

Review

**Marine Genetic Resources:
An Intellectual Property Perspective**

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The following review is based on the presentation “Marine genetic resources, including the fair and equitable sharing of benefits: An intellectual property perspective” at the workshop:

Conservation and sustainable use of marine biological diversity
of areas beyond national jurisdiction (BBNJ)

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Marine Genetic Resources: An Intellectual Property Perspective

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The BBNJ Agreement is not yet in force, in accordance with article 68(1) of the BBNJ Agreement which reads as follows: “This Agreement shall enter into force 120 days after the date of deposit of the sixtieth instrument of ratification, approval, acceptance or accession“. It is open for signature since 20 September 2023.⁴ As of 24 October 2023 there are 82 Signatories and no ratification, approval, acceptance or accession.

This review was updated on 15 October 2023.

After about 20 years of negotiations in different fora,⁵ the United Nations (UN) adopted on 19 June 2023 the Agreement under the United Nations Convention on the Law of the Sea on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction (BBNJ Agreement).⁶ The BBNJ Agreement is intended to ensure conservational and sustainable use of marine biodiversity in areas beyond national jurisdiction.

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³ The Hugo Grotius gGmbH – non-profit society for the advancement of legal sciences is a Germany based science and research society established in 2014 and a non-governmental organization (NGO) in special consultative status with the Economic and Social Council (ECOSOC) of the United Nations since 2023 and in observer status with the United Nations Environment Programme (UNEP). Website: <https://hugo-grotius.org>. GERiT ID: [390149277](https://www.gerit.org/390149277).

⁴ Depositary Notification, UN Doc. [C.N.202.2023.TREATIES-XXI.10](https://www.un.org/press/docs/2023/20230723.TREATIES-XXI.10.doc.html), 20/07/2023.

⁵ For the development of this initiative: Andree Kirchner, *Bioprospecting, marine scientific research and the patentability of genetic resources* in: Norman A. Martínez Gutiérrez, Serving the Rule of International Law, Routledge 2010, pp. 119-135; Iris Kirchner-Freis and Andree Kirchner, *Genetic Resources of the Sea* in: David Joseph Attard (ed.), The IMLI Manual on International Maritime Law, Volume I: The Law of the Sea, Oxford University Press 2014, pp. 377-395.

⁶ Agreement under the United Nations Convention on the Law of the Sea on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction, UN Doc. [A/CONF.232/2023/4](https://www.un.org/press/docs/2023/20230619.CONF.232/2023/4.doc.html), 19/06/2023. Text of the BBNJ Agreement and further information: <https://www.un.org/bbnj/>.

Part II of the new BBNJ Agreement deals with marine genetic resources (MGRs) of areas beyond national jurisdiction, i.e. the high seas and the Area (Art. 1(2), BBNJ Agreement), the digital sequence information (DSI) on MGRs, and the fair and equitable sharing of the benefits arising from their utilization.

Marine Genetic Resources

Marine Genetic Resources (MGRs) are defined in the BBNJ Agreement as “any material of marine plant, animal, microbial or other origin containing functional units of heredity of actual and potential value“ (Art. 1(8), BBNJ Agreement). MGRs are organisms from the deepest areas of the oceans, including e.g. slugs, sponges, fungi, seaweed, algae, bacteria etc. As they are subject to extremes of pressure, temperature and sometimes toxicity, they have unique molecular and metabolic characteristics that allow their survival in such conditions. These unique qualities makes them of actual and potential scientific, industrial and commercial value, especially for the pharmaceutical, food, cosmetics and alternative energy sectors.

The access and the analysis of MGRs require expensive technologies. It is not surprising that most of the research, patenting and commercialization are carried out by companies and research institutions in a limited number of developed Countries. Therefore, developing Countries are not presently engaged in these research activities but are interested in a mechanism for the sharing of both monetary and non-monetary benefits with developed Countries in a fair and equitable manner.

Digital Sequence Information

Although Digital Sequence Information (DSI) has reached a great awareness, the term itself is currently undefined, still not used in a uniform way, and interpreted differently by different stakeholders. It is a placeholder term to genetic sequence data as well as all the data and information which is derived from MGRs. In the present context it therefore refers to immaterial, electronically saved data on genetic resources, including other related information as interpretations of such data stored, e.g. in open access databases for research and development purposes.

The access to physical samples of genetic material, e.g. microorganisms, animals or plants, to develop new products, becomes insofar more and more obsolete due to the new technologies in fields such as bioinformatics. It was therefore a necessity to include DSI on MGRs and made it part of the provision of the BBNJ Agreement relating to fair and equitable sharing of benefits.

As many states fear that access and benefit sharing regulations will be undermined by the use of digital sequence information on genetic resources from public databases, discussion on that issue also take place in other

different United Nations fora and instruments, such as in the context of the Convention on Biological Diversity (CBD).⁷ In this respect the Conference of the Parties (COP) to the CBD decided in December 2022 at its fifteenth meeting to establish a multilateral mechanism for benefit-sharing from the use of DSI on genetic resources.⁸ They also established an Ad Hoc Open-ended Working Group on Benefit-sharing from the use of DSI on Genetic Resources to undertake further development of the multilateral mechanism.⁹ An equation of genetic resources with DSI seems therefore no longer sought.

Marine Genetic Resources in International Law

International Law already regulates the access to and the fair and equitable sharing of benefits of MGRs, e.g. the CBD from 1992 and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization from 2010.¹⁰ But MGRs from areas beyond national jurisdiction are outside the scope of the CBD and its Nagoya Protocol, which is limited to areas within national jurisdiction (Art. 4(a), CBD). Therefore it was essential to develop a new international legally binding instrument. One of the key elements of the BBNJ Agreement is the creation of a new mechanism for the fair and equitable sharing of benefits arising from activities with respect to MGRs and DSI on MGRs from areas beyond national jurisdiction. This mechanism in the BBNJ Agreement is groundbreaking because for the first time stakeholder, e.g. companies, will be required to contribute and to share financial and other benefits when using MGRs beyond national jurisdiction.

But the international negotiations to reach such a mechanism at all had proved to be extremely difficult due to the lack of consensus on whether the principles of the “freedom of the high seas” (Part VII of the United Nations Convention of the Law of the Sea (UNCLOS)¹¹ — the resources belong to those who first access and exploit them — or the principle on the “common heritage of humankind” (Part XI of UNCLOS) — the resources belong to all — should apply to MGRs in areas beyond national jurisdiction. In the end a compromise was successfully reached. Subject to Art. 7 BBNJ Agreement the parties to the BBNJ Agreement shall be guided by both principles.

⁷ Text of CBD: <https://www.cbd.int/convention/>.

⁸ Conference of the Parties to the Convention on Biological Diversity, UN Doc. [CBD/COP/DEC/15/9](#), 19/12/2022.

⁹ First meeting of the Ad Hoc Open-ended Working Group on Benefit-sharing from the Use of Digital Sequence Information on Genetic Resources, 14-18 November 2023 in Geneva, Switzerland. Further information: <https://www.cbd.int/dsi-gr/>.

¹⁰ Text of the Nagoya Protocol: <https://www.cbd.int/abs/>.

¹¹ Text of UNCLOS: https://www.un.org/Depts/los/convention_agreements/texts/unclos/unclos_e.pdf.

Clearing-House Mechanism

At different stages of both the collection and the utilization of MGRs and DSI on MGRs, interested parties will have to notify the newly created Clearing-House Mechanism (Art. 12, BBNJ Agreement).

The Clearing-House Mechanism shall consist primarily of an open access-platform (Art. 51(2), BBNJ Agreement). The centralized platform will be managed by the secretariat and shall enable Parties to access, provide and disseminate information with respect to MGRs of areas beyond national jurisdiction.

The notification will allow for the monitoring of the collection and the use of MGRs, as well as to link it to the proper benefit sharing obligations afterwards. The BBNJ Agreement lists in detail the information that shall be notified to the Clearing-House Mechanism six months or as early as possible prior to the collection in situ of MGRs of areas beyond national jurisdiction (Art. 12(2) BBNJ Agreement), e.g.:

- subject matter of the research;
- geographical areas in which the collection is to be undertaken;
- the name(s) of the sponsoring institution(s);
- opportunities for scientists of all States, in particular scientists from developing States, to be involved in or associated with the project.

As soon as it becomes available but no later than one year from the collection of MGRs it is obligatory to notify to the Clearing-House mechanism about (Art. 12(5), BBNJ Agreement), e.g.:

- the repository or database where DSI on MGRs is or will be deposited;
- where the MGRs, that were collected, are being held;
- a report of the geographical area from which marine genetic resources were collected and insofar available.

If the collected MGRs and DSI from MGRs are subject to utilization including commercial products or processes, further information will need to be notified as soon as it becomes available (Art. 12(8), BBNJ Agreement), including e.g.:

- where the results of the utilization can be found, such as publications, patents granted and products developed;
- where the original sample that is subject of utilization is held,
- information on sales of relevant products, if available.

Monitoring and transparency

Monitoring and transparency of activities with respect to MGRs and DSI on MGRs from areas beyond national jurisdiction shall be achieved through notification to the Clearing-House Mechanism through the use of the “BBNJ standardized batch identifier” (Art 16(1), BBNJ Agreement). The use of the BBNJ standardized batch identifier is a technically attainable way to solve the question of provenance and to track the movements of the MGRs and the

DSI on MGRs. It will be automatically generated by the Clearing-House Mechanism upon notification on the collection of MGRs (Art. 12(3), BBNJ Agreement). This tag groups all associated sequence information, samples and products that result from the point of the collection to the point of use and track where and how a sample or the information are used and has a material outcome, like a patent or a product. The use of the BBNJ standardized batch identifier ensures in this way that the benefits arising from activities with respect to MGRs and DSI on MGRs of areas beyond national jurisdiction could be shared in a fair and equitable manner.

Non-monetary benefits

According to the BBNJ Agreement, monetary and non-monetary benefits arising from activities with respect to MGRs and DSI on MGRs shall be shared in a fair and equitable manner (Art. 14, BBNJ Agreement).

Non-monetary benefits are to be shared e.g. in the form of access to samples and DSI, open access to scientific data, capacity building and the transfer of marine technology as well as increased technical and scientific cooperation (Art. 14(2), BBNJ Agreement).

Monetary benefits

Monetary benefits from the utilization of MGR and DSI on MGR of areas beyond national jurisdiction including commercialization shall be shared fairly and equitably through a newly established financial mechanism (Art. 52, BBNJ Agreement) for the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction (Art. 14(5), BBNJ Agreement).

After the entry into force of the BBNJ Agreement developed Parties to the Agreement shall pay an annual contribution to the newly established financial mechanism in the amount of 50 percent of, and in addition to, their assessed contributions (Art. 14(6), BBNJ Agreement). The BBNJ Agreement mandates the Conference of the Parties to replace the initial benefit-sharing modality (Art. 14(7), BBNJ Agreement) through modalities for the sharing of monetary benefits from the utilization of MGRs and DSI on MGRs of areas beyond national jurisdiction, e.g. milestone payments, payments related to the commercialization of a products including payments of a percentage of the revenue from sales of products (Art. 14(7), BBNJ Agreement).

The financial mechanism shall assist developing States Parties in the implementation of the BBNJ Agreement including through funding in support of capacity building and the transfer of marine technology (Art. 52(3), BBNJ Agreement).

Intellectual property rights and MGRs

The connection between access and benefit-sharing (ABS) regimes and intellectual property rights (IPR) has always been a controversial issue.

In the BBNJ Agreement is — apart from notification obligations on patents granted (Art. 12(8), BBNJ Agreement) — no reference to IPR on products that originated from MGRs collected in areas beyond national jurisdiction.

During the negotiations to the new BBNJ Agreement developed Countries like the USA, Switzerland, Norway, Japan and the EU, among others, strongly opposed addressing intellectual property (IP) in the instrument, as IPR would not be within the scope of the BBNJ Agreement and would not be the appropriate forum to discuss such issues, since institutions as the World Intellectual Property Organization (WIPO) and World Trade Organization (WTO) already do so.

Intellectual property law sets out the monopoly rights and protection relating to new products and inventions. It has to be stressed that MGRs as such are not patentable. But if they are modified through human intervention through the application of biotechnology for example — and the resulting invention is novel, inventive and industrially useful — the invention can be patented. The number of patents originating from MGRs is increasing and a small number of developed Countries account for 90 percent of patents related to MGRs. Consequently, developing Countries would like benefits to be shared more fairly and equitably.

World Intellectual Property Organization

WIPO is a specialized agency of the United Nations with 193 member states, established in 1967. It is a global forum for intellectual property, policy, services, information and cooperation.

WIPO administers 26 international treaties on IP, including the Paris Convention for the Protection of Industrial Property and the Patent Cooperation Treaty (PCT). These treaties provide a framework for the protection of IP in the member states.

Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore

The Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (IGC) of WIPO has dealt with a range of issues concerning the interplay between IP and genetic resources. The IGC was established by the WIPO General Assembly in 2000 as a forum for discussions on intellectual property and genetic resources, traditional knowledge and folklore. The IGC's mandate covers the development of an international instrument on IPRs and genetic resources, complying with regulations on access and benefit sharing with a possible relevance for marine genetic resources in areas beyond national jurisdiction.

WIPO does not address the regulation of ABS regimes of genetic resources as such, but WIPO Member States consider whether and to what extent the IP system could be used to ensure compliance by users of genetic resources with ABS regimes.

Centre stage in the discussions in this context is a patent disclosure requirement (PDR), which would require patent applicants seeking patents for inventions, that are based on genetic resources and associated traditional knowledge, to include as part of the patent application information about the source or origin of the genetic resources and associated traditional knowledge. The disclosure obligation could prevent misappropriations and promote the fair and equitable sharing of benefits between users and providers of genetic resources and associated traditional knowledge. In this way the IP system could also support the implementation of the obligations in the BBNJ Agreement related to the notification obligations, which will allow for the monitoring of the collection and the use of MGRs, as well as to link it to the proper benefit sharing obligations afterwards, monitored by the use of the BBNJ standardized batch identifier, a technically feasible way to solve the question of provenance of the MGRs and the DSI on MGRs.

Currently, information on the source or origin of genetic resources is usually not disclosed. So far the patent law only imposes a general obligation on patent applicants, as referred to in Article 5 of the Patent Cooperation Treaty (PCT), “to disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art”.

But disclosure requirements are part of various proposals to reform international, regional and national patent law, e.g. the Agreement on Trade-Related Aspects of Intellectual Property Rights, commonly known as the TRIPS Agreement, which was adopted in 1994 by the World Trade Organization (WTO).

In addition some countries have already adopted some form of PDRs — voluntary or mandatory for the patent application — in their national legislation, all different in terms of their binding nature, scope and consequences in case of non-compliance.¹²

Way to the Diplomatic Conference

The General Assembly of WIPO decided in 2022 to fast-track negotiations on genetic resources and associated traditional knowledge by convening a Diplomatic Conference no later than 2024 to conclude an International Legal Instrument relating to intellectual property, genetic resources and traditional knowledge associated with genetic resources. The negotiations should be based on a draft international legal instrument which was prepared by a

¹² WIPO, Key Questions on Patent Disclosure Requirements for Genetic Resources and Tradition Knowledge, 2020, Annex: Disclosure Requirement Table.

former chair of the IGC, Ian Goss - the so-called Chair's Text.¹³ It should constitute the substantive articles of the „Basic Proposal“, and any other contributions by Member States.

Special Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

The IGC of WIPO met in a Special Session from 4-8 September 2023 and agreed on a number of revisions to the substantive articles of the Basic Proposal and decided to transmit that proposal to the Preparatory Committee of the Diplomatic Conference, as the substantive articles of the Diplomatic Conference.¹⁴

The Draft Text¹⁵ proposes to establish a mandatory patent disclosure requirement (Art. 3, Draft Text). Patent applicants would be required to disclose the country of origin of the genetic resources or in cases where the information is not known to the applicant, the source of the genetic resources, if the claimed invention is materially / directly based on genetic resources. Patent applicants would also be required to disclose the Indigenous People or local community that provided the traditional knowledge associated with genetic resources or in cases where the information is not known to the applicant, the source of the traditional knowledge associated with genetic resources, if the claimed invention is materially / directly based on traditional knowledge associated with genetic resources. In cases where none of the aforementioned information is known, the patent applicant should be required to declare so. Patent offices should provide guidance to patent applicants how to meet the disclosure requirements, but they should not be obliged to verify the authenticity of the disclosure.

If the patent applicants do not comply with the mandatory disclosure requirements, appropriate, effective and proportionate legal, administrative and / or policy measures — subject to national law — should be applied. The patent applicant should have the opportunity to rectify a failure to disclose the required information. Apart from fraudulent intention on the disclosure requirement, no Contracting Party should revoke or render unenforceable a patent solely on the basis of an applicant's failure to disclose the required information (Art. 6, Draft Text).

¹³ Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources, Annex to the WIPO Doc. [WIPO/GRTKF/IC/43/5](#), dated 03/05/2022.

¹⁴ Special Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, WIPO Doc. [WIPO/GRTKF/IC/SS/GE/23/4](#), dated 08/09/2023.

¹⁵ Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources, Annex to WIPO Doc. [WIPO/GRTKF/IC/SS/GE/23/4](#), dated 08/09/2023.

It is recognized that a number of mandatory disclosure regimes at the national and regional level already exist. In this respect the Draft Text proposes a non-retroactivity clause in order to maintain legal certainty within the patent system. No obligations of this instrument should be imposed in relation to patent applications which have been filed prior to the ratification of or accession to this instrument (Art. 5, Draft Text).

Information systems and databases of genetic resources and traditional knowledge, associated with genetic resources, should be established in consultation, where applicable, with Indigenous People and local communities and other stakeholders (Art. 7, Draft Text). The information systems should be accessible to patent offices for the purposes of search and examination of patent applications and to avoid in this way the problem of erroneous patents, which do not fulfill patentability requirements, such as novelty, inventiveness or industrial applicability.

The definitions of „genetic material“ and „genetic resources“ correspond with the definitions in Article 2 of the Convention on Biological Diversity as well as with the definition of marine genetic resources in Article 1(8) of the BBNJ Agreement. The Draft Text requires explicitly that the instrument should be implemented in a mutually supportive manner with other international agreements relevant to this instrument (Art. 8, Draft Text).

The Draft Text includes a review of the scope and contents of the instrument such as the possible extension of the disclosure requirement to other areas of intellectual property and to derivatives and other issues arising from new and emerging technologies that would be relevant for the application of the instrument. The review should take place no later than four years after the entry into force of this instrument (Art. 9, Draft Text).

Preparatory Committee of the Diplomatic Conference

In preparation for the Diplomatic Conference, the Preparatory Committee of the Diplomatic Conference to conclude an International Legal Instrument relating to intellectual property, genetic resources and traditional knowledge associated with genetic resources met from September 11 to 13, 2023.

The Preparatory Committee decided to incorporate in the Basic Proposal for the Diplomatic Conference, the agreements reached during the Special Session of the IGC.¹⁶

¹⁶ Preparatory Committee of the Diplomatic Conference to Conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources, WIPO Doc. [GRATK/PM/5](#), dated 13/09/2023.

The Preparatory Committee also considered and approved the draft administrative provision and final clauses for the instrument,¹⁷ which were modeled on the corresponding provisions of recent WIPO-administered treaties for further consideration by the Diplomatic Conference.¹⁸

The meeting of the Preparatory Committee was adjourned to be reconvened at a future date to consider the draft agenda and the dates and venue of the Diplomatic Conference.¹⁹

Next steps and final remarks

The ongoing negotiations in the IGC of WIPO were also considered during the negotiations to the BBNJ Agreement. Countries had divergent views on whether and how IP issues should be addressed in the new BBNJ Agreement. In this context it was argued that intellectual property rights should be left to WIPO and/or the WTO as the appropriate forum to take care of IP questions, instead of addressing IP rights — including mandatory disclosure of origin requirements in patent applications — in the BBNJ Agreement. Therefore, the decision of WIPO to convene a Diplomatic Conference to adopt an international legal instrument relating to intellectual property, genetic resources and traditional knowledge associated with genetic resources no later than 2024, attracted and attracts very high interest in different fora.

The Draft Text mentions explicitly that the instrument should be implemented in a mutually supportive manner with other international agreements relevant to this instrument (Art. 8, Draft Text).²⁰ The notes to the Chair's Text²¹ make it also very clear that "[...] there is no reference to issues related to access and benefit-sharing or to misappropriation, as these issues are already dealt with in other international instruments, such as the Convention on Biological

¹⁷ Preparatory Committee of the Diplomatic Conference to Conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources, WIPO Doc. [GRATK/PM/2](#), dated 10/07/2023

¹⁸ Preparatory Committee of the Diplomatic Conference to Conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources, WIPO Doc. [GRATK/PM/5](#), dated 13/09/2023.

¹⁹ Preparatory Committee of the Diplomatic Conference to Conclude an International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources, WIPO Doc. [GRATK/PM/5](#), dated 13/09/2023.

²⁰ Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources, Annex to WIPO Doc. [WIPO/GRTKF/IC/SS/GE/23/4](#), dated 08/09/2023.

²¹ Draft International Legal Instrument Relating to Intellectual Property, Genetic Resources and Traditional Knowledge Associated with Genetic Resources, prepared by Ian Goss, Annex to WIPO Doc. [WIPO/GRTKF/IC/43/5](#), dated 03/05/2022, notes on Article 1 of the Chair's Text.

Diversity (CBD), 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 (Nagoya Protocol), the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) of the Food and Agriculture Organization of the United Nations and the World Health Organization's Pandemic Influenza Preparedness Framework, 2011. [...]".

The new BBNJ Agreement could be added to the list of the international conventions and treaties already mentioned in the notes to the Chair's Text.



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