of generating scientific knowledge, opportunities and wealth). Global potential increases greatly (and to a greater extent than with the other two approaches), therefore all States have the opportunity to benefit. **D)** Potential benefits to be shared from utilization of MGR from ABNJ, according to **status quo/without ILBI** and according to the **open access, capacity building and inclusive innovation** approach.

in commerce’ IP can be legally protected, for example with patents, copyright or trademarks, allowing people to receive recognition or financial benefit from their inventions.² IP issues are dealt with under relevant IP instruments, including World Intellectual Property Organization (WIPO) treaties such as the Patent Cooperation Treaty (PCT) and

the WIPO Copyright Treaty (WCT).³ However, access to and use of genetic resources are dealt with by access and benefit-sharing (ABS) mechanisms under the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (29 October 2010, entered into force 12 October 2014). At present, it remains unclear the

² <https://www.wipo.int/treaties/en>.

³ http://www.science-international.org/sites/default/files/reports/open-dat-a-in-big-data-world_long_en.pdf.

extent to which IP will be addressed within the ILBI, and so the interaction between the ILBI and various WIPO treaties cannot yet be determined. Article 12 within the draft text of a BBNJ agreement refers to IP and makes general statements such as ‘States Parties shall implement this Agreement in a manner consistent with the rights and obligations of States under the relevant agreements concluded under the auspices of the World Intellectual Property Organization and the World Trade Organization’ (June 2019). However, it is important to note that central components related to IP (which may potentially be linked to MGR of ABNJ) will be dealt with under the relevant IP instruments.

The authors acknowledge that IP and associated rights and restrictions exist, and that these are fundamental for potential development of products (such as pharmaceuticals) from MGR of ABNJ. Open access to MGR data is important for research and development (R&D) for commercial purposes, and patenting of inventions resulting from use of open access MGR data can help to drive innovation [14]. In addition, IP rights play an important role within the biotechnology business model, in order to secure return on (financial) investment, and are also crucial with regards to how biotechnology R&D is funded. However, whilst it is recognized that IP law plays an important role in the way that MGR from ABNJ will be utilized and regulated, the authors do not intend to make any statements that may affect the use or existence of IP rights (including patents). Therefore, a detailed review of IP law and its interaction with MGR is out of the scope of this paper.

3. Open access and capacity building

3.1. Open data

The concept of ‘open data’ could be an important way of focusing on open access with specific reference to data. Open data must be ‘intellectually open’, indicating that data can be thoroughly scrutinised and re-used as is appropriate [15]. ‘Open Data in a Big Data World’⁴ suggest that a specific list of criteria (see Table 2) should be satisfied in order to classify data as open.

According to Science International (2015), ‘open data should be the default position for publicly funded science’ and is critical for ensuring that all of society can benefit [9].⁵ Therefore, an assessment of existing scientific good practices with regards to the way that data is stored, accessed and shared in current, open access organizations/projects would be useful for BBNJ negotiations and for determining how data-sharing can be improved.

Open access to MGR data is important for R&D and can help to drive innovation. This approach could be represented by the bold, solid arrow

Table 2
List of criteria which should be satisfied in order to classify data as open data.^a

Criteria	Description of criteria
Discoverable	a web search can readily reveal their existence
Accessible	the data can be electronically imported into or accessed by a computer
Intelligible	there must be enough background information to make clear the relevance of the data to the specific issue under investigation
Assessable	users must be able to assess issues such as the competence of the data producers or the extent to which they may have a pecuniary interest in a particular outcome
Useable	there must be adequate metadata (the data about data that makes it useable), and where computation has been used to create derived data, the relevant code, sometimes together with the characteristics of the computer, needs to be accessible

^a http://ocw.metu.edu.tr/pluginfile.php/4339/mod_resource/content/0/week3content.pdf.

⁴ <http://www.science-international.org/>.

⁵ The term ‘emerging and established MGR States’ in this paper refers to the degree to which States are currently capable of utilizing MGR from ABNJ.

(status quo/without ILBI) in Fig. 2, whereby innovation is encouraged to a degree, but not to the extent it could be if capacity building and inclusive innovation were also adopted. As a result, both emerging and established MGR user States⁶ grow slightly in terms of capability to utilize MGR from ABNJ and to develop scientific knowledge, opportunities and wealth. However, as also indicated by Blasiak, et al. (2018), in order to promote inclusion of a greater number and variety of stakeholders, open access must be accompanied by capacity building. This approach is depicted by the bold, dashed arrow (open access, capacity building and inclusive innovation) in Fig. 2 and may facilitate maximum possible growth of capability for both emerging and established MGR user States (in terms of generating scientific knowledge, opportunities and wealth), as well as potential in terms of conservation and sustainable use of BBNJ. As a result, all States may have a greater opportunity to benefit from utilization of MGR from ABNJ.

3.2. Open access to MGR data and associated capacity building

Open access to MGR data is vital for providing everyone around the world, regardless of location or economic status, with opportunities to conduct R&D on MGR [9,10,12]. Open access also emerged during Preparatory Committee sessions (meetings held in preparation for the IGC) as an important tool for sharing of benefits derived from utilization of MGR from ABNJ and could be a key element for the ILBI. To a certain degree, the scientific community already implements in practice the concept of open access to data from ABNJ [10]. For example, it is a common requirement for publicly funded institutions to deposit taxonomic and genetic data in public databases [16].

However, uneven levels of access to MGR data from ABNJ still exist between countries [17]. This disparity is due mostly to the scientific skills needed to conduct research on marine biodiversity, the cost and scientific skills needed to undertake molecular screening and biodiversity assessment, and the scientific skills needed to analyse the data produced. There is, therefore, clearly a strong link between disparity in access to MGR data and the need for capacity building [17]. Efforts linked to capacity development in terms of MSR could therefore enable a greater number of States to take part in the utilization of MGR. According to Mohammed [12]; capacity building and technology transfer under a new treaty should ‘enhance least developed countries’ ability to identify, assimilate, transform and apply scientific knowledge and technological knowhow’.

3.3. Key elements for open access and capacity building in existing genetic resource initiatives

Factors which contribute towards facilitating open access to genetic resource data and capacity building can be identified through an analysis of existing genetic resource initiatives (Table 3). Key elements include: low-cost, openness (section 2.2.1); long-term infrastructure (section 2.2.2) and other tools (section 2.2.3). These elements could facilitate engagement in, and potential benefits from, utilization of MGR from ABNJ - paving the way for inclusive innovation as an approach to utilization of MGR from ABNJ (Section 3).

3.3.1. Low-cost and open to all

Low-cost access to and retrieval of data is a critical factor in the operation of open access initiatives. Access to data may be via freely accessible databases, with either free or low-cost access to data, which could then potentially be used to synthesise material in laboratories. Low-cost access with limited burdens can promote widespread use of data by all interested parties, irrespective of location, status or capacity. The ‘The Earth Microbiome Project’ (EMP), as described by Thompson, et al. [18] is an example of an initiative which embraces the low-cost

⁶ <https://biobricks.org/bpa/developers/>.

Table 3
Existing genetic resources initiatives which foster open access and capacity building.

Genetic Resource Initiative	Description	Elements for open access	Elements for capacity building
GenBank	The National Institute of Health genetic sequence database, an annotated collection of all publicly available DNA sequences	Low cost and open to all	Educational activities/ knowledge transfer and training
Global Genome Biodiversity Network (GGBN)	An international network of institutions that share an interest in long-term preservation of genomic samples representing the diversity of non-human life on Earth	Low cost and open to all	Educational activities/ knowledge transfer and training
Biological Innovation for Open Society (BIOS)	An open-access patent database which collates IP data from multiple national patent offices, with the aim of improving the process of interpreting and filtering IP	Low cost and open to all	Educational activities/ knowledge transfer and training
BioBricks	An information technology system with interchangeable parts, developed with the aim of building biological systems in living cells	Low cost and open to all. Long-term infrastructure	Educational activities/ knowledge transfer and training
International Genetically Engineered Machine Competition (iGEM)	An independent, non-profit organization dedicated to the advancement of synthetic biology, education and competition, and the development of an open community and collaboration	Low cost and open to all. Long-term infrastructure	Educational activities/ knowledge transfer and training. Entrepreneurship
Open Source Seed Initiative (OSSI)	An organization that maintains a mechanism through which plant breeders can openly access plant genetic resources worldwide	Long-term infrastructure	Educational activities/ knowledge transfer and training. Entrepreneurship
Open Source Drug Discovery (OSDD)	A global, translational platform for drug discovery where ‘the best minds can collaborate & collectively endeavor to solve the complex problems associated with discovering novel therapies’	Long-term infrastructure. Attribution	Educational activities/ knowledge transfer and training
Global Open Data for Agriculture	A group of partners which support ‘the proactive sharing of	Low cost and open to all	Educational activities/

Table 3 (continued)

Genetic Resource Initiative	Description	Elements for open access	Elements for capacity building
and Nutrition (GODAN)	open data to make information about agriculture and nutrition available, accessible and useable ⁷		knowledge transfer and training
The Earth Microbiome Project (EMP)	A collaborative effort to collect microbial samples and data across the biomes and habitats of our planet	Low cost and open to all	Educational activities/ knowledge transfer and training

open access approach. Such data can then be further annotated by the research community.

The BioBricks foundation, a specific brand of genetic, interchangeable parts, was established in 2006 with the mission to ‘ensure that the engineering of biology is conducted in an open and ethical manner to benefit all people and the planet’.⁷ BioBricks developers also initiated the iGEM foundation – an International Genetically Engineered Machine Competition. Physical DNA in the form of non-patented genes are sent to users by the BioBricks foundation for a small handling fee. In case users are able to synthesise their own material (such as DNA), using freely available code data from the BioBricks and iGEM databases and websites, then no costs are involved (since no material parts need to be sent out).⁸ By keeping costs to a minimum, the potential number of researchers from States at all levels of development who are able to access and use the BioBrick parts is maximized.

Other highly relevant examples of open access, genetic resource initiatives include GenBank and the Global Genome Biodiversity Network (GGBN). The GenBank database holds a collection of all publicly available (hence open access) DNA sequences, whilst the GGBN represents a network of institutions aiming to preserve and share genomic samples. However, the distinction must be made between databases that are open access (such as GenBank and BIOS) and associations of scientists (such as the GGBN) which adopt an open access policy with regards to genetic materials. Whilst both of these initiatives promote open access, the sharing of data is easier and usually cheaper than the physical sharing of genetic sample material. This is partly because data can be shared instantly online via internet databases/data portals and does not require the packaging and shipping of physical material, but also due to the finite nature of material which does not apply to data. Therefore, whilst sharing of sample material will undoubtedly be important, the sharing of MGR data can be seen as a more immediate and more straight-forward form of access to MGR and also of benefit-sharing.

The Biological Innovation for Open Society (BIOS) is another initiative working to ensure that data related to patents is openly accessible. BIOS is an open-access patent database which collates IP data from several national patent offices, with the objective of improving the process of interpreting and filtering IP [19].⁹ This helps users search for patents filed at various national and international patent offices.

3.3.2. Long-term infrastructure

Information communication technology (ICT) can be used to enable easy access to data. Open online platforms are a type of ICT infrastructure that are utilized in this way. BioBricks is an initiative which makes

⁷ http://parts.igem.org/Main_Page.

⁸ <http://www.bios.net/daisy/bios/home>.

⁹ http://parts.igem.org/Help:An_Introduction_to_BioBricks; <http://igem.org/Software>.

use of a long-term, sustainable ICT system and open source software¹⁰. The BioBrick parts (or building blocks) are physical material (such as standardized DNA sequences and genes) as well as coding information, which users can access to synthesis their own physical material. These parts can be built and incorporated into living cells, such as *E. coli*, and/or used to design and assemble larger synthetic biological systems [20]. In order¹¹ to achieve this, BioBricks maintains an open source, shared publishing platform for scientific research that people from both academia and industry can use, while still allowing a system with a certain degree of ownership to be built on this open platform. This is similar to open source software. Open source can be described as ‘a subset of free software that is made available under a copyright license approved by the Open Source Initiative as conforming with the Open Source Definition’.¹² Open source software is strict since it requires that any new software built on the existing open source software must also be open source. The open source nature is, therefore, maintained and can be described as ‘viral’ [21]. The concept of ‘open source’ began as a movement within the software industry in the early 1990’s and developed over time into a business model [22]. The best-known product of the open source model is Linux, an alternative operating system to Microsoft’s Windows. Building on the Linux concept, biologists started creating open source bioinformatics tools for data mining, visualization, simulation, statistics, integration and analysis [23]. Open source in this context then refers to the open origin of contributors as opposed to the source code [22]. In other words, biological open source models are based on a community of participation [24,25]. Open source R&D is an approach which enables scientists to work together across organizations, disciplines and borders, with the aim of solving problems in which they all share a common interest [22]. As such, long-term infrastructure to support inclusive innovation could be inspired by open source. However, it is noted that open source regarding software may not necessarily be directly applied to situations in highly regulated sectors or industries.

3.3.3. Attribution

Patents today are typically used to protect IP and to secure a return on (financial) investment. However, patents also serve the role as a tool to share information and enable benefit-sharing (i.a. through licensing). This role could be explored more in the future. Tools, such as attribution, are recognized as important elements in encouraging open access to data. Attribution is way in which to copy, distribute, display and perform work and also to acknowledge the author/licensor/inventor for it (e.g. indicating ‘by author x’) [26]. Some scientists view attribution as an important reward of science [27]. These tools can therefore be useful for promoting the sharing of and open access to data.

According to Sugumaran [28]; the ‘OSDD aspires to use patents as a tool for attribution rather than a means of revenue-generation’. Micro-attribution is a mechanism used by the OSDD which enables individual contributions of information to be tracked using patented information that is submitted and used by the online virtual system [28]. Patents are therefore used as a tool for attribution, encouraging the sharing and wider dissemination of information, and could also be seen as an important means of tracking benefit-sharing. Patents promote disclosure as patented information is readily available through patent databases. These databases potentially provide a straightforward way of maintaining open access to data, though not the right to utilize the innovation developed by the patent owner, unless the patent owner agrees or until the 20-year exclusivity period is over.

¹⁰ http://ocw.metu.edu.tr/pluginfile.php/4339/mod_resource/content/0/week3content.pdf.

¹¹ <https://opensource.org/node/878>.

¹² <https://creativecommons.org/about/>.

4. Inclusive innovation

4.1. Operationalizing inclusive innovation with regards to utilization of MGR from ABNJ

In order for open access to MGR from ABNJ to become a reality in practice, scientific networks need to strengthen and grow [11]. Bio-repositories and databases will need to become better linked so that difficulties and burdens currently associated with access are reduced. Effective capacity building in this particular situation will involve knowledge transfer together with targeted training or education programmes [9]. The combination of open access and capacity building efforts could remove some currently existing barriers for States in terms of capability to conduct scientific R&D on MGR from ABNJ. This will be discussed further in section 4. Clear provisions for open access together with capacity building could lay the foundation for inclusive innovation with regards to utilization of MGR from ABNJ.

4.2. Structural elements supporting inclusive innovation in existing genetic resource initiatives

As with open access (and capacity building), potential key elements which may encourage inclusive innovation can be identified through the analysis of existing genetic resource initiatives (see Table 4), such as those described in section 3.3. The aim of the following discussion is to look beyond these examples with a view to identifying elements of inclusive innovation in existing genetic resource initiatives that could provide inspiration and potentially be adopted through a BBNJ agreement as part of a benefit-sharing mechanism for MGR.

4.2.1. Appropriate IP sharing arrangements, including Creative Commons licensing

In order to promote participation and collaboration in MSR linked to MGR, it is important that data can be shared. Licensing has emerged as an appropriate approach for application and sharing of data derived from MSR and marine bioprospecting [29]. Licensing refers to the management of IP assets in a specific way that enables dissemination of innovation according to pre-defined terms. Creative Commons licenses,

Table 4
List of existing genetic resources initiatives which adopt principles of inclusive innovation.

Genetic Resource Initiative	Description	Elements for inclusive innovation
BioBricks	An information technology system with interchangeable parts, developed with the aim of building biological systems in living cells	Public domain approach
Open Source Seed Initiative (OSSI)	An organization that maintains a mechanism through which plant breeders can openly access plant genetic resources worldwide	Appropriate IP protection arrangements, including (creative commons) licensing
Open Source Drug Discovery (OSDD)	A global, translational platform for drug discovery where ‘the best minds can collaborate & collectively endeavor to solve the complex problems associated with discovering novel therapies’	Appropriate IP protection arrangements, including (creative commons) licensing. Generation of knowledge in a cumulative, cooperative, collaborative and inclusive manner, such as through the use of Public Private Partnerships (PPP) and Open Collaboration. Public domain approach. Online communities and networks

defined as non-exclusive, non-revocable public copyright licenses, facilitate the legal sharing, reuse and possibly also the free distribution of 'knowledge and creativity to build a more equitable, accessible, and innovative world'¹³ [26]. This is conducted in accordance with terms that are flexible and legally sound. Creative Commons licenses provide a 'way to manage the copyright terms that attach automatically to all creative material under copyright'.¹⁴ In other words, authors can grant people the right to share, use and build upon their own work [26]. In terms of MGR, this may, for example, apply to databases and in cases where DNA sequences are annotated or labelled.

Licensing, as a means by which IP owners can choose to exercise their rights, can be seen to remove the barriers that some people may expect to encounter when working with IP protected data. As a result, licensing could promote the engagement and collaboration of a greater number of people in the R&D process, thereby facilitating and encouraging inclusive innovation. Additional, potential advantages associated with the use of licenses, together with a collaborative sharing framework and variety of motivated participants, include the fact that benefits can accrue locally (such as treatments for local diseases, improved health, employment and payment of tax to the local state).

In certain cases, such as for neglected diseases, the OSDD system could have value. Whilst partners to the OSDD are free to patent as they wish, sharing of results in the public domain is encouraged. The OSDD 'promotes patenting based on the general public license that ensures that the subsequent innovations which follow on from the existing patent remain openly accessible through the OSDD community through its viral clauses' [28].¹⁵ This approach limits exclusion from accessing or using the public information [26,28]. In addition, this approach promotes affordability and accessibility by ensuring that pharmaceutical products and treatments for neglected diseases are licensed non-exclusively.

4.2.2. Generation of knowledge in a cumulative, cooperative, collaborative and inclusive manner, such as through the use of public private partnerships (PPP) and Open Collaboration

The generation of scientific knowledge in a manner that is cumulative, cooperative, collaborative and inclusive may help to encourage inclusive innovation with regards to utilization of MGR from ABNJ. This form of knowledge creation may be facilitated through the use of PPPs and Open Collaboration. Whilst there is no single definition, the term PPP is generally interpreted as referring to 'forms of cooperation between public authorities and the world of business which aim to ensure the funding, construction, renovation, management or maintenance of an infrastructure or the provision of a service' [30]. PPPs are an approach towards IP management which encourages the participation of a variety of stakeholders [26]. Open access as part of a structured entity, such as a PPP, can enable open access to have more impact than a stand-alone open access database and can also be seen as the operationalization of capacity building. For example, by interacting with PPPs, open access can become more collaborative. PPPs provide a format to meaningfully engage the private sector and can be a tool to bring innovative finance into ABNJ [31]. Motives for participation in a PPP differ. Whilst academic researchers may focus more on publication of results, the private sector will aim to generate profits and return on investment [32,33]. A common PPP focus is on the sharing and pooling of complementary skills [26].

4.2.3. Public domain approach

A public domain approach has been identified as an element within existing genetic resource initiatives which may promote inclusive innovation. This approach can be used when there is no need or desire to control access, or when access is open. The term 'public domain'

therefore indicates that nobody can be excluded from having access to or using data that are in the public domain [26]. Genetic resource data in the public domain may include previously patented products/processes (once the patent right has expired), products/processes which are not patented, as well as those for which a patent has been declined.¹⁶ A public domain approach is achieved when samples and related data are shared publicly, eventually through international networks of bio-repositories or international networks with established databases creating common pools [10]. The BioBricks Foundation uses such an approach, with a mission to 'ensure that the engineering of biology is conducted in an open and ethical manner to benefit all people and the planet'. The OSDD initiative also uses the public domain approach to benefit-sharing. Advantages of the public domain approach (together with open access) include low monetary costs, local accrual of benefits (such as access to resources or development of solutions to local challenges), greater innovation, transparency and openness.

4.2.4. Online communities and networks

In order for stakeholders to work together and participate in inclusive innovation, ICT infrastructure is needed to support the establishment of online communities and associated collaborations [24,25]. Data, new discoveries and applications have little inherent use unless they can be utilized in the search for solutions to challenges. To help find these solutions, the OSDD and the Council of Scientific and Industrial Research (CSIR), India, partnered with an ICT company to develop a search engine-based portal.¹⁷ The aim of the portal is to enable researchers to form collaborative online networks, with potential to create virtual, distributed laboratories for furthering R&D associated with discovery and development of new drugs to treat Tuberculosis [25]. The portal integrates social networking with scientific workflows, giving all people involved the opportunity to interact in a way that is simple and which promotes effective dialogue that can lead to progress towards the research objectives [24,25]. This form of global collaboration and engagement with a vast community of other researchers, as permitted by the existence of the online portal, provides a valuable tool for promoting inclusive innovation.

5. ILBI negotiations: embracing clear provisions for open access and capacity building, thereby paving the way for inclusive innovation

5.1. Open access and capacity building in the ILBI

Clear provisions for open access to MGR data, together with associated capacity building, will be required to implement the ILBI. This could lead naturally to inclusive innovation. Key elements for open access, capacity building and inclusive innovation in existing genetic resource initiatives have been identified and demonstrate the merits of this type of approach. However, MGR from ABNJ present a different case compared to genetic resources within national jurisdiction. Key elements (such as low-cost and open to all, long-term infrastructure and attribution) can be used as a starting point, to identify potential solutions that could inspire and underpin the inclusive innovation approach. Broggiato, et al. (2018) suggest a regime for sharing benefits from MGR that would promote open access to data while keeping the burden on users (and providers) to a minimum. In other words, access could be free of restrictions (such as excessive access tolls), but the procedure may be accompanied by the requirement to record a minimum amount of information, together with potential benefit-sharing obligations. This would not assume ownership of data, but would be more concerned with the rights to use it and enabling open access to data.

Aspects to consider during ILBI negotiations could include the

¹³ <https://creativecommons.org/faq/#what-are-creative-commons-licenses>.

¹⁴ <http://www.osdd.net/>.

¹⁵ <https://opensource.org/node/878>.

¹⁶ <http://sysborg2.osdd.net/web/guest>.

¹⁷ <http://www.iobis.org/>.

following points:

A) Introduction of means to coordinate, strengthen and support global research and data connections

A large amount of marine-related data already exists in open, online databases. By coordinating, strengthening and supporting global connections between various existing biorepositories and databases, MGR could become increasingly open and accessible [10]. Support for data repositories, including existing systems, to host and share data from ABNJ will be important for sharing benefits, including by providing information on where data can be found and how to access them. The Ocean Biogeographic Information System (OBIS) is 'a global open-access data and information clearing-house on marine biodiversity for science, conservation and sustainable development'.¹⁸ OBIS represents a suitable existing platform for hosting and sharing data from BBNJ and, in some regards, already fulfils this role¹⁹. A key strength of OBIS is its international network of national and regional nodes, and the coordination within IOC-UNESCO. However, in order to provide a long-term solution for MGR benefit-sharing, OBIS would likely require additional resources [34].

B) Coupling of open access to MGR data with capacity building

Open access to MGR data could be coupled with capacity building, such as access to equipment, training and long-term support for infrastructure to level the playing field and to provide all States with fairer opportunities in terms of capability to utilize MGR from ABNJ. Doing so would provide a solid foundation for inclusive innovation and support of benefit-sharing under an ILBI.

5.2. Strengths of the inclusive innovation approach

An approach which harnesses open access, capacity building and inclusive innovation has great potential in terms of promoting meaningful participation of, and collaboration with, many States/stakeholders in the sustainable utilization of MGR from ABNJ. In addition, this approach could enhance global marine scientific knowledge, accelerate the rate of discoveries and R&D project development, and facilitate the equitable sharing of benefits.

5.2.1. Facilitating greater participation of states and stakeholders in the utilization of MGR from ABNJ

A working environment which fosters the concepts of open access, capacity building and inclusive innovation could facilitate the engagement of a greater number and diversity of States/stakeholders in the R&D process associated with MGR from ABNJ. This has the potential to reduce disparity between States in terms of differential access capabilities [35]. In addition, open access coupled with capacity building, could encourage participation in the inclusive innovation process by removing potential barriers that might be associated with capability to conduct R&D on MGR.

5.2.2. Enhancing global scientific knowledge, opportunities and wealth with regards to MGR from ABNJ

An open innovation approach, whereby access to data and capacity building form key pillars of benefit-sharing, could offer advantages such as enhancing capability to utilize MGR, as well as scientific knowledge, opportunities and wealth associated with utilization of MGR from ABNJ (see Fig. 2).

5.2.2.1. Scientific knowledge. It is thought that a high diversity of MGR exists in ABNJ, a large proportion of which has yet to be identified. Combining open access, capacity building and inclusive innovation could help to broaden and speed up the process of discovery and product development. This would enable (marine) scientific research to advance

at a scale and rate that would simply not be possible with a more restrictive, less inclusive and less open access regime. By conducting research on a wider variety of material and in collaboration with a larger number of diverse partners, the rate and probability of genetic resource discoveries with implications for new, life-enhancing and/or commercially viable products would be enhanced [10]. For example, enhanced scientific R&D could have a direct impact on the number and variety of pharmaceutical products available to civil society in the near future. In addition, inclusive innovation could create a feedback loop that increases basic scientific knowledge regarding BBNJ, that could in turn promote conservation and sustainable use of BBNJ by supporting successful establishment of ABMT such as MPAs.

5.2.2.2. Opportunities (local and global). The approach outlined in this paper will provide critical advantages for a number of important, global issues. By promoting the participation of researchers, professionals, students and teachers around the world, it is possible to leverage expertise in order to facilitate particular objectives, such as finding cures to some of the world's most deadly diseases or understanding how best to protect different parts of the ocean [36]. Tapping into this vast resource at the global scale provides unique and valuable opportunities [24,25]. Inclusive innovation would also promote streamlining of local expertise into R&D, thereby fostering local needs. In turn, a variety of benefits could be provided for a number of different sectors linked to science, business and also society [24,25].

5.2.2.3. Inclusive wealth. By facilitating and advancing global innovation on the basis of effective knowledge generation, economic value could potentially be created. Inclusive participation and collaboration in this process may provide successful outcomes for all parties involved, as they have the chance to benefit not only from the products developed, but also from the knowledge transfer and the opportunities associated with participating in the process itself. Enhanced information-sharing in this form has been shown to encourage discovery and in turn benefit the entrepreneur [37]. Just as in the case of cooperation between smaller and larger enterprises, pursuing entrepreneurship collaboratively allows parties to preserve their creativity and flexibility [38]. Therefore, both emerging and established MGR user States could potentially benefit from the innovation potential (as illustrated in Fig. 2. A, 2. B and 2. C) if the ILBI provides a common framework to support joint exploration of the results.

The private sector could also stand to gain from open access and inclusive innovation. Since the probability of discovering a genetic resource with true potential for commercialization and financial reward is slim, inclusivity and collaboration with a variety of different partners could improve the odds and play an important role in promoting their success [39,40].

5.2.3. Promoting more equitable benefit-sharing

As inclusive innovation becomes established, it could become self-perpetuating due to the creation of a feedback loop (see Fig. 1). The process of inclusive innovation will help to improve further utilization of MGR due to enhanced knowledge creation together with refinement of techniques, methodology and equipment. As a result, the quality and quantity of generated benefits could be improved. This is depicted in Fig. 2.D.i and .D.ii, with the size of the benefit-sharing bubble becoming larger as a result of open access, capacity building and inclusive innovation. These benefits could potentially then be shared in a more equitable manner, to further facilitate participation in inclusive innovation (G7 people-centered action plan on innovation, skills and labor, 2017). These benefits may be realized through capacity building and by providing a wider variety of projects for any given state/stakeholder to participate in.

¹⁸ <http://www.iobis.org/>.

6. Conclusion

By providing all States and stakeholders with open access to MGR data, together with the required capacity building (needed to equip parties with the capability to conduct R&D on these resources), barriers which currently limit utilization of MGR from ABNJ could be diminished. Open access and capacity building are crucial elements for inclusive innovation that support benefit-sharing from genetic resources. Incorporating robust measures for these elements into the ILBI would lay the foundation for an inclusive innovation approach to utilization of MGR from ABNJ, which could enable the meaningful participation of a greater number and variety of States/stakeholders. Such an approach could support a range of outcomes, from enhancing scientific knowledge, creating new opportunities to participate in R&D and share in the benefits from genetic resources. Open access, capacity building and inclusive innovation will not be the whole answer in terms of utilization of MGR from ABNJ, but implementation of this concept could enable a broad range of States (and the global community as a whole) to participate in and benefit significantly more than they currently do.

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Declaration of competing interest

MJ is founder of, has shares in, and consultant to GyreOx Ltd, a company that uses marine genetic resources from areas within national jurisdiction to develop potential drug molecules.

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Acronyms

ABMT: Area-Based Management Tools
ABNJ: Areas Beyond National Jurisdiction
ABS: Access and Benefit-Sharing
BBNJ: Biodiversity Beyond National Jurisdiction
DSGR: Deep Sea Genetic Resources
EIA: Environmental Impact Assessment
ILBI: international legally binding instrument
IP: intellectual property
LDCs: Least Developed Countries
MGR: marine genetic resources
MPA: marine protected areas
MSR: marine scientific research
R&D: research and development
UNCLOS: United Nations Convention on the Law of Sea
UNGA: United Nations General Assembly