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GENETIC RESOURCES OF THE SEA

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13.1 Introduction

Marine organisms and the genetic information that they contain are of growing scientific and commercial interest. Their potential for biotechnological, pharmaceutical, and cosmetic applications are of particular value, especially in combating human diseases. The exploration for and exploitation of marine resources is not limited to coastal waters; most of the organisms from which the new marine genetic resources derive, are found, for example, near hydrothermal vents. Not only because of the huge potential of marine genetic resources, many States have expressed their concerns regarding the legal status, the exploration for, and exploitation of these organisms, as well as the patentability of inventions derived from them, when they are located in areas beyond national jurisdiction.

Beside the fact that there are different ways of understanding what the term genetic resources means, there is also a debate concerning whether marine genetic resources are covered by existing international legal instruments.

This contribution takes a closer look to the applicable international legal framework, including the United Nations Convention on the Law of the Sea (UNCLOS), the Convention on Biological Diversity (CBD), and various intellectual property rights agreements.

* Presentations of a workshop on legal aspects regarding marine genetic resources in the framework of the European Maritime Day 2013 may be found at: <https://www.youtube.com/user/ISRIMde> accessed 6 July 2014.

13.2 What are Genetic Resources?

UNCLOS refers to 'natural resources',[1] 'living resources',[2] and 'non-living resources'.[3] The term 'marine genetic resources' or 'genetic resources of the sea' is not specifically used. However, activities related to marine genetic resources are covered by the relevant general principles of UNCLOS and therefore are covered by UNCLOS.[4] It has been considered that these terms are broad enough to include animals, plants, and microorganisms such as bacteria, fungi, and their genetic material.[5]

CDB uses the term 'genetic resources' for the purpose of this Convention as meaning 'genetic material of actual or potential value', whereas 'genetic material' is 'any material of plant, animal, microbial, or other origin containing functional units of heredity'.[6]

Hence, UNCLOS and CBD cover similar subject matters regarding the term genetic resources. Although there exists no agreed international definition of marine genetic resources so far, based on the CBD definition of genetic resources the term marine genetic resources can be defined as 'marine plants, animals and microorganism and parts thereof containing functional units of heredity that are of actual or potential value'.[7]

13.3 Legal Framework for Genetic Resources

13.3.1 Genetic resources within areas of national jurisdiction

(a) UNCLOS

In its internal waters and territorial sea, the coastal State has not only sovereignty over its territorial sea as well as its bed and subsoil, but also over the resources

[1] United Nations Convention on the Law of the Sea (Montego Bay, opened for signature 10 Dec. 1982, entered into force 16 Nov. 1994) 1833 UNTS 3 (UNCLOS), Arts 56(1), 77(1), 77(2), 77(4), 79(2), 145(b), 193, 194(3), 246(5), and 249(2).

[2] UNCLOS, Preamble, and Arts 1(1)(4), 21(1), 56(1), 61(1), 61(2), 62(1), 62(2), 62(3), 69(1), 69(2), 69(3), 69(4), 69(5), 70(1), 70(2), 70(3), 70(4), 70(5), 70(6), 71, 72(1f), 73(1), 77(4), 117, 118, 119(1), 124, 246(5), 277, and 297.

[3] UNCLOS, Arts 56(1), 77(4), 82(1), and 246(5).

[4] 'Report of the Secretary-General on Oceans and the Law of the Sea', UN Doc A/62/66, 12 Mar. 2007, s 188.

[5] L Glowka, 'The Deepest of Irony: Genetic Resources, Marine Scientific Research, and the Area' (1996) 12 *Ocean Yearbook* 154, 168; and MI Jeffrey, 'Bioprospecting: access to genetic resources and benefit-sharing under the Convention on Biodiversity and the Bonn Guidelines' (2002) 6 *Sing J Int'l & Comp L* 747, 776.

[6] Convention on Biological Diversity (Rio de Janeiro, 5 June 1992, entered into force 29 Dec. 1993) 1760 UNTS 79 (CBD), Art. 2.

[7] CBD, 'Identification of Technical Options for the Conservation and Sustainable Use of Deep Seabed Genetic Resources Beyond National Jurisdiction', Doc UNEP/CBD/SBSTTA/11/11 (2005), para 10.

found therein.[8] This exclusive coastal State jurisdiction is only restricted by the right of innocent passage for foreign ships.[9] Such a passage is innocent 'so long as it is not prejudicial to the peace, good order or security of the coastal State'.[10] Therefore, the passage is not considered to be innocent when a foreign ship engages, inter alia, in 'any fishing activities' and 'carrying out of research or survey activities'.[11] Marine scientific research can also only be conducted with regard to marine genetic resources 'with the express consent of and under the conditions set forth by the coastal'.[12] This also applies to the conduct of bioprospecting, which again depends completely on the consent of the coastal State. It is not necessary to examine the regime of bioprospecting in the territorial sea where the coastal State enjoys full sovereignty regarding the authorization and conduct of 'pure' marine scientific research.[13] According to the 2007 Report of the United Nations (UN) Secretary-General on Oceans and the Law of the Sea, which is yearly submitted to the UN General Assembly, the report does not make an explicit distinction—as the 2004 Report does—between 'pure' academic research and 'applied' research carried out for commercial purpose, usually called 'bioprospecting' but pointed out:

> In the absence of a formal definition, it has been suggested that marine scientific research under UNCLOS encompasses both the study of the marine environment and its resources with a view to increasing humankind's knowledge (so-called 'pure' or 'fundamental' research), and research for the subsequent exploitation of resources (so-called 'applied' research).[14]

With regard to the exclusive economic zone (EEZ) the coastal State has sovereign rights for the purpose of, inter alia, 'exploring and exploiting, conserving and managing the natural resources, whether living or non-living, of the waters superjacent to the sea-bed and of the sea-bed and its subsoil'.[15] In particular, the coastal State shall determine the allowable catch of the living resources in its exclusive economic zone.[16]

The coastal State also exercises sovereign rights over the continental shelf for the purpose of exploring it and exploiting its natural resources.[17] The natural resources

[8] UNCLOS, Art. 2; 'Report of the Secretary-General', UN Doc A/62/66, 12 Mar. 2007 (n 4) s 191.

[9] UNCLOS, Art. 17.

[10] UNCLOS, Art. 19(1).

[11] UNCLOS, Art. 19(2).

[12] UNCLOS, Art. 245.

[13] A Kirchner, 'Bioprospecting, Marine Scientific Research and the Patentability of Genetic Resources' in NA Martínez Gutiérrez (ed.), *Serving the Rule of International Maritime Law: Essays in Honour of Professor David Joseph Attard* (Routledge, 2010) 123.

[14] 'Report of the Secretary-General', UN Doc A/62/66, 12 Mar. 2007 (n 4) s 203.

[15] UNCLOS, Art. 56(1).

[16] UNCLOS, Art. 61(1).

[17] UNCLOS, Art. 77(1).

of the continental shelf 'consist of the mineral and other non-living resources of the sea-bed and subsoil together with living organisms belonging to sedentary species, that is to say, organisms which, at the harvestable stage, either are immobile on or under the sea-bed or are unable to move except in constant physical contact with the sea-bed or the subsoil'.[18] No one may undertake activities on the continental shelf without the express consent of the coastal State.[19]

For marine scientific research in the EEZ and on the continental shelf, the consent of the coastal State is obligatory.[20] The consent of a coastal State shall, in normal circumstances, be granted to other States or to competent international organizations wishing to conduct marine scientific research exclusively for peaceful purposes and in order to increase marine scientific knowledge of the marine environment for the benefit of all mankind.[21] The coastal State may, however, withhold its consent when, inter alia, the particular marine scientific research project 'is of direct significance for the exploration and exploitation of natural resources, whether living or non-living'.[22] In consequence, the coastal State must, in normal circumstances, grant its consent to 'pure' marine scientific research projects by other States or competent organizations under the provision of Article 246(3), while bioprospecting as a commercially oriented research project may fall into the exception of Article 246(5) and thus may be denied by the coastal State.[23]

(b) CBD

Subject to the CBD, State parties to the convention 'shall implement this Convention with respect to the marine environment consistently with the rights and obligations of States under the law of the sea'.[24] Therefore, the situation under UNCLOS corresponds with the principles of the CBD as to which the 'access to genetic resources rests with the national governments and is subject to national legislation'[25] and 'to the prior informed consent of the Contracting Party providing such resources'.[26] Each contracting party to the CBD, however, 'shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties'.[27] Furthermore, each contracting party 'shall take legislative, administrative, or policy measures . . . with the aim of

[18] UNCLOS, Art. 77(4).
[19] UNCLOS, Art. 77(2).
[20] UNCLOS, Art. 246(2).
[21] UNCLOS, Art. 246(3).
[22] UNCLOS, Art. 246(5).
[23] Kirchner (n 13) 123.
[24] CBD, Art. 22(2).
[25] CBD, Art. 15(1).
[26] CBD, Art. 15(5).
[27] CBD, Art. 15(2).

sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources'.[28] In addition to this, the 6th Conference of Parties of the CBD in 2002 adopted the 'Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization'.[29] The guidelines apply to all genetic resources covered by the CBD with the exclusion of human genetic resources,[30] and works out the details of the provisions of Article 15 of the CBD detailing types of benefit-sharing arrangements.[31] The Bonn Guidelines, as voluntary rules[32] on access and benefit-sharing measures, were recognized as a useful step, but already in 2002 there were demands for the development of additional legally binding measures. In October 2010 the 'Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization' to the CBD[33] was adopted, amplifying the provisions on access and equitable sharing of benefits arising from the commercial and other utilization of genetic resources with the contracting party providing such resources.[34]

13.3.2 Genetic resources beyond areas of national jurisdiction

While marine genetic resources found within areas of national jurisdiction are to be accessed subject to the provisions of UNCLOS, the CBD, and other international provisions, the regulation of genetic resources beyond national jurisdiction is much more problematic. Areas beyond national jurisdiction include the 'High Seas' (Part VII of UNCLOS) and the 'Area' (Part XI of UNCLOS). It is unclear whether marine genetic resources would fall under the regime of the Area or that of the high seas, a question which is indeed significant.[35]

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[28] CBD, Art. 15(7).

[29] Decision VI/24 of the 6th COP to the CBD, 'Access and Benefit-Sharing as Related to Genetic Resources', The Hague, Apr. 2002, 7–19.

[30] 'Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization', UN Doc UNEP/CBD/COP/6/20 (2002), Art. I, C (Bonn Guidelines).

[31] Bonn Guidelines.

[32] Bonn Guidelines, s A, Annex, para 7.

[33] Decision X/1 of the 10th COP to the CBD, 'Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation to the Convention on Biological Diversity', UN Doc UNEP/CBD/COP/10/27 (2010), Nagoya, 29 Oct. 2010, (Nagoya Protocol), <http://www.cbd.int/abs/doc/protocol/certified-text-protocol.pdf> accessed 8 August 2014.

[34] Cf. also <https://absch.cbd.int> accessed 6 July 2014.

[35] 'Letter dated 15 May 2008 from the Co-Chairpersons of the Ad Hoc Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction addressed to the President of the General Assembly', UN Doc A/63/79, 16 May 2008, s 36.

(a) CBD

Besides UNCLOS, the CBD includes the term 'genetic resources'. Nevertheless, the jurisdictional scope of the CBD is limited to marine areas within national jurisdiction.[36] The provisions of the CBD therefore do not apply to genetic resources beyond national jurisdiction. Parties are required to cooperate with other contracting parties directly or, where appropriate, through competent international organizations in respect of areas beyond national jurisdiction, for the conservation and sustainable use of biological diversity.[37]

(b) UNCLOS

(i) **Area** In Part XI of UNCLOS, 'Area' is defined as 'the sea-bed and ocean floor and subsoil thereof [which leaves out those genetic resources which might be found in the water column above the seabed] beyond the limits of national jurisdiction'.[38] The Area and its resources are declared to be 'the common heritage of mankind'.[39] No claim of sovereignty or sovereign rights by States over any part of the Area or its resources, nor an appropriation of any part thereof by any State or natural or juridical person, shall be recognized.[40] The Area must be used exclusively for peaceful purposes[41] and any activities in the Area—which means all activities of exploration for and exploitation of the resources of the Area[42]—shall be carried out for the benefit of mankind as a whole.[43] The applicability of these principles to the Area shall be ensured by the International Seabed Authority (ISA) based in Kingston, Jamaica.[44]

The resources of the Area to which this special status applies are defined as 'all solid, liquid or gaseous mineral resources in situ in the Area at or beneath the seabed, including polymetallic nodules' which, when recovered from the Area are called 'minerals'.[45] Subject to this provision, the ISA only has a mandate to regulate the exploitation of mineral resources, which comprises only non-living resources and therefore does not include marine genetic resources.[46]

(ii) **High Seas** Does the inapplicability of the regime regarding the Area (Part XI UNCLOS) mean that marine genetic resources are not covered by UNCLOS at

36 CBD, Art. 4(a).
37 CBD, Art. 5.
38 UNCLOS, Art. 1(1).
39 UNCLOS, Art. 136.
40 UNCLOS, Art. 137(1).
41 UNCLOS, Art. 141.
42 UNCLOS, Art. 1(3).
43 UNCLOS, Art. 140(1).
44 Cf. UNCLOS, Art. 157(1). Cf. <http://www.isa.org.jm> accessed 6 July 2014.
45 UNCLOS, Art. 133.
46 MH Nordquist et al. (ed.), *United Nations Convention on the Law of the Sea 1982: A Commentary*, (Martinus Nijhoff, 2002) vol. VI, 76.

all? According to Article 86 UNCLOS the 'High Seas' include 'all parts of the sea that are not included in the exclusive economic zone, in the territorial sea or in the internal waters of a State, or in the archipelagic waters of an archipelagic State'. This does also include the superjacent waters to the Area, i.e. 'The waters lying immediately above the sea-bed or deep ocean floor up to the surface'.[47] The high seas are open to all States, whether coastal or landlocked,[48] and reserved for peaceful purposes.[49] Claims of sovereignty over any part of the high seas are invalid.[50] Ships sailing on the high seas are subject to the exclusive jurisdiction of their flag State.[51]

The freedom of the high seas includes, inter alia, the freedom of fishing and the freedom of scientific research.[52] UNCLOS does not define the term 'marine scientific research', although it provides the legal regime for the conduct of marine scientific research. According to the 2007 Report of the UN Secretary-General on Oceans and the Law of the Sea, marine scientific research under UNCLOS covers both 'pure' academic research and 'applied' research carried out for commercial purposes, usually called 'bioprospecting' as it is difficult to differentiate between the two types of research in the context of increasing partnerships between public research institutions and the industry.[53]

Bioprospecting in the high seas would presumably fall under the freedom of the high seas and in particular under the freedom of scientific research.[54] In such a case, bioprospecting activities as well as marine scientific research in the high seas would only be subject to flag State jurisdiction, e.g. the laws and regulations of the State under whose flag the vessel conducting the activities related to bioprospecting and marine scientific research is operating, provided that these activities would be conducted with due regard for the interests of other States in their exercise of the freedom of the high seas, and with due regard for the rights under UNCLOS with respect to activities in that area.[55]

Marine genetic resources in the high sea and in the Area could therefore be subject to an open-access regime, as the marine genetic resources could be treated as part

[47] UN/Office for Ocean Affairs and the Law of the Sea, The Law of the Sea—Baselines: An Examination of the Relevant Provisions of the United Nations Convention on the Law of the Sea (United Nations, 1989), 64, <http://www.un.org/Depts/los/doalos_publications/publicationstexts/The_Law_of_the_Sea_Baselines.pdf> accessed 18 May 2014.

[48] UNCLOS, Art. 87(1).

[49] UNCLOS, Art. 88.

[50] UNCLOS, Art. 89.

[51] UNCLOS, Art. 91(1).

[52] UNCLOS, Art. 87(1).

[53] 'Report of the Secretary-General', 12 Mar. 2007, UN Doc A/62/66 (n 4) s 203.

[54] UNCLOS, Art. 87(1)(f).

[55] UNCLOS, Art. 87(2); Kirchner (n 13) 124.

of the high seas under international law and could be freely exploited without any control by the international community.

(iii) Possible solutions for areas beyond national jurisdiction In the 1995 Report of the UN Secretary General, concerns about the access and benefit-sharing of genetic resources were raised:

> The scientific and commercial value of deep seabed genetic resources has raised questions regarding the legal status of these resources and activities involving them. The Convention on the Law of the Sea does not specifically refer to such resources, since their potential use was not known to the negotiators. It has been suggested that if found in areas beyond the national jurisdiction of any State these resources fall within the high seas legal regime and are freely accessible to all States subject to the rights and obligations of other States. While the term 'living resources' in the Convention might be broad enough to include free living and symbiotic micro-organisms, the collection and subsequent use of microbial genetic resources is not necessarily analogous to traditional methods of harvesting marine living resources. They are studied as part of marine scientific research and may be passed to industry for biotechnological applications. It has therefore been suggested that a fundamental consideration in discussions would be the legal status and nature of marine scientific research involving these resources.[56]

In 2004, an 'Ad Hoc Open-ended Informal Working Group to study issues about the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction' was established by the General Assembly.[57] Although various meetings took place, the working group has not yet found a solution to various disputed issues regarding marine genetic resources, for example, the applicability of the provisions of UNCLOS to marine genetic resources beyond areas of national jurisdiction and the respective regulations as the discussions of the delegations of the last three years'[58] Meetings of the Working Group shows:

> Some other delegations expressed the view that the regime set out under Part XI of the Convention was only applicable to the mineral resources of the Area. The view was expressed in favour of discussing the possibility of regulating marine genetic resources in areas beyond national jurisdiction, including the classification of those resources as the common heritage of mankind. Some delegations were of the view that marine genetic resources beyond areas of national jurisdiction were governed by Part VII of the Convention related to the high seas. They held that

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[56] 'Report of the Secretary-General on the Law of the Sea', UN Doc A/50/713, 1 Nov. 1995, s 243.

[57] Resolution adopted by the General Assembly on Oceans and the Law of the Sea, UN Doc A/RES/59/24, 4 Feb. 2005, s 73.

[58] Annex, 'Report to the Ad Hoc Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction and Co-Chair's summary of discussions', UN Doc A/68/399, 23 Sept. 2013, ss 17 and 19 (Working Group Report, UN Doc A/68/399, 23 Sept. 2013); Annex, 'Co-Chairs' summary of discussions at the Ad Hoc Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction', UN Doc A/69/82, 5 May 2014, ss 49–57.

> the non-exhaustive list of high seas freedoms set out in the Convention was not restricted to activities in the water column but also included activities involving or impacting the seabed and subsoil, such as the laying of cables and pipelines, the construction of artificial islands and installations and, in some cases, fishing practices and scientific research. Several delegations pointed out that the expression 'areas beyond national jurisdiction' referred to two maritime areas, namely the high seas and the Area, whose nature and legal regime were different. They observed that, according to General Assembly resolution 2749 (XXV) and Part XI of the Convention, the Area and its resources were governed by the principle of 'common heritage of mankind', which they considered to be part of customary international law. They noted that the regulation of activities in the oceans and use of their resources depended on the maritime zones in which they were conducted or found. The resources of the seabed and ocean floor beyond areas of national jurisdiction, including the living resources, were, therefore, resources of the Area and the principles enshrined in Part XI of the Convention were also applicable to marine genetic resources from the Area. In this respect, attention was drawn to the responsibilities entrusted to the International Seabed Authority with regard to marine scientific research and the protection of the marine environment.[59]

The existence of the discussed regulatory gap in UNCLOS is based on the fact that the drafters of UNCLOS (from 1973 to 1982) obviously did not have the necessary knowledge of the actual value of marine genetic resources based in the Area or the High Sea.[60]

The identification of gaps in the legal framework was also stated by several delegations of the 2013 Meeting of the Working Group but nevertheless UNCLOS is recognized by the delegations of the 2013 Meeting as the legal framework for the conservation and sustainable use of marine biodiversity beyond areas of national jurisdiction. Some delegations pointed out that UNCLOS would provide the principles for the conservation and sustainable use of marine biodiversity beyond areas of national jurisdiction.[61]

The delegations of the 2012 Meeting and of the 2013 Meeting of the Working Group offered different perspectives on the issue. Some delegations stressed the serious global economic and social implications of access to the exploitation of genetic resources in the absence of a legal regime.[62] Some other delegations asked for clarification as to the extent to which bioprospecting was currently taking place, and as to its consequences for the environment and for commercial and

[59] 'Report of the Ad Hoc Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction and Co-Chair's summary of discussions', UN Doc A 67/95, 13 June 2012, s 15 (Working Group Report, UN Doc A 67/95, 13 June 2012).

[60] Nordquist et al. (n 46) vol. VI, 76.

[61] Working Group Report, UN Doc A/68/399, 23 Sept. 2013 (n 58) s 39.

[62] Working Group Report, UN Doc A 67/95, 13 June 2012 (n 59) s 16; Working Group Report, UN Doc A/68/399, 23 Sept. 2013 (n 58) s 27.

non-commercial aspects, as well as aspects of intellectual property rights.[63] It was also considered whether the term marine genetic resource only covers marine genetic resources from the seabed and subsoil, or also those from the water column.[64] With regard to the benefits arising from the use of marine genetic resources from areas beyond national jurisdiction, it was suggested that it should be considered as to whether benefit sharing is desirable, and to what extent and how this could be best achieved.[65] Some delegations considered the Nagoya Protocol[66] as well as the instruments of the International Treaty on Plant Genetic Resources for Food and Agriculture[67] of the Food and Agriculture Organization (FAO) of the UN.[68] Suggestions were made that options for benefit sharing should address monetary and non-monetary benefits for an adequate distribution; and that the participation of developing countries in strategic alliances between public sector scientific institutions and private sector biotechnology companies should be supported. It was also suggested that the benefits from research and prospecting could be shared consistently with the goals of UNCLOS.[69]

Several delegations of the 2013 Meeting and of the 2014 Meeting of the Working Group expressed the view that marine genetic resources, including, for example, questions on the sharing of benefits and the transfer of marine technology should be the main issue for the future negotiation of an implementing agreement to UNCLOS. Some of the delegations pointed out that in addition to marine scientific research, intellectual property issues relating to marine biodiversity of areas beyond national jurisdiction were key issues that needed to be addressed in a future implementing agreement.[70]

13.4 International Intellectual Property Rights

The exploitation and management of marine genetic resources beyond national jurisdiction becomes ever more accessible for multinational companies and is beginning to play a role in the international market. In this context, the international protection of intellectual property rights (IPR) is important for the commercialization of marine genetic resources. Any genetic material that is

63 Working Group Report, UN Doc A 67/95, 13 June 2012 (n 59) s 18.
64 Working Group Report, UN Doc A 67/95, 13 June 2012 (n 59) s 18.
65 Working Group Report, UN Doc A 67/95, 13 June 2012 (n 59) s 18.
66 See Nagoya Protocol.
67 International Treaty on Plant Genetic Resources for Food and Agriculture (Rome, 3 Nov. 2001) 2400 UNTS 303, <ftp://ftp.fao.org/docrep/fao/011/i0510e/i0510e.pdf> accessed 5 June 2014 (International Plant Treaty).
68 Working Group Report, UN Doc A 67/95, 13 June 2012 (n 59) s 18.
69 Working Group Report, UN Doc A 67/95, 13 June 2012 (n 59) s 19.
70 Working Group Report, UN Doc A/68/399, 23 Sept. 2013 (n 58) s 48; Working Group Report, UN Doc A/69/82, 5 May 2014 (n 58) ss 49-57.

commercialized and protected by IPR reduces the value available to other source nations and the international community in general.[71] Patent holders of biotechnology products which derive from marine genetic resources taken from areas beyond national jurisdiction retain a monopoly over the information and the value that they receive from the marine genetic resources for twenty years and exclude third parties from production. Commercial sectors that might benefit from the exploration and exploitation of marine genetic resources include chemistry, pharmacology, cosmetics, food, and agriculture.

The Institute of Advanced Studies at the United Nations University continue to document the use of marine genetic resources from both within and beyond areas of national jurisdiction.[72] Most of the organisms from which these marine genetic resources derive are found near hydrothermal vents on the deep seabed.[73] Although the filing of patents relating to marine genetic resources is increasing, only 10 States account for some 90 per cent of the patents related to marine genetic resources.[74] This is due to the fact that only industrialized nations have the capability to commercialize marine genetic resources as a result of the immense costs and the technology needed for getting marine genetic resources from deep-seabed areas. Therefore members of the 'Group of 77' (G-77) argued, during the eighth meeting of the United Nations Open-ended Informal Consultative Process on Oceans and the Law of the Sea (UNICPOLOS) in 2007, that marine genetic resources should be treated as common heritage resources regulated by the ISA through a benefit-sharing regime, while members of the developed countries stressed that marine genetic resources should be treated as subject to the provisions of UNCLOS relating to the freedom of the seas.[75]

Patents are on the one hand an incentive, offering recognition for creativity and material reward for marketable inventions. Such an incentive encourages innovation, which assures that the quality of human life is continuously enhanced. On the other hand, the majority of the international community does not benefit from the patent protection of products derived from marine genetic resources beyond national jurisdiction granted to the patent holders. A patent is granted as an exclusive right for a limited period of time, i.e. usually twenty years. Patent protection means that the invention cannot be commercially made, used, distributed, or sold

[71] RJ McLaughlin, 'Exploiting Marine Genetic Resources beyond National Jurisdiction and the International Protection of Intellectual Property Rights: Can they coexist?' in D Vidas (ed.), *Law, Technology and Science for Oceans in Globalisation: IUU Fishing, Oil Pollution, Bioprospecting, Outer Continental Shelf* (Martinus Nijhoff, 2010) 379.

[72] United Nations University, 'Environmental Sustainability and Governance', <http://unu.edu/research/environmental-sustainability-and-governance.html> accessed 18 may 2014.

[73] 'Report of the Secretary-General on Oceans and the Law of the Sea', UN Doc A/66/70/Add.2, 22 Mar. 2011, s 167.

[74] 'Report of the Secretary-General', UN Doc A/66/70/Add.2, 22 Mar. 2011 (n 73) s 168.

[75] McLaughlin (n 71) 375.

without the patent owner's consent. These extensive rights are conferred in exchange for publication of information on the invention.

13.4.1 World Intellectual Property Organization

The Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (IGC) of the World Intellectual Property Organization (WIPO) has dealt with a range of issues concerning the interplay between intellectual property 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.[76] 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. The work has covered three main areas:[77]

(a) Defensive protection of genetic resources

The term 'defensive protection of genetic resources' refers to a set of strategies aimed to ensure that third parties do not gain illegitimate or unfounded IPRs over traditional knowledge/traditional cultural expression subject matter and related genetic resources.[78] These measures include the creation of improved search tools and classification systems for patent examiners when they examine patent applications which claim genetic resources.[79]

(b) Intellectual property issues in mutually agreed terms

The IGC prepared a database as a capacity-building tool to provide information resources for those seeking assistance on current practices relating to contracts or licenses concerning IP, access and benefit sharing, and genetic resources. This should facilitate the understanding of the process of negotiating and concluding contracts in this area, potentially for the benefit of a wide range of institutions and communities with an interest in the IP aspects of access to genetic resources.[80]

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[76] WIPO General Assembly, 'Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore', WIPO Doc WO/GA/26/6, 25 Aug. 2000, s 13. Cf. <http://www.wipo.int/tk/en/igc/> accessed 6 July 2014.

[77] Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, 'Genetic Resources: Revised List of Options and Factual Update', 15 Sept. 2010, WIPO Doc WIPO/GRTKF/IC/17/6.

[78] Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, 'Glossary of Key Terms Related to Intellectual Property and Genetic Resources', WIPO Doc WIPO/GRTKF/IC17/INF/13, 4 Oct. 2010, s 6 ('Glossary of Key Terms', WIPO/GRTKF/IC17/INF/13, 4 Oct. 2010).

[79] WIPO, 'Genetic Resources', <www.wipo.int/tk/en/genetic/> accessed 18 May 2014.

[80] Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, WIPO Doc WIPO/GRTKF/IC17/INF/11, 20 Oct. 2010, s 22 ('Note on Updating WIPO's Online Database', WIPO/GRTKF/IC17/INF/11, 20 Oct. 2010).

The database is also meant to provide an empirical basis for the development of guide contractual practices, guidelines, and model IP clauses for contractual agreements on access to genetic resources and benefit sharing and work on policy issues related to IP aspects of contracts and licenses concerning access to genetic resources and benefit sharing.[81]

(c) Disclosure requirements in patent applications

Particularly interesting in the context of equitable benefit sharing is the disclosure requirement for patent protection.[82] Patent law 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'.[83] In practice, it is questionable, however, how many disclosure requirements are actually needed. Therefore, various disclosure requirements are proposed for national and international patent laws. In this context, three broad functions have been considered for disclosure methods relating to genetic resources:[84]

- to disclose any genetic resources actually used in the course of developing the invention (a descriptive or transparency function, pertaining to the genetic resources itself and its relationship with the invention);
- to disclose the actual source of the genetic resources (a disclosure function, relating to where the genetic resources was obtained)—this may concern the country of origin (to clarify under which jurisdiction the source material was obtained), or a more specific location (for instance, to ensure that genetic resources can be accessed), so as to ensure the invention can be duplicated or reproduced;
- to provide an undertaking or evidence of prior informed consent (a compliance function, relating to the legitimacy of the acts of access to genetic resources)—this may entail showing that genetic resources used in the invention were obtained and used in compliance with applicable laws in the country of origin or in compliance with the terms of any specific agreement recording prior informed consent; or showing that the act of applying for a patent was in itself undertaken in accordance with prior informed consent.

13.4.2 World Trade Organization

Another implication of the absence of an agreed legal regime on marine genetic resources beyond national jurisdiction is the issue of the application of the

[81] 'Note on Updating WIPO's Online Database', WIPO/GRTKF/IC17/INF/11, 20 Oct. 2010 (n 80) s 22.

[82] IGC has prepared a technical study on this issue, with input from many WIPO Member States, Technical Study on Disclosure Requirements in Patent Systems related to genetic resources and traditional knowledge, WIPO Publication 786(E) (2004).

[83] 'Glossary of Key Terms', WIPO/GRTKF/IC17/INF/13, 4 Oct. 2010 (n 78) 6.

[84] 'Glossary of Key Terms', WIPO/GRTKF/IC17/INF/13, 4 Oct. 2010 (n 78) 6.

Agreement on Trade-Related Aspects of Intellectual Property Rights, commonly known as the TRIPS Agreement, which was adopted in 1994 by the World Trade Organisation (WTO).[85] To become a member of WTO, the Uruguay Round side-agreements, including the TRIPS Agreement, has to be accepted. Although many developing States are dissatisfied with the contents of the TRIPS Agreement, most of them do not risk their membership in the WTO with respect to concerns in relation to intellectual property rights.[86]

The TRIPS Agreement has expanded the scope of intellectual property rights to cover the modern needs arising from global trade and, in particular, the need for uniform national standards. Even though it does not explicitly mention genetic resources, it refers to 'micro-organisms' and 'micro-biological processes', without defining the term. The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure does not define the term either, but is to be understood in a broad sense.[87] In practice, micro-organisms include biological and genetic material.[88]

Article 27(1) of the TRIPS Agreement obliges the State parties to the Agreement to make patents 'available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable for industrial application'.[89] Debates continue as to what extent inventions deriving from marine genetic resources are 'new' and therefore patentable under the TRIPS Agreement. The TRIPS Agreement does not provide patent protection for simply discovering existing organisms. Provided that the highly technical processes involved in identifying, isolating, and reproducing genetic material and making it capable for industrial application, these concerns are inappropriate. In Europe, a specific Directive was enacted in 1998: Directive 98/44/EC on the legal protection of biotechnological inventions regulates the patentability of bio-technology. The directive also clarifies that biological material is a patentable invention if it is new, involves an inventive step, and is susceptible of industrial application,[90] as long as it has been isolated from its natural environment or

[85] Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 Apr. 1994, entered into force 1 Jan. 1995), Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations 320 (1999), 1869 UNTS 299 (TRIPS Agreement). Cf. <http://www.wto.org/english/tratop_e/trips_e/trips_e.htm> accessed 6 July 2014.

[86] McLaughlin (n 71) 76.

[87] WIPO, Guide to the Deposit of Microorganisms under the Budapest Treaty, Dec. 2008, Introduction (para b, iv), <http://www.wipo.int/export/sites/www/treaties/en/registration/budapest/guide/pdf/introduction.pdf> accessed 18 May 2014.

[88] P Oldham, *Global Status and Trends in Intellectual Property Claims: Microorganisms* (Lancaster University, 2004) 33.

[89] TRIPS Agreement, Art. 27(1).

[90] Directive 98/44/EC of the European Parliament and of the Council, on the legal protection of biotechnological inventions, 6 July 1998, OJ L 213/13 (30 July 1998), Art. 3(1) (Directive 98/44/EC).

produced by means of a technical process, even if it previously occurred in nature.[91]

Subject to Article 27(2) of the TRIPS Agreement, WTO members can exclude inventions from patentability to prevent commercial exploitation of the invention within their territory when this is necessary to protect public order or morality, including to protect human, animal, or plant life or health or to avoid serious prejudice to the environment. Subject to Article 27 (3) of the TRIPS Agreement, members can also exclude from patentability plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. Therefore, according to the TRIPS Agreement, WTO members still have the right to decide which inventions correspond with public order or morality.[92] Governments are therefore allowed, on the one hand, to exclude some kinds of inventions from patenting, such as plants, animals, and essentially biological processes. On the other hand, with regard to marine genetic resources, the TRIPS agreement does not prevent the patenting, for example, of microorganisms as the main source of novel compounds.[93]

Particularly interesting in the context of equitable benefit sharing is the disclosure requirement for patent protection under the TRIPS agreement. Subject to Article 29 (1) of the TRIPS agreement, inventions shall be disclosed in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application. In practice, it is questionable how much information is really disclosed due to confidentiality reasons, disclosure requirements are—as mentioned—part of the various proposals to reform international, regional, and national patent laws.[94]

Amendments to Articles 27.3(b) and 29 of the TRIPS agreement are being discussed under the Doha Development Agenda. Paragraph 19 of the 2001 Doha Declaration stated that the Council for TRIPS should review Article 27.3 (b) and examine the relationship between the TRIPS Agreement and the CBD.[95] The discussions in the TRIPS Council include the following ideas and proposals:

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[91] Directive 98/44/EC, Art. 3(2).

[92] KE Zewers, 'Debated Heroes from the Deep Sea—Marine Genetic Resources' (2008) 2 *WIPO Magazine*, <http://www.wipo.int/wipo_magazine/en/2008/02/article_0008.html> accessed 5 June 2014.

[93] S Arico, 'Marine Genetic Resources in Areas beyond National Jurisdiction and Intellectual Property Rights' in Vidas (71) 389.

[94] For further details, see Section 13.4.1.

[95] The Doha Round was officially launched at the WTO's Fourth Ministerial Conference in Doha, Qatar, in Nov. 2001. The Doha Ministerial Declaration provided the mandate for the negotiations, including on intellectual property, WTO Doc WT/MIN(01)/DED/1, 20 Nov. 2001.

A group—represented by Brazil, China, Colombia, Ecuador, India, Indonesia, Peru, Thailand, the ACP Group, and the African Group—wants to amend the TRIPS agreement. Patent Applicants are required to disclose the country providing such resources as the country of origin of such resources or a country that has acquired the genetic resources in accordance with the CBD.[96]

Switzerland has proposed amendments to the regulations of WIPO's PCT so that patent applicants are required by national patent legislation to declare the source of genetic resources.[97]

The European Union has expressed the view that the TRIPS Agreement should be amended in order to reconcile or harmonize the Agreement with the CBD. Patent applicants should disclose the geographic origin of genetic resources. Failure to disclose should lie outside the ambit of patent law, such as i.e. in civil law or in administrative law.[98]

The United States has stated that the objectives of the CBD regarding access to genetic resources and benefit sharing could be best achieved by national laws outside the patent system.[99]

The report of the Director General Pascal Lamy, dated 21 April 2011, summarizes the informal consultative process to the present date as an ongoing discussion:

> Members have consistently voiced support for the principles and objectives of the CBD, including the principle of prior informed consent and the principle of equitable sharing of benefits. They have agreed on the need to take steps to avoid erroneous patents, including through the use of databases, as appropriate, to avoid patents being granted on existing traditional knowledge or genetic resources subject-matter. None of proposals discussed disclosure requirements, databases, or the use of contracts was argued to be a stand-alone response or complete solution to all problems outlined. Members continue to differ on whether the formulation and application of a specific, tailored disclosure mechanism relating in particular to genetic resources would be useful and effective in ensuring that patent system promoted CBD objectives, or whether other mechanisms should be preferred. This discussion underscored the benefits of understanding more fully the practical and operational context of the existing disclosure mechanism that have been implemented in national systems.[100]

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[96] Draft Decision to Enhance Mutual Supportiveness between the TRIPS Agreement and the CBD, WTO Doc TN/C/W/59, 19 Apr. 2011, 2.

[97] The Relationship between the TRIPS Agreement and the CBD and the Protection of Traditional Knowledge and Folklore, and the Review of Implementation of the TRIPS Agreement under Article 71.1, WTO Doc IP/C/W/446, 30 May 2005, 1.

[98] 'Review of Article 27.3(b) of the TRIPS Agreement, and the Relationship between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore', WTO Doc IP/C/W/383, 17 Oct. 2002, 11.

[99] 'Article 27.3 (b); Relationship between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore', WTO Doc IP/C/W/434, 26 Nov. 2004, 5.

[100] 'Report on Issues Related to the Extension of the Protection of Geographical Indications Provided for in Article 23 of the TRIPS Agreement to Products other than Wines and Spirits and

The current IPR framework is still under development, which also results in an existing regulatory gap on access and benefit sharing related to marine genetic resources in areas beyond national jurisdiction.

13.5 Regulating Genetic Resources beyond Areas of National Jurisdiction: Ways to Fill the Regulatory Gap

Given the importance of biological and genetic resources in areas beyond national jurisdiction, for example, in discovering new substances of benefit to the livelihood and well-being of humankind, the international community ought to find—particularly in the light of the common heritage of mankind principle—a solution. Any solution should be based on fair and equitable benefit sharing.[101] Many different approaches have been discussed and are still under consideration in the framework of the Ad Hoc Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction.[102]

13.5.1 Expansion of the ISA mandate

(a) Article 133 UNCLOS

It has been suggested that a solution to this regulatory gap is to expand the mandate of the ISA.[103] Therefore, Article 133 UNCLOS could be amended: 'Resources' could be defined not only as 'minerals' but also as 'living and non-living resources'.[104] Expanding the mandate could, however, be declined by those States who are of the view that marine genetic resources beyond areas of national jurisdiction found in the Area are not recognized as common heritage resources governed by Part XI.

(b) Article 82 UNCLOS: model for an international royalty system

Article 82 UNCLOS already provides royalties for non-living resources of the continental shelf exploited beyond the 200-nm limit. Article 82(4) UNCLOS establishes the principle that the payments and contributions are to be made through the ISA (Articles 156, 157 UNCLOS). The scope of Article 82 UNCLOS

those Related to the Relationship between the TRIPS Agreement and the CBD', WTO Doc WT/GC/W/633, 21 Apr. 2011, 6.

101 Kirchner (n 13) 124.

102 Working Group Report, UN Doc A/69/82, 5 May 2014 (n 58).

103 Working Group Report, UN Doc A/69/82, 5 May 2014 (n 58) s 51.

104 T Greiber, 'Access and Benefit Sharing in Relation to Marine Genetic Resources from Areas beyond National Jurisdiction: Study in Preparation of the Informal Workshop on Conservation of Biodiversity beyond national jurisdiction' (Federal Agency for Nature Conservation, Dec. 2011) 29, <http://www.bfn.de/fileadmin/MDB/documents/service/Skript_301.pdf> accessed 5 June 2014.

could be expanded so that marine genetic resources based on the outer continental shelf and the seabed Area are also covered by Article 82 UNCLOS.[105] As this idea could also be argued by those States that do not regard marine genetic resources as a part of the common heritage of mankind, it may be a possible model for a benefit-sharing mechanism for the international community[106] which—subject to Article 82 UNCLOS—already provides royalties for non-living resources exploited beyond the 200-nm limit.

13.5.2 Multilateral benefit-sharing mechanism

The delegations of the 2012 Meeting of the Ad Hoc Open-ended Informal Working Group studying issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction discussed the types of benefits envisioned, as well as examples of sharing of those benefits:

> In relation to the sharing of benefits arising from the use of marine genetic resources from areas beyond national jurisdiction, a suggestion was made to consider information sharing and assess whether benefit sharing was desirable and, if so, to what extent and how this could be best achieved. Some delegations were of the view that the experience gained from the implementation of the Nagoya Protocol along with other instruments such as the International Treaty on Plant Genetic Resources for Food and Agriculture of the Food and Agriculture Organization of the United Nations, could usefully be considered.[107]

Article 10 of 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 provides a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources to support the conservation of biological diversity and the sustainable use of its components globally.

The Member States of the European Union already referred, at the 2008 Meeting of the Working Group, to the International Treaty on Plant Genetic Resources for Food and Agriculture[108] of the FAO. This treaty was concluded in 2001 to include a mechanism for benefit sharing which keeps material in the public domain. It can be easily accessed, provided that the recipient of material commits to comply with predetermined conditions for the fair and equitable sharing of benefits.[109]

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105 Greiber (n 102) 29.

106 McLaughlin (n 71) 380.

107 Working Group Report, UN Doc A 67/95, 13 June 2012 (n 59) s 18.

108 Cf. International Plant Treaty, Art. 14.

109 EU, 'United Nations—General Assembly: Ad Hoc Open-ended Informal WG to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction: Agenda item 5(d) (New York)—Statement of behalf of the European Union by Mr Aleksander Cicerov, Minister Plenipotentiary at the Permanent Mission of Slovenia to the United Nations', 30 Apr. 2008.

Such a 'multilateral system' in the framework of UNCLOS might even be an option for marine genetic resources. Rather than asking for new instruments to deal with new challenges, the applicability of UNCLOS should be confirmed. How UNCLOS should be interpreted regarding the scope of Part XI of UNCLOS on the Area or of an international agreement related to the purpose of UNCLOS could be determined by the International Tribunal for the Law of the Sea (ITLOS),[110] which also has jurisdiction of the Seabed Disputes Chamber, for example in an advisory opinion.[111] Article 191 UNCLOS is the key provision in relation to the advisory jurisdiction of the Chamber. Article 191 UNCLOS provides that the Chamber 'shall' give advisory opinions. The chamber is therefore obliged to give such an opinion[112] provided three conditions are met:

- the request is from the Assembly or the Council,
- the request concerns legal questions, and
- the legal questions have arisen within the scope of the Assembly's or Council's activities.

Subject to Article 130 of the Rules of the Tribunal,[113] the chamber shall consider whether the request for an advisory opinion relates to a legal question pending between two or more parties. When the Chamber so determines, Article 17 of the Statute of Tribunal[114] applies, as well as the provision of those rules concerning the application of that Article.[115] Any judge may attach a separate or dissenting opinion to the advisory opinion of the Chamber.[116] The advisory opinions of the Chamber have no binding effect.

The Tribunal itself may give an advisory opinion on a legal question if an international agreement related to the purpose of the Convention specifically provides for the submission to the Tribunal of a request for such an opinion.[117] As the Seabed Disputes Chamber deals with questions which refer to activities in the Area, the legal question must cover activities which do not refer to activities in the Area.[118]

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110 UNCLOS, Art. 187.

111 Kirchner (n 13) 128.

112 Nordquist et al. (n 46) vol. VI, 641.

113 International Tribunal for the Law of the Sea, Rules of the Tribunal, Doc ITLOS/8, 17 Mar. 2009, <http://www.itlos.org/fileadmin/itlos/documents/basic_texts/Itlos_8_E_17_03_09.pdf> accessed 18 May 2014 (ITLOS Rules).

114 International Tribunal for the Law of the Sea, Statute of the International Tribunal for the Law of the Sea (ITLOS Statute), <http://www.itlos.org/fileadmin/itlos/documents/basic_texts/statute_en.pdf> accessed 8 August 2014.

115 ITLOS Rules, Art. 130(2).

116 ITLOS Rules, Art. 135(3).

117 ITLOS Rules, Art. 138(1).

118 MH Nordquist et al. (ed.), *United Nations Convention on the Law of the Sea 1982: A Commentary* (Martinus Nijhoff, 1989) vol. V, 416.