INTELLECTUAL PROPERTY RIGHTS BEYOND NATIONAL JURISDICTION

A REGIME FOR PATENTING PRODUCTS ON MARINE GENETIC RESOURCES OF THE DEEP SEABED AND HIGH SEAS

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1. Introduction

Marine genetic resources ("MGRs") deriving from deep-sea marine organisms (bacteria, animals, plants, seaweeds, etc.) have shown great potential in the field of medicine and are considered of significant value for future research and developments. Potential fields of application for MGRs include antioxidant, antifungal, anti-HIV,

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antibiotic, anti-cancer, anti-tuberculosis, and anti-malarial uses.[1] Major pharmaceutical firms, including Merck, Lilly, Pfizer, Hoffman-Laroche, and Bristol-Myers Squibb, have marine biology departments.[2] The global market for marine biotechnology was estimated at $2.4 billion in 2004, with an estimated average growth of 5.9% per year from 1999 to 2007.[3] According to the results of International Census of Marine Microbes, "the value of the ecosystem services provided by coral reefs is estimated at more than $5 million per square kilometre per year, in terms of revenues from genetic material and bioprospecting."[4]

From a legal point of view, it is unclear under which regime MGRs fall and under what conditions they can be patented. Three main legal instruments contribute to the parameters of their legal regime: the United Nations Convention on the Law of the Sea ("LOSC"),[5] the Convention on Biological Diversity ("CBD")[6] and the Trade Related Intellectual Property Rights Agreement ("TRIPS").[7] As a preliminary mark it has to be highlighted that LOSC does not contain any provision explicitly regulating MGRs and it does not use the expression "area beyond national jurisdiction." Rather, it provides that areas beyond the national jurisdiction of coastal states are either part of the high seas regime or of the Area of the deep seabed.

Article 86 stipulates that "[t]he provisions of [Part VII High Seas] apply to all parts of the sea that are *not* included in the exclusive

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[1] F. DE LA CALLE, *Marine Genetic Resources. A Source of New Drugs: The Experience of the Biotechnology Sector*, 24 *International Journal of marine and Costal Law* (2009) 209.

[2] K. E. ZEWERS, *Bright Future for Marine Genetic Resources, Bleak Future for Settlement of Ownership Rights: Reflections on the United Nations Law of the Sea Consultative Process on Marine Genetic Resources*, 5 *Loyola University Chicago International Law Review* (2008) 151, at 156–58.

[3] D. WESTWOOD LTD., *Marine Industries Global Market Analysis*, 1 *Marine Foresight Series* (2005) 117, available at www.marine.ie .

[4] U.N. Secretary-General, *Oceans and the Law of the Sea: Rep of the Secretary-General*, U.N. Doc. A/62/66 (12 March 2007) [hereinafter U.N. Secretary-General, *Oceans Rep.*] para. 61. More than 2,700 scientists, from 80 different countries, put 10 years effort together in order to realize the most precise and reliable census of marine life. For more information on marine life, discovery and research, see Census of Marine Life, available at www.coml.org.

[5] United Nations Convention on the Law of the Sea, opened for signature 10 December 1982, 1833 U.N.T.S. 397.

[6] Convention on Biological Diversity, June 5, 1992, 1760 U.N.T.S. 79.

[7] Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 15 April 1994, 869 U.N.T.S. 299.

economic zone, in the territorial sea or in the internal waters of a State, or in the archipelagic waters of an archipelagic State" (emphasis added). High seas are the water column not included in areas submitted to coastal states' jurisdiction and superjacent the Area of the deep seabed and, eventually, the continental shelf (art. 76 LOSC). The floor and the subsoil of the areas beyond national jurisdiction fall under the Area[8] regulated by Part XI of LOSC (arts 131-191). This distinction creates one of the elemental problems when applying LOSC to MGRs; their locale is not easily ascertainable. For instance, how does one determine in which of the two regimes a microbe living in symbiosis with the local fauna falls, or perhaps a microbe found in the proximity of a thermal vent? It is, however, important to outline the main characteristics of both regimes in order to foresee the legal framework which might regulate MGRs and related issues.

"The Area"—the floor and the subsoil of areas beyond national jurisdiction—is subject to the regime of the "common heritage of mankind" (art. 136 LOSC).[9] In 1970, the General Assembly adopted a resolution, declaring that "[t]he sea-bed and ocean floor, and the subsoil thereof, beyond the limits of national jurisdiction . . . as well as the resources of the area, are the common heritage of mankind."[10] In those years, the optimism concerning technological developments fuelled the rise of a regime promoting a New International Economic Order[11]

[8] The Area is considered the floor and the subsoil of areas beyond national jurisdiction. *Id.* art 1, para. 1.

[9] The common heritage of mankind was first introduced by the Maltese representative, Arvid Pardo, in a speech in front of the U.N. General Assembly in 1967; see U.N. GAOR, 22d Sess., U.N. Doc. A/C.1/PV.1516 (1 November 1967) at 14.

[10] *Declaration of Principles Governing the Sea-Bed and the Ocean Floor, and the Subsoil Thereof, beyond the Limits of National Jurisdiction*, G.A. Res. 2749 (XXV), U.N. GAOR, 25th Sess., Supp. No. 28, U.N. Doc. A/RES/25/2749 (XXV) (17 December 1970).

[11] In the 1960s and 1970s, the countries with newfound independence from their colonial occupant considered colonialism as an avatar of capitalism. D. BENN, *Multilateral Diplomacy and the Economics of Change*, Kingston, 2003, at 1-3. For this reason they claimed a new international economic order that will help solving the inequalities between developing and developed states, which translates to the difference between the new independent states and the former colonial powers. See also M. SORNARAJAH, *The New World Economic Order and Equity*, *in* R.K. DIXIT, C. JAYARAJ (eds.), *Dynamics of international law in the new millennium*, New Delhi, 2004, at 209.

which conveys the idea of equity in economic relations.[12] This is reflected in Article 137 on the legal status of the Area and its resources:

> 1. No State shall claim or exercise sovereignty or sovereign rights over any part of the Area or its resources, nor shall any State or natural or juridical person appropriate any part thereof. No such claim or exercise of sovereignty or sovereign rights nor such appropriation shall be recognized.
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> 2. All rights in the resources of the Area are vested in mankind as a whole, on whose behalf the Authority shall act. These resources are not subject to alienation. (…)
>
> 3. No State or natural or juridical person shall claim, acquire or exercise rights with respect to the minerals recovered from the Area except in accordance with this Part.

When LOSC was negotiated, the existence of genetic resources in the Area and their possible economic value was unknown. As a result, Article 133 defines resources as "all solid, liquid or gaseous mineral resources *in situ* in the Area at or beneath the seabed, including polymetallic nodules." This narrow definition of the resources has led some to posit that the common heritage of mankind regime does not apply to MGRs.[13] Another reason for the non-application of the common heritage regime to MGRs is that the exploitation and management of the resources would be accompanied by the International Seabed Authority ("ISA")'s position in a leading role, which features a composition that is potentially ill-suited for the management of MGRs.[14] The principal organ of the ISA, the Council, is composed of member states' representatives and in particular of those states which have a leading role in the polymetallic nodules industry

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[12] L. Migliorino, *Sfruttamento dei fondi marini e nuovo ordine economico internazionale, trasferimento della tecnologia e controllo delle multinazionali*, *in* T. TREVES ET AL. (eds.), *Lo sfruttamento dei fondi marini*, Milan, 1982, at 82; J. BRUNNÉE, *Common Areas, Common Heritage and Common Concern*, *in* D. BODANSKY ET AL. (eds.), *The Oxford Handbook of International Environmental Law*, Oxford, 2007, at 561–62.

[13] D. LEARY, *International Law and Genetic Resources of the Deep Sea*, *in* D. VIDAS (ed.), *Law, Technology and Science for Oceans in Globalisation*, Leiden, 2010, at 47.

[14] T. TREVES, *Principles and Objectives of the Legal Regime Governing Areas Beyond Nation Jurisdiction*, *in* E. J. MOLENAAR, A. G. OUDE ELFERINK (eds.), *The International Legal Regime of Areas Beyond National Jurisdiction: Current and Future Developments*, Leiden, 2010, at 17–18.

(art. 161 LOSC). These groups may lack sufficient motivation or qualifications to protect MGRs and the related industry.

However, article 246, applicable in the exclusive economic zone and on the continental shelf, includes marine scientific research projects carried out "in order to increase scientific knowledge of the marine environment for the benefit of all mankind" and "of direct significance for the exploration and exploitation of natural resources, whether living or non-living." No provision of LOSC distinguishes between marine scientific research carried out for commercial purposes on the one hand, and research which does not have direct commercial potential or which is not suitable for commercial exploitation on the other.[15] Indeed, bioprospecting—i.e., the research, collection, and utilization of biological and genetic resources with the aim of applying the knowledge derived for scientific and/or commercial purposes[16]—falls under the notion of "marine scientific research." Therefore, any bioprospecting done in the Area must be performed in compliance with Article 143, which provides:

> 1. Marine scientific research in the Area shall be carried out exclusively for peaceful purposes and for the benefit of mankind as a whole, in accordance with Part XIII (…).
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> 3. States Parties may carry out marine scientific research in the Area. States Parties shall promote international cooperation in marine scientific research in the Area by:
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> (a) participating in international programmes and encouraging cooperation in marine scientific research by personnel of different countries and of the Authority;
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> (b) ensuring that programmes are developed through the Authority or other international organizations as appropriate for the benefit of developing States and technologically less developed States (…);
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> (c) effectively disseminating the results of research and analysis when available, through the Authority or other international channels when appropriate.

[15] T. SCOVAZZI, *The Seabed Beyond the Limits of National Jurisdiction: General and Institutional Aspects*, *in* E. J. MOLENAAR, A. G. OUDE ELFERINK (eds.), *The International Legal Regime*, at 58.

[16] K. TEN KATE, S.A. LAIRD, *The Commercial Use of Biodiversity*, London, 1999, at 19.

Even if MGRs in the Area cannot be considered part of the common heritage of mankind regime, they reasonably fall under "common concerns" in the sense that they are resources in which the majority of states have an interest because of their location—in areas beyond national jurisdiction—and so potentially exploitable by all states, and they are also common because of their potential benefits to mankind.[17] To consider MGRs as common concerns would root the creation of a legal regime, which would regulate MGRs and their exploitation in the view of protecting such common concerns for the benefit of mankind.

However, Article 143 of LOSC on marine scientific research could be applicable to MGRs located in the Area and thus govern bioprospecting carried out in the Area, but not in the water column. Likewise, Article 135 LOSC states that the legal status of the waters superjacent to the Area and of the air space above those waters should not be undermined by the regime created by Part XI.[18] In the water column, beyond national jurisdiction, all states enjoy the freedom of scientific research, guaranteed by Articles 87.1(f) and 257.[19]

Alternatively, Article 241 applies to both the Area as well as the water column and provides that "[m]arine scientific research activities shall not constitute the legal basis for any claim to any part of the marine environment or its resources." The collection of samples for the creation of biotechnologies could be considered as being in the interest of the "community."[20] Just like all the activities carried out in areas beyond national jurisdiction, it has to be conducted with regard to the international community's interest. This notion is buttressed by the LOSC's preamble stating that:

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[17] "[c]ertains domaines ne concernent pas les intérêts d'un Etat par rapport aux autres, mais touchent aux intérêts fondamentaux de la grande majorité des Etats, c'est-à-dire – pour ceux qui croient qu'elle existe – aux intérêts de la communauté internationale." T. SCOVAZZI, *La notion de patrimoine culturel de l'humanité dans les instruments internationaux*, in J. A. R. NAFZIGER, T. SCOVAZZI (eds), *Le patrimoine culturel de l'humanité*, Leiden, 2008, at 3.

[18] Article 135 of LOSC on the legal status of the superjacent waters and air space states that: "Neither this Part nor any rights granted or exercised pursuant thereto shall affect the legal status of the waters superjacent to the Area or that of the air space above those waters."

[20] F. ORREGO VICUNA, *Les législations nationales pour l'exploitation des fonds marins et leur incompatibilité avec le droit international*, 24 *Annuaire Français de Droit International* (1978) 810, at 812.

> The States Parties to this Convention (…) will promote the peaceful uses of the seas and oceans, the equitable and efficient utilization of their resources, the conservation of their living resources,
>
> Desiring by this Convention to develop the principles embodied in resolution 2749 (XXV) of 17 December 1970 in which the General Assembly of the United Nations solemnly declared inter alia that the area of the seabed and ocean floor and the subsoil thereof, beyond the limits of national jurisdiction, as well as its resources, are the common heritage of mankind, the exploration and exploitation of which shall be carried out for the benefit of mankind as a whole, irrespective of the geographical location of States.

These paragraphs of the Preamble encourage interpreting relevant LOSC provisions to be applied to MGRs. Such sentiment takes inspiration from the common heritage of mankind regime, as embodied in the U.N. General Assembly Resolution 2749.[21] However, for a truly complete and uncontested application of Part XI to MGRs, the parties must agree to an amendment to the Convention. Unfortunately, such an event would require long negotiations given the disagreements, discussed later, that prevail with regard to the application of intellectual property rights ("IPRs") over biotechnologies[22].

It stands to question whether the existing international regulation of IPRs, specifically patents, as set out by TRIPS, is compatible with the complex legal regime of MGRs. Their conservation and exploitation constitute common concerns because they are located in areas beyond national jurisdiction. MGRs should therefore enjoy protection in line with the existing legal instruments concerning common interests, such as biodiversity and genetic resources for food and agriculture. In this light, this article suggests that the exploitation of MGRs should be carried out according to two fundamental principles that are enshrined in the CBD: (i) the prior and informed consent to access to MGRs and (ii) the fair and equitable sharing of benefits from these resources.

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[21] Declaration of Principles Governing the Sea-Bed and the Ocean Floor, and the Subsoil Thereof, beyond the Limits of National Jurisdiction, G.A. Res. 2749 (XXV), U.N. GAOR, 25th Sess., Supp. No. 28, U.N. Doc. A/RES/25/2749 (XXV) (Dec. 17, 1970).

[22] See *infra* para. 2.

In view of these overlapping legal regimes (TRIPS, CBD and LOSC), any attempt at regulating the management and the exploitation of MGRs stands within the wider debate on the fragmentation of international law.[23] This paper will demonstrate that the different legal regimes likely operate in support of one another to create a workable legal regime for MGRs. Compatibility clauses and recent normative developments in each regime testify to an interdependence between the LOSC, the CBD, and the TRIPS. In short, legal quarrels relating to the management and exploitation of MGRs illustrate an inter-systemic dialogue and the need of such dialogue in order to form a coherent legal framework for MGRs.[24]

The following analysis is divided into two sections. The first part aims at identifying the principles and rules governing MGRs' overall legal regime by demonstrating how the management and exploitation of MGRs falls within several legal systems. The second part explores alternative legal solutions as well as institutional mechanisms of coping with the management of MGRs. To this extent, it will analyze four legal solutions based on the joint application of existing legal tools, and three possible institutional scenarios that guarantee the principles of protection and the "common" management of MGRs.

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[23] On this topic, see also INTERNATIONAL LAW COMMISSION, *Fragmentation of International Law*, U.N. Doc. A/CN.4/L.682 (13 April 2006); E. BENVENISTI, G. W. Downs, *The Empire's New Clothes: Political Economy and the Fragmentation of International Law*, 60 *Stanford Law Review* (2007) 595; B. CONFORTI, *Unité et fragmentation du droit international: "glissez, mortels, n'appuyez pas!"*, 111 *Revue générale de droit international public* (2007) 5; A. FISCHER-LESCANO. G. TEUBNER, *Regime-Collisions: The Vain Search for Legal Unity in the Fragmentation of Global Law*, 25 *Michigan Journal of International Law* (2004) 999; D. FRENCH, *Treaty Interpretation and the Incorporation of Extraneous Legal Rules*, 55 *International and Comparative Law Quarterly* (2006) 300. See generally *Symposium, Post-ILC Debate on Fragmentation of International Law*, 17 *Finnish Yearbook of International Law* (2006); T. TREVES, *Fragmentation of International Law: the Judicial Perspective*, 23 *Comunicazioni e studi* (2007) 821.

[24] On the interdependence and theoretical debates of legal regimes, see generally L. Gradoni, *Systèmes juridiques internationaux: une esquisse*, in H. RUIZ FABRI, L. GRADONI (eds.), *La circulation des concepts juridiques: le droit international de l'environnement entre mondialisation et fragmentation*, Paris, 2009, at 27; B. SIMMA, *Self-Contained Regimes*, 16 *Netherlands Yearbook of International Law* (1985) 111; B. SIMMA, D. PULKOWSKI, *Of Planets and the Universe: Self-Contained Regimes in International Law*, 17 *European Journal of International Law* (2006) 483.

2. Fragmentation and Coordination Between Existing Regimes: MGRs in TRIPS and CBD

Inventions obtained from genetic resources, including MGRs, can be patented according to Part II, Section V of the TRIPS, which provides minimum standards of intellectual property protection.[25] TRIPS was concluded under the auspices of the World Trade Organization ("WTO"). WTO state members (and parties to the Agreement) number approximately 155 and 130 of them are also contracting parties of LOSC.[26] TRIPS establishes that "patents shall be available for any inventions, whether products or processes, in all field of technology, provided that they are new, involve an inventive step and are capable of industrial application" (art. 27.1). Therefore, patents can be granted on inventions based on MGRs if these three essential conditions are simultaneously fulfilled. According to Article 28, a patent confers on its owner a series of exclusive rights, including the

[25] C. M. CORREA, *Patents Rights*, in C. M. CORREA A. A. YUSUF (eds.), *Intellectual Property and International Trade: the TRIPS Agreement*, 2d ed., The Hague, 2008, p. 227; C. M. CORREA, *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*, Oxford, 2007; D. J. GERVAIS, *L'accord sur les ADPIC*, Brussels, 2010; D. J. GERVAIS, *The TRIPS Agreement: Drafting History And Analysis*, London, 3d ed, 2008; M. MATSUSHITA, T. J. SCHOENBAUM, P. C. MAVROIDIS, *The World Trade Organization: Law, Practice, and Policy*, Oxford, 2d ed. 2006, p. 699. The grant of patents on biotech inventions has given rise to a strong debate between developed and developing WTO member countries. As we will explain below, it constitutes one of the main subjects discussed within the Doha Round. The regulation of biotechnologies in international law and the patentability of biotech inventions have also been examined in many scholarly writings. *See also*, N. BOSCHIERO (ed.), *Bioetica e biotecnologie nel diritto internazionale e comunitario: Questioni generali e tutela della proprietà intellettuale*, Torino, 2006; J. CURCI, *The Protection of Biodiversity and Traditional Knowledge in International Law of Intellectual Property*, Cambridge, 2010, P. 30; F. FRANCIONI, T. SCOVAZZI (eds.), *Biotechnology and International Law*, Oxford, , 2006; C. R. MCMANIS (ed.), *Biodiversity and the Law: Intellectual Property, Biotechnology and Traditional Knowledge*, London, 2007; B. ONG (ed.), *Intellectual Property and Biological Resources*, Singapore, 2004; R. PAVONI, *Biodiversità e biotecnologie nel diritto internazionale e comunitario*, Milano, 2004 [hereinafter *Pavoni, Biodiversità e biotecnologie*]. The present study does not aim at analyzing the whole range of the general controversial issues concerning the grant of patents on biotech inventions. On the contrary, it will be focused only on the examination of those aspects specifically concerning the grant of patents on MGRs, taking their special characteristics and their location into consideration.

[26] *Understanding the WTO: Members and Observers*, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm.

right to prevent third parties, not expressly authorized to the contrary, from making, using, offering for sale, selling, or importing the product or the process covered by patent. These protections shall not end before twenty years of the filing date (art. 33 TRIPS).

TRIPS, like other treaties, must be interpreted in the light of the general principles on treaty interpretation enshrined in the Vienna Convention on the Law of Treaties ("VCLT").[27] The dispute settlement system of the WTO "serves (…) to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law"[28] and the principles provided in Articles 31 and 32 of the VCLT have attained status of customary international law in the WTO Appellate Body's reports.[29] According to Article 31.1 VCLT, TRIPS shall be "interpreted in good faith in accordance with the ordinary meaning to be given to its terms in their context and in the light of its object and purpose." Reference should then be made to Article 7 TRIPS, which sets out the objectives and establishes that the protection and enforcement of IPRs: "should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare". Moreover, pursuant to Article 31.2 VCLT, TRIPS shall be interpreted in the context[30] of the preambulary statements of the Agreement establishing the WTO, "allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of

[27] Vienna Convention on the Law of Treaties, May 23, 1969, 1155 U.N.T.S. 331; *see* I. VAN DAMME, *Treaty Interpretation by the WTO Appellate Body*, 21 *European Journal of International Law* (2010) 605, 620.

[28] Understanding on Rules and Procedures Governing the Settlement of Disputes, art. 3. 2, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, 1869 U.N.T.S. 401 [hereinafter DSU].

[29] Appellate Body Report, *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R, at 16–17 (Apr. 29, 1996).

[30] *See generally* M. VILLIGER, *Commentary on the 1969 Vienna Convention on the Law of Treaties*, Leiden, 2009, 415, 427–29 [hereinafter VILLIGER, *Vienna Convention Commentary*]; *see also*, M. VILLIGER, *The 1969 Vienna Convention on the Law of Treaties – 40 Years After*, *in* 344 *Recueil des Cours. Collected Courses of The Hague Academy of International Law* (2009) 113–34.

economic development".[31] Finally, as clarified by the Appellate Body, the WTO Agreements shall not be interpreted in "clinical isolation."[32] On the contrary, they should be read through the lens of subsequent practice,[33] and of "any relevant rules of international law applicable in the relations between the parties."[34]

Applying Article 31.3(c) VCLT to the WTO Agreements may require consideration of other international law provisions, either customary or conventional, that are both binding on the parties and simultaneously applicable to the issue at stake.[35] When dealing with the

[31] Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154.

[32] The expression was used by the Appellate Body in the case *United States – Standards for Reformulated and Conventional Gasoline*, *supra* note 29, para. 14. On the relationship between WTO agreements and international law, see G. MARCEAU, *Fragmentation in International Law: The Relationship between WTO Law and General International Law - A Few Comments from a WTO Perspective*, 17 *Finnish Yearbook of International Law* 5 (2006); G. MARCEAU, *Conflict of Norms and Conflicts of Jurisdiction: The Relationship between the WTO Agreement and MEAs and Other Treaties*, 35 *Journal of World Trade* (2001) 1081; G. MARCEAU, A. TOMAZOS, *Comments on Joost Pauwelyn's Paper: 'How to Win a WTO Dispute Based on Non-WTO Law?*', in S. GRILLER (ed.), *At the Crossroads: The World Trading System and the Doha Round*, Wien, 2008, 54, 56; J. PAUWELYN, *Conflict of Norms in Public International Law: How WTO Law Relates to Other Rules of International Law*, Cambridge, 2003, 25, 35; J. PAUWELYN, *The Application of Non-WTO Rules of International Law in WTO Dispute Settlement*, in P. F. J. MACRORY (ed.), *The World Trade Organization: Legal, Economic and Political Analysis*, New York, 2005, 1405; *see also* I. VAN DAMME, *Treaty Interpretation by the WTO Appellate Body*, cit.; I. VAN DAMME, *Some Observations About the ILC Study Group Report on the Fragmentation of International Law: WTO Treaty Interpretation Against the Background of Other International Law*, 17 *Finnish Yearbook of International Law* (2006) 21.

[33] VCLT, *supra* note 27, art. 31.3(b); G. NOLTE, *Subsequent Practice as a Means of Interpretation in the Jurisprudence of the WTO Appellate Body*, *in* E. CANNIZZARO (ed.), *The Law of Treaties Beyond the Vienna Convention*, Oxford, 2011, 138, 140–41; M. VILLIGER, *Vienna Convention Commentary*, cit., at 431.

[34] VCLT, *supra* note 27, art. 31.3(c); M. VILLIGER, *Vienna Convention Commentary*, cit., at 432.

[35] The notion of "parties" as provided by art. 31 3(c) VCLT, is controversial. *See* U. LINDERFALK, *Who Are 'The Parties'? Article 31, Paragraph 3(c) of the 1969 Vienna Convention and the 'Principle of Systemic Integration' Revisited*, 55 *Netherlands International Law Review* (2008) 343, 347. On the application of the systemic interpretation criterion by the WTO dispute settlement bodies, "it makes sense to interpret art. 31.3(c) as requiring consideration of those rules of international law which are applicable in the relations between all parties to the treaty which is being interpreted." *See* Panel Report, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, para. 7.70, WT/DS291/R, WT/DS292/R, WT/DS293/R (Sept. 29, 2006). On its interpretation, M. YOUNG, *The WTO's Use of*

grant of patents on inventions from MGRs, relevant provisions of international law can be found in LOSC and CDB, which, as noted before, contribute to framing the MGRs' legal regime and provide for their legal status and management. Therefore, when applying TRIPS in this field and interpreting its rules, LOSC and CBD provisions could be considered rules of international law relevant to the grant of patents on inventions derived from them.

The CBD's objectives consist of "the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies" (art. 1). Pursuant to the CBD, states have the sovereign right to exploit their own natural resources[36] and the authority to regulate foreign states public institutions, and private institutions access to them.[37]

Even if some maintain that the CBD cannot directly apply to MGRs, neither in the water column nor in the deep seabed beyond national jurisdiction, because of the CBD's limited territorial scope[38] and the bilateral nature of the exploitation scheme[39], it is here submitted that MGRs can fall within the reach of it[40]. This conclusion is based on the fact that the CBD must be interpreted consistently with the LOSC when it comes to marine biodiversity before any application to MGRs can be made. According to Article 237 LOSC, its Part XII "are *without*

Relevant Rules of International Law: an Analysis of the Biotech *Case*, 56 *International and Comparative Law Quarterly* (2007) 907, 914–15; B. MCGRADY, *Fragmentation of International Law or "Systemic Integration" of Treaty Regimes: EC-Biotech Products and the Proper Interpretation of Article 31(3)(c) of the Vienna Convention on the Law of Treaties*, 42 *Journal of World Trade* (2008) 589, 614; E.-U. PETERSMANN, *The WTO Dispute Over Genetically Modified Organisms: Interface Problems of International Trade Law, Environmental Law and Biotechnology Law*, in F. FRANCIONI, T. SCOVAZZI (eds.), *Biotechnology and International Law*, cit., 173; A. THOMISON, *A New Controversial Mandate for the SPS Agreement: The WTO Panel's Interim Report in the E. C. – Biotech Dispute*, 32 *Columbia Journal of Environmental Law* (2007) 287, 307.

[36] Art. 3 CBD.

[37] Art. 15 CBD.

[38] Art. 4 CBD.

[39] N. MATZ-LÜCK, *The Concept of the Common Heritage of Mankind: Its Viability as a Management Tool for Deep-Sea Genetic Resources*, *in* E. J. MOLENAAR, A. G. OUDE ELFERINK (eds.), *The International Legal Regime of Areas Beyond National Jurisdiction: Current and Future Developments*, cit, at 63.

[40] On this point see A. BONFANTI, S. TREVISANUT, *TRIPS on the High Seas: Intellectual Property Rights on Marine Genetic Resources*, cit., at 208.

prejudice to the specific obligations assumed by States under special conventions and agreements concluded previously which relate to the protection and preservation of the marine environment and *to agreements which may be concluded in furtherance of the general principles set forth in this Convention*" and "specific obligations assumed by States under special conventions, with respect to the protection and preservation of the marine environment, should be carried out in a manner consistent with the general principles and objectives of this Convention" (emphasis added).

This provision highlights how the LOSC has an interdependent relationship with the existing instruments in the field of marine environment.[41] This must be kept in mind when turning to the relevant provisions of the CBD, namely Article 4, which provides for its application, in relation to each Contracting Party: "(a) In the case of components of biological diversity, in areas within the limits of its national jurisdiction; and (b) *In the case of processes and activities, regardless of where their effects occur, carried out under its jurisdiction or control,* within *the area of its national jurisdiction or beyond the limits of national jurisdiction*" (emphasis added). A correct interpretation of the latter criterion leads to consider the CBD applicable to MGRs, as they are subject to the activities and the processes put in place beyond national jurisdiction by a contracting States or by a private actor, a research institute, or a pharmaceutical company having its nationality.

This interpretation would be in line with the recommendation of the Subsidiary Body on Scientific, Technical and Technological Advice of the CBD ("SBSTTA"):

> (c) Concerned about the threats to genetic resources in the deep seabed beyond national jurisdiction, requests Parties and urges other States, having identified activities and processes under their jurisdiction and control which may have significant adverse impacts on deep seabed ecosystems and species in these areas, as requested in paragraph 56 of decision VII/5, to take measures to urgently manage such practices in vulnerable deep seabed

[41] S. TREVISANUT, *La Convention des Nations Unies sur le droit de la mer et le droit de l'environnement: développement intrasystémique et renvoi intersystémique*, in H. RUIZ FABRI, L. GRADONI (eds.), *La circulation des concepts juridiques: le droit international de l'environnement entre mondialisation et fragmentation*, cit., at 415.

ecosystems with a view to the conservation and sustainable use of resources, and report on measures taken as part of the national reporting process.[42]

This statement was echoed by Decision VIII/21 of the eighth CBD Conference of the parties, stressing the potential application of the CBD to the issue at hand and the active role states parties of the CBD are called to play in the shaping of a regime for MGRs[43], as well as by the solutions drafted by the recently adopted Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the CBD ("Nagoya Protocol") [44].

The CBD provides for two mandatory principles governing access to genetic resources. First, the access to genetic resources is subject to the prior and informed consent of the national authority of the state on the territory or jurisdiction where the resource is located (art. 15.5 CBD). Second, the terms that authorize access are agreed upon between the provider state and the user (art. 15.4 CBD). The content of the terms comprising the second principle is left to the discretion of the parties. Nonetheless, the terms should ensure that benefits arising from the economic exploitation of the resources are fairly and equitably shared between the user and the provider state (art. 15.7 CBD). Due to the vagueness of the notion of "fair and equitable sharing of benefits," which the CBD does not define precisely, and considering that neither a model contract nor standard clauses are provided by the convention, such an objective cannot be easily reached.

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[42] Eleventh Meeting of the Subsidiary Body on Scientific, Technological & Technological Advice [SBSTTA], Montreal, Can., Nov. 28–Dec. 2, 2005, *Recommendation XI/8: Marine and coastal biological diversity: conservation and sustainable use of deep seabed genetic resources beyond the limits of national jurisdiction*, para. 4(c) (2005), *available at* http://www.cbd.int/recommendation/sbstta/?id=10967.

[43] Eighth Meeting of the Conference of the Parties to the Convention on Biological Diversity, Curitiba, Braz., Mar. 20–31, 2006, *Decision VIII/21: Marine and coastal biological diversity: conservation and sustainable use of deep seabed genetic resources beyond the limits of national jurisdiction*, para. 3 (2006).

[44] Tenth Meeting of the Conference of the Parties to the Convention on Biological Diversity, Nagoya, Jap., Oct. 29, 2010, *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*, U.N. Doc. UNEP/CBD/COP/DEC/X/1, *available at* http://www.cbd.int/abs/text/ [hereinafter *Nagoya Protocol*].

Indeed, practice demonstrates that the corresponding obligation is seldom fulfilled.[45]

Given the practical difficulties faced by states and private operators with regard to sharing, the 2002 Conference of the parties to the CBD adopted the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (the "Bonn Guidelines").[46] This nonbinding instrument aims at facilitating access to genetic resources and ensuring that benefits of any commercialization are duly shared with provider states. The Bonn Guidelines clarify the means through which the prior and informed consent and the fair and equitable benefit sharing should be applied by national governments and suggest legal formula according to which they could be concretely fulfilled. Additionally, the CBD framework was recently expanded with the adoption of the early mentioned Nagoya Protocol, adopted by the Conference of the parties on October 29, 2010, after lengthy negotiations.[47]

3. A Legal Regime for MGRs: Feasible Solutions

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[45] N. BOSCHIERO, *Le biotecnologie tra etica e principi generali del diritto internazionale*, in N. BOSCHIERO (ed.), *Bioetica e biotecnologie nel diritto internazionale e comunitario: Questioni generali e tutela della proprietà intellettuale*, cit., at 70-71; J. CARR, *Agreements That Divide: TRIPs vs. CBD and Proposals for Mandatory Disclosure of Source and Origin of Genetic Resources in Patent Applications*, 18 *Jornal of Transnational Law & Policy* (2008) 131, 134; J. S. MILLER, *Impact of the Convention on Biological Diversity: The Lessons of Ten Years of Experience with Models for Equitable Sharing of Benefits*, *in* C. R. MCMANIS (ed.), *Biodiversity and the Law: Intellectual Property, Biotechnology and Traditional Knowledge*, cit., at 58, 65–66; J.-F. MORIN, *Les accords de bioprospection favorisent-ils la conservation des ressources génétiques?*, 34 *Revue de droit de l'Université de Sherbrooke* (2003), at 307.

[46] Sixth Meeting of the Conference of the Parties to the Convention on Biological Diversity, The Hague, Neth., Apr. 7–9, 2002, *Decision VI/24/A: Annex: Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization*, U.N. Doc. UNEP/CBD/COP/6/20, *available at* http://www.cbd.int/decision/cop/?id=7198 [hereinafter *Bonn Guidelines*]; *see generally* W. B. CHAMBERS, *Emerging International Rules on the Commercialization of Genetic Resources: The FAO International Plant Genetic Treaty and the CBD Bonn Guidelines*, 6 *Journal of World Intellectual Property* (2003) 311; M. I. JEFFERY, *Intellectual Property Rights and Biodiversity Conservation,* cit., at 747; S. TULLY, *The Bonn Guidelines on Access to Genetic Resources and Benefit Sharing*, 12 *Review of European Community and International Environmental Law* (2003) 84.

[47] *Nagoya Protocol*, *supra* note 44, arts. 26–27.

Despite the possibility that extra-territorial activities involving MGRs may still be attributable to a specific state, it remains to be determined who would be responsible for overseeing the administration of the legal regime.

It has been correctly noted that "it is hard to see how the majority of the international community will benefit from the monopoly protection provided to patent holders of biotechnology products derived from MGRs taken from ocean areas beyond national jurisdiction."[48] Considering this inequity in light of the undeniable contribution intellectual property protection provides to scientific and technological development, "states should seriously discuss viable and realistic options for (…) sharing benefits in a fair and equitable way."[49] In this light, this section (A) examines the means through which the international obligations can be met when MGRs are concerned and (B) identifies which would be the most appropriate authority as a counterparty of the users.

[48] R. J. 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*, cit., at 379.

[49] Third Meeting of the U.N. 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, New York, U.S., Feb. 1–5, 2010, *EU Intervention on Agenda Item 5.g – Marine Genetic Resources, with a Particular Focus on the Relevant Regime in accordance with the Convention*, at 2 (on file with the authors) [hereinafter U.N. Working Group, *EU Intervention on Agenda Item 5.g*]. According to Tullio Scovazzi, "[w]hile a specific regime for the exploitation of genetic resources is lacking, the aim of sharing the benefit among all States, which was the main aspect of the seminal proposal made by Arvid Pardo, can still be seen as the paramount objective embodied in the LOS Convention for everything that takes place in the Area. Also in the field of genetic resources, the application of the principle of freedom of the sea (that is the 'first-come-first-served' rule) leads to inequitable and hardly acceptable consequences. New cooperative schemes have to be envisaged at the international level, based on the objective of the benefit of all States. This is also in full conformity with the principle of fair and equitable sharing of the benefits arising out of the utilization of genetic resources set forth by Article 1 of the CBD". *See* T. SCOVAZZI, *Seabed Beyond the Limits of National Jurisdiction*, cit., at 57; *see also* S. ARICO, *Marine Genetic Resources in Areas beyond National Jurisdiction and Intellectual Property Rights*, in D. VIDAS (ed.), *Law, Technology and Science for Oceans in Globalisation*, cit., 385.

A. Possible Legal Frameworks

i. MGRs and the Bonn Guidelines

The first solution to be explored considers the provisions of the Bonn Guidelines in guaranteeing both the protection of intellectual property and the fair and equitable benefit sharing for patented products based on MGRs.

The Bonn Guidelines provide clarifications that facilitate the concrete application of CBD and, in particular, the enforcement of both the prior and informed consent and the fair and equitable benefit sharing obligations.[50] In order to pursue these objectives, the Bonn Guidelines establish that contracting parties shall set up National Focal Points, i.e., domestic authorities focused on the management of the access procedure to genetic resources by foreign institutions which also aim to enter into the agreements addressed to define the terms of such an access.[51] Pursuant to the guidelines, these terms should be agreed on a case-by-case basis.[52] The National Focal Points should also develop framework agreements, as well as standardize material transfer agreements and benefit-sharing arrangements.[53] Moreover, "[b]enefits should be directed in such a way as to promote conservation and sustainable use of biological diversity"[54], and ethical concerns of parties and stakeholders should be taken into consideration in drafting the mutually agreed terms.[55] Near-term, medium-term, and long-term benefits should be considered and monetary and nonmonetary benefits may be agreed upon.[56]

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[50] W. B. CHAMBERS, *Emerging International Rules on the Commercialization of Genetic Resources*, cit., at 316; M. I. JEFFERY, *Intellectual Property Rights and Biodiversity Conservation,* cit., 747; S. TULLY, *The Bonn Guidelines on Access to Genetic Resources and Benefit Sharing*, cit., at 84.

[51] *Bonn Guidelines*, *supra* note 46, para. 13.

[52] *Id.* para. 41.

[53] *Id.* paras 42(b)(iii)–(iv).

[54] *Id*. para. 48.

[55] *Id*. para. 43(a).

[56] Among the suggested examples listed in Appendix II for monetary benefits are: up-front payments, milestone payments, payment of royalties, license fees, special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity, salaries and preferential terms, research funding, joint ventures, and joint ownership of relevant intellectual property rights. *Id.* app. II, para. 1. The list of nonmonetary

Some of the means suggested by the Bonn Guidelines are suitable with MGRs and should be applied in order to guarantee the fair and equitable sharing of the benefits accrued from their exploitation. Among them, the attribution of payments; the setting up of joint ventures; the constitution of joint ownership on relevant IPRs; the sharing of research and development results; the transfer of relevant knowledge and technology; and the collaboration, cooperation and contribution in scientific research and development programs; and the payment of royalties.

ii. MGRs and the Nagoya Protocol

The possible approaches outlined in the Bonn Guidelines could be further strengthened by the hopeful Nagoya Protocol's entry into force in the future. The Protocol defines the modalities according to which the parties shall enforce the principles of prior and informed consent and the fair and equitable benefit sharing obligations, as set out in the CBD.[57] The content of many of its articles is either directly inspired or influenced by the Bonn Guidelines.

However, it goes further than them in establishing the issuance of internationally recognized certificates by the competent national authorities.[58] Such certificates shall show that the genetic resource has been obtained, accessed, and used in accordance with prior informed consent, and that mutually agreed terms have been entered into. They shall contain minimum information, such as the identities of the issuing national authority, the provider, and the user, and shall specify the subject matter covered and the geographic location of the access activity, the uses permitted and the correspondent restrictions, as well

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benefits includes sharing of research and development results, participation in product development, admittance to *ex situ* facilities of genetic resources and to databases, transfer of knowledge and technology under fair and most favorable terms, access to scientific information relevant to conservation and sustainable use of biological diversity, contributions to the local economy and to research directed towards priority needs, such as health and food security, as well as collaboration, cooperation and contribution in scientific research, development programs, education, and training. *Id.* app. II, para. 2.

[57] *Nagoya Protocol*, *supra* note 44, art. 10.

[58] *Id.* art. 6.3(e), art. 13.2, art. 17.2–4.

as the conditions of transfer to third parties.[59] Lastly, the certificates shall contain a link to the mutually agreed terms regulating the benefit sharing.

Moreover, the Protocol provides that parties shall establish clear rules and procedures for mutually agreed terms.[60] Such terms, to be set out in writing, may include a dispute settlement clause and terms on monetary and nonmonetary benefit sharing, as well as on subsequent third-party use. Monetary and nonmonetary benefits are listed in the Annex and are directly inspired by the Bonn Guidelines.[61] Accordingly, parties shall encourage the development, update, and use of model contractual clauses for mutually agreed terms, as well as the draft of codes of conduct and best practice standards in relation to access and benefit-sharing, in consultation with users and providers from key sectors.[62] The Protocol likewise provides that parties shall take measures to monitor the utilization of genetic resources, for instance, by establishing checkpoints and disclosure requirements.[63]

Finally, the Nagoya Protocol addresses the specific cases in which access and benefit-sharing of genetic resources occur in transboundary situations or in situations in which it is not possible to grant or obtain prior informed consent. This is done through the Protocol's provision that establishes a Global Multilateral Benefit-Sharing Mechanism.[64] The parties agree to further develop its functional modalities according to their needs. Additionally, with regard to benefits, the Protocol states that benefits arising from the utilization of resources shall be used to support the conservation of biological diversity and the sustainable use of its components globally.

Thus the Nagoya Protocol appears to represent a workable solution for the management of MGRs. Indeed, the Protocol pursues the same legal objectives as the Bonn Guidelines—the fulfillment of the prior and informed consent and of the fair and equitable benefit sharing obligations—but may prove more effective. The Protocol is binding and provides for some solutions that are particularly suitable for MGRs, such as the creation of a Global Multilateral Benefit-Sharing

[59] *Id.* art. 17.4.
[60] *Id.* art. 5, art. 6.3(g), art. 18.
[61] *Id*. Annex.
[62] *Id.* arts. 19–20.
[63] *Id.* art. 17.
[64] *Id.* art. 10.

Mechanism and the issuance of internationally recognized certificates. Should the former be effectively implemented, it could guarantee the conservation of biological diversity and the equitable sharing of benefits, while overcoming some of the specific difficulties of MGRs' management. Finally, should a specific international body ultimately enjoy the competence to authorize access to and commercial exploitation of MGRs, the issuance of international recognized certificates would certainly contribute to guaranteeing their correct administration and to avoiding abuses.

iii. MGRs and the Possibility of a "Disclosure of Origin" Clause

According to the Doha Ministerial Declaration, the TRIPS Council is called upon to "examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity," as well as to review the TRIPS relevant provisions.[65] Negotiations are still underway since the topic gives rise to strong debates between developed and developing countries.[66] Up to now, the main outcome of such negotiations is a proposition to insert a "disclosure of origin clause" within the TRIPS. Such a provision should have the effect of ensuring the respect of the CBD's obligations at the moment of filing a patent application on inventions based on genetic resources detained by

[65] World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/1, 41 I.L.M. (2002) 746 (hereinafter Doha Declaration), para. 19.

[66] The positions endorsed by the Member states, as well as the relevant documents filed, are available at the WTO website, www.wto.org. A summary of these positions is also provided by the Council for Trade-Related Aspects of Intellectual Property Rights, *Note by the Secretariat: The Relationship between the TRIPs Agreement and the Convention on Biological Diversity*, IP/C/W/368/Rev.1 (Feb. 8, 2006) (hereinafter *TRIPs Agreement & Biological Diversity Convention*], *available at* http://www.wto.org/english/tratop_e/trips_e/ipcw368_e.pdf. On the negotiation see Council for Trade-Related Aspects of Intellectual Property Rights, *Minutes of the Meeting, 8–9 June 2010*, IP/C/M/63 (Oct. 4, 2010); General Council Trade Negotiations Comm., *Report on the 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 those Related to the Relationship Between the TRIPs Agreement and the Convention on Biological Diversity*, WT/GC/W/633 (Apr. 21, 2011) [hereinafter *Report on the Extension of the Protection of Geographical Indications*].

provider countries.[67] However, as we will see below, negotiations are still ongoing and show certain unpredictability with regard to the formulation and the actual insertion of the clause.

Starting with the beginning of the Doha Round in 2001 up to the 2011 consultations some member states, such as the United States and Japan, have maintained that no conflict exists between CBD and TRIPS, implying that the contractual approach provided in the CBD is a means to its own end.[68] Others, in particular developing countries, pushed in favour of amending the TRIPS, in order to insert a disclosure of origin clause. As we will see, some other WTO member countries have since significantly modified their positions. Among them, the European Union, who originally claimed that the topics should be dealt with outside the ambit of patent law (i.e. in civil or administrative law), and Switzerland, who supported the insertion of a disclosure of origin clause in the Patent Cooperation Treaty,[69] out of the WTO forum.[70]

After long debates, in July 2008, a group of fifty-two member states, composed mostly of developing countries, such as the African, Caribbean and Pacific Group (ACP Group), India, Brazil, Peru, as well as China, South Africa, and the African Group, joined together with Switzerland and the European Union to agree on a common "Draft Modalities Text" ("DMT").[71] The sponsoring states proposed to amend TRIPS through the insertion in the text of a mandatory disclosure of origin requirement.[72] According to the DMT, in order to comply with

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[67] On the insertion of a disclosure of origin clause, see G. DUTFIELD, *Sharing the Benefits of Biodiversity: Is there a Role for the Patent System?*, *in* G. SAMPSON, J. WHALLEY (eds.), *The WTO, Trade, and the Environment*, Cheltenham, 2005, 511; M. A. GIRSBERGER, *Transparency Measures under Patent Law regarding Genetic Resources and Traditional Knowledge: Disclosure of Source and Evidence of Prior Informed Consent and Benefit-Sharing*, 7 *Journal of World Intellectual Prop*erty (2004) 451; M. I. JEFFERY, *Intellectual Property Rights and Biodiversity Conservation: Reconciling the Incompatibilities of the TRIPS Agreement and the Convention on Biological Diversity*, *in* B. ONG (ed.), *Intellectual Property and Biological Resources*, cit., at 186–87; *see generally* J. DE WERRA, *Fighting Against Biopiracy: Does the Obligation to Disclose in Patent Applications Truly Help?*, 42 *Vanderbilt Journal of Transnational L*aw (2009) 143, 146–50.

[68] *See TRIPs Agreement & Biological Diversity Convention*, *supra* note 66.

[69] Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7654, 1160 U.N.T.S. 1979.

[70] *See TRIPs Agreement & Biological Diversity Convention*, *supra* note 66.

[71] Trade Negotiations Comm., *Draft Modalities for TRIPs Related Issues*, TN/C/W/52 (July 19, 2008) [hereinafter *DMT*].

[72] *Id.* According to paragraph 4 of the *DMT*, "Members agree to amend the TRIPS Agreement to include a mandatory requirement for the disclosure of the country

the latter requirement, either the provider country or the source of the genetic resources shall be disclosed in patent applications.

The insertion of the fourth mandatory requirement for patentability (additional to the novelty, inventive step, and industrial application requirements) into TRIPS would guarantee that patents would be released only for inventions complying with the principles set by the CBD. Therefore, DMT would represent a very desirable compromise between developing countries and some developed states.[73] However, due to the vagueness of DMT, the following consultations "have not created convergence [but] have certainly shed light on the divergences."[74] Member states have been debating four main points concerning not only the legal character of misappropriation, administrative costs, and burdens connected with the introduction of the disclosure of origin clause, but also the adequacy of alternative measures. Additionally, debates include the legal character and enforcement possibilities of a national based approach.[75] Each of the debated points is crucial for patents on MGRs. The debate has not yet been settled and the situation has not yet concretely evolved after the adoption of the Nagoya Protocol.[76] Even if the outcome can hardly be predicted, it is uncertain that a definite, precise, and adequate compromise on a disclosure of origin clause can be reached, one that would be capable of guaranteeing the enforcement of the prior and informed consent as well as the fair and equitable sharing of benefit. However, in the unlikely event that such an outcome be reached, it could be very useful for the management of MGRs.

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providing/source of genetic resources, and/or associated traditional knowledge for which a definition will be agreed, in patent applications. Patent applications will not be processed without completion of the disclosure requirement."

[73] It is worth noting that, notwithstanding the wide participation to *DMT*, the compromise is not supported by the United States and Japan.

[74] Pascal Lamy, Dir.–Gen., Trade Negotiations Comm., Opening Statement at Committee Meeting (Mar. 22, 2010), *available at* www.wto.org/english/news_e/news10_e/tnc_dg_stat_22mar10_e.htm.

[75] *See Report on the Extension of the Protection of Geographical Indications*, *supra* note 66.

[76] *Nagoya Gives New Context to Old Views in Intellectual Property Council*, WORLD TRADE ORG. (Mar. 1, 2011), http://www.wto.org/english/news_e/news11_e/trip_01mar11_e.htm.

iv. MGRs and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture Model

The last workable model for MGRs' management to examine is the International Treaty on Plant Genetic Resources for Food and Agriculture ("ITPGRFA").[77] It pursues the same objectives as the CBD, even if its field of application *ratione materiae* is narrower, i.e. only plant genetic resources for food and agriculture (art. 1.1 ITPGRFA).

The treaty establishes the Multilateral System, set forth in Article 10, which aims at facilitating access to genetic resources and providing for the fair and equitable sharing of the benefits arising from their use. Pursuant to Article 12.3(d), genetic materials can be accessed by legal and natural persons only through the Multilateral System. Access is provided for the purpose of utilization and conservation for research, breeding, and training for food and agriculture, so long as the use does not include chemical, pharmaceutical, and/or other nonfood/feed industrial uses. Recipients cannot claim any intellectual property or other rights that limit access to the resources from the Multilateral System, or their genetic parts or components.

[77] International Treaty on Plant Genetic Resources for Food and Agriculture, Nov. 3, 2001, 2400 U.N.T.S. 303 [hereinafter ITPGRFA]. The ITPGRFA's contracting parties number 123; neither Japan nor the United States have ratified it, even though the United States is a signatory as of 2002. For more information on the ITPGRFA, see W. B. CHAMBERS, *Emerging International Rules on the Commercialization of Genetic Resources*, cit.; see also C. M. CORREA, *The Access Regime and the Implementation of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture in the Andean Group Countries*, 6 *Journal of World Intellectual Property* (2003) 795; L. CREMA, *Draft Procedures and Operational Mechanisms to Promote Compliance and to Address Issues of Non-Compliance under the 2001 International Treaty on Plant and Genetic Resources for Food and Agriculture*, *in* T. TREVES ET AL. (eds.), *Non-compliance Procedures and Mechanisms and the Effectiveness of International Environmental Agreements*, 2009, 137, 137–52; C. FRISON, T. DEDEURWAERDERE, M. HALEWOOD, *Intellectual Property and Facilitated Access to Genetic Resources under the International Treaty on Plant Genetic Resources for Food and Agriculture*, 32 *Eur. Intell. Prop. Rev.* (2010) 1; C. GERSTETTER et al., *The International Treaty on Plant Genetic Resources for Food and Agriculture within the Current Legal Regime Complex on Plant Genetic Resources*, 10 *Journal of World Intellectual Property* (2007) 259; M. LIGHTBOURNE, *The FAO Multilateral System for Plant Genetic Resources for Food and Agriculture: Better than Bilateralism?*, 30 *Washington University Journal of Law & Policy* (2009) 465, 467–71; R. PAVONI, *Accesso alle risorse fitogenetiche e diritti di proprietà intellettuale dopo il trattato della FAO del 2001*, 58 *La comunità internazionale* (2003) 369.

Pursuant to Article 12.4, access to genetic resources and benefit sharing shall be governed by agreements entered into by the interested legal or natural persons, acting as providers and recipients, in accordance with the Standard Material Transfer Agreement ("SMTA").[78] The content of the SMTA complies with the ITPGRFA's relevant provisions. SMTA states that, if the recipient commercializes a product incorporating genetic resources covered by the Multilateral System, he/she shall pay a fixed percentage of the sales into the mechanism established by the Governing Body for this purpose (the Trust Fund, or Trust Account),[79] or according to alternative payment scheme defined within the SMTA.[80] Finally, articles 13 ITPGRFA and 6.9 SMTA additionally provide that the recipient shall make all nonconfidential information that results from research and development carried out on the resources supplied available to the Multilateral System, shall share nonmonetary benefits that result from such research and development, and shall facilitate access to technologies for conservation and use of genetic resources.

Therefore, the ITPGRFA provides a workable model for MGRs and a useful compromise for the drafting of a specific legal regime.[81]

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[78] Such an agreement was adopted by the Governing Body, with Resolution 1/2006 of 16 June 2006. Governing Body of the Int'l Treaty on Plant Genetic Res. for Food & Agric., Res.1/2006, U.N. Doc. IT/GB-1/06/Report App. G (2006), *available at* ftp://ftp.fao.org/ag/agp/planttreaty/agreements/smta/SMTAe.pdf [hereinafter SMTA], *See* C. CHIAROLLA, *Plant Patenting, Benefit Sharing and the Law Applicable to the Food and Agriculture Organisation Standard Material Transfer Agreement*, 11 *J. World Intell. Prop.* (2008) 1; C. LAWSON, *Intellectual Property and the Material Transfer Agreement under the International Treaty on Plant Genetic Resources for Food and Agriculture*, 31 *European Intellectual Property Rev*iew (2009) 244–45.

[79] ITPGRFA, *supra* note 77, art. 19, para. 3(f), art. 6, para. 7, art. 6, para. 8; SMTA, *supra* note 78, annex 2.

[80] SMTA, *supra* note 78, art. 6.11, annexes 3–4.

[81] According to the concluding remarks presented by the co-chairpersons of Informal Working Group, "practical measures to address the conservation and sustainable use of marine genetic resources in areas beyond national jurisdiction should be studied, without prejudice to ongoing discussions on their relevant legal regime." 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, Remarks transmitted by letter dated May 15, 2008 from Co-Chairpersons appointed pursuant to resolution 62/215 (2007) to the President of the General Assembly, paras 39, 54(e), U.N. Doc. A/63/79 (May 16, 2008). To this extent, a proposal had been endorsed also by the European Union and its member states, noting that "it is important to take note of the Multilateral System established by the International Treaty on Plant Genetic Resources for Food and Agriculture." U.N.

The obligations established by the ITPGRFA, if applied with the necessary adjustments to MGRs, would guarantee that the prior and informed consent and the fair and equitable benefit sharing obligations are enforced. Firstly, creating a centralized system, such as the Multilateral System, appointed with the task of overseeing the access to MGRs and the equitable sharing of the benefits arising from the commercialization of the products based on them, would guarantee that equitable outcomes are reached. In contrast to the mutually agreed terms required by the CBD, the content of which is left to the discretion of the parties, the standardization of the material transfer agreements and their negotiations under competent authorities' supervision, such as the Governing Body, would ensure that equitable results are obtained (art. 12.4 ITPGRFA). Secondly, following the position of those who propose that "the benefits associated with the exploitation of genetic resources of the deep sea could be shared by establishing a form of trust fund from royalties or other fees collected from developers of biotechnology derived from hydrothermal vents on the high seas,"[82] a "trust fund" for payments received could be instituted as a means for guaranteeing the enforcement of the benefit sharing obligation.

B. Institutional Solutions

i. Attributing a Primary Role to the International Seabed Authority (ISA)

The legal solutions call for an institutional mechanism that has competence over the MGRs in areas beyond national jurisdiction and that can take the role of "national state" for application of CBD principles and to the eventual entry into force of the Nagoya Protocol.

Working Group, *EU Intervention on Agenda Item 5.g*, *supra* note 49, at 2. The point is dealt with also by the "Report on Oceans and Law of the Sea," which extensively describes the FAO Treaty's objectives and obligations. *See Oceans and the Law of the Sea*, *supra* note 4, paras 112–13.

[82] D. LEARY, *International Law & Deep Sea* cit., at 176.

Some suggest that the ISA should be the governing international body for MGRs.[83]

Due to the fact that the commercial value of MGRs was unknown by LOSC negotiators and that in 1970 the U.N. General Assembly declared the Area common heritage of mankind beyond its mineral resources, MGRs can thus fall within the common heritage regime.[84] This "dynamic" interpretation of the LOSC would be in conformity with the principles embodied in the preamble of the convention. However, as demonstrated above, the common heritage regime provided by Part XI applies only to MGRs located on the soil of the Area; the MGRs located in the water column cannot come within such legal framework. This distinction leads to a confusion when attempting to create a comprehensive legal regime because, firstly, the distinction between MGRs on the floor or in the subsoil of the Area and those in the water column is not easy, and secondly, retaining the differentiation based on location would created a fragmented legal regime rather than a unique regime addressing MGRs in their entirety.

To address this complication, an amendment that would support a dynamic interpretation of LOSC text as far as the mandate of the ISA is concerned has been suggested.[85] As it stands, the composition of the ISA is oriented towards the mineral industry.[86] A change in the ISA's makeup has to be decided either by amendment or through a second agreement for the implementation of Part XI.[87] This would demand an unlikely diplomatic effort in light of the contrasting positions supported by LOSC states parties and the above mentioned doctrinal debates on MGRs' legal status. Moreover, such a solution would also exclude states that are not parties to the LOSC, but who still have an interest in MGRs. Conversely, it might induce non-parties to ratify the convention. In terms of institutional economics, this solution is

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[83] L. A. DE LA FAYETTE, *Institutional Arrangements for the Legal Regime Governing Areas Beyond National Jurisdiction – Commentary on Tullio Scovazzi*, in E. J. MOLENAAR, A. G. OUDE ELFERINK (eds.), *The International Legal Regime*, at 79.

[84] *Ibid.*

[85] "Nothing prevents States from expanding the mining focus of the ISA and granting to it some broader management competences within the Area." See T. SCOVAZZI, *Seabed Beyond the Limits of National Jurisdiction* cit., at 59.

[86] T. TREVES, *Principles and Objectives* cit., at 13–14.

[87] See Agreement relating to the Implementation of Part XI of the United Nations Convention on the Law of the Sea of 10 December 1982, adopted on 28 July 1994, 1896 U.N.T.S. 41 (140 LOSC states parties are also parties to this Agreement).

interesting because it builds on an existing system and an existing structure.

However, the ISA is not party to the CBD and cannot become one; according to Article 34 CBD, only states and regional economic integration organizations can become parties. For the time being, it is the only existing body having some jurisdiction in the field of MGRs and, in particular, it has the right and duty to "adopt appropriate rules, regulations and procedures for *inter alia* (…) the protection and conservation of the natural resources of the Area and the prevention of damage to the flora and fauna of the marine environment" (art. 145 LOSC). However, the ISA is called upon to play a role in assessing the environmental impact of activities and processes only in the Area, and as such, the water column still remains outside its authority.

Nevertheless, mining activities may have an impact on ecosystems in the Area and thus on MGRs.[88] Stakeholders interested in the exploitation of such resources (both states and private actors) should support the involvement of the ISA in the concrete management of the MGRs, which by default implies its involvement in the broader debate.[89] The ISA, with its competences and co-operative role,[90] should be one of the institutions called upon to manage the exploitation of MGRs. Problems of coordination between international institutions may still arise because of possible overlaps of control. The Nagoya Protocol offers a suitable, even if weak, solution, in stating that "[d]ue regard should be paid to useful and relevant ongoing work or practices under [*other international instruments relevant to this Protocol*] and relevant *international organizations*" (art. 4.3). For creating and implementing a Global Multilateral Benefit-Sharing Mechanism for MGRs, parties would have to take into consideration the work and practices of the ISA (art. 10).

Some more problems may however come up when not all the parties to one agreement (for instance a future agreement on MGRs) are parties to other agreements (including CBD, LOSC, or TRIPS). An

[88] T. SCOVAZZI, *Mining, Protection of the Environment, Scientific Research and Bioprospecting: Some Considerations on the Role of the International Sea-Bed Authority*, 19 *International Journal of Marine and Coastal Law* (2004) 383.

[89] N. MATZ-LÜCK, *The Concept of the Common Heritage of Mankind* cit., at 72; T. SCOVAZZI, *Mining, Protection of the Environment* cit., at 399–407.

[90] T. SCOVAZZI, *Mining, Protection of the Environment* cit., at 407–08.

inter-systemic approach and a systemic interpretation of the relevant provisions might then be the solution.

ii. Implementation Agreements or Management Convention Alternatives

Two alternative options exist in which the ISA is part of the debate but not "the one and only" for the management of MGRs. Firstly, states could adopt an implementation agreement, following the example of the 1995 United Nations Agreement for the Implementation of the Provisions of the United Nations Convention on the Law of the Sea of December 10, 1982, relating to the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks ("Straddling Stocks Agreement").[91] A second option would be the adoption of an ad hoc convention for the management and the protection of MGRs in areas beyond national jurisdiction. Both solutions are supported by the Nagoya Protocol which asks future parties to consider "the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources (…) for which it is not possible to grant or obtain prior informed consent" (art. 10). A specialized instrument might contain such a mechanism and would likewise be consistent with the Nagoya Protocol (art. 4.2-4).

(a) The Possibility of an Implementation Agreement

Some authors suggest studying the Area regime and the Straddling Stocks Agreement in parallel, in order to delineate a feasible and viable regime for MGRs in areas beyond national jurisdiction.[92]

[91] United Nations Agreement for the Implementation of the Provisions of the United Nations Convention on the Law of the Sea of December 10, 1982, relating to the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks, opened for signature Dec. 4, 1995, 2167 U.N.T.S. 3 (entered into force 11 December 2001) [hereinafter Straddling Stocks Agreement]. Seventy-seven LOSC parties have also ratified party of the Straddling Stocks Agreement. See Chronological Lists of Ratifications of, Accessions and Successions to the Convention and the Related Agreements, available at: www.un.org/depts/los/.

[92] T. TREVES, *Principles and Objectives* cit., at 13–15.

Both regimes are *leges speciales* in respect to the high seas general regime in the sense that the latter does not apply when the former does. Moreover, they both deal with the management, protection, and exploitation of natural resources and both create systems of control based on international institutions. However, the Straddling Stocks Agreement relies on sub-regional and regional organizations differing from the Area centralized system.

Considering that MGRs are renewable resources, and that their variety might be better protected at a regional or sub-regional level, the Straddling Stocks Agreement option is of some interests. It presents a pragmatic solution as it depends on regional organizations, and would hopefully guarantee an effective protection due to the proximity of the competent organ with both the MGRs and the state or private actor interested in their exploitation. This option can also have lower costs for coastal states of regional seas where governance bodies already exist. This is perfectly in line with Recommendation XI/8 of the SBSTTA,[93] which:

> *urges* Parties and other States to cooperate within *the relevant international and/or regional organizations* in order to promote the conservation, management and sustainable use of marine biodiversity in areas beyond national jurisdiction, including deep seabed genetic resources (para. 4.f – emphasis added).

Presumably, this solution would also promote a direct involvement of the industry and private actors that operate in the considered regional area. Consequently, this solution could better promote the particular interests of a region.

However, some drawbacks of such a decentralized system persist. In particular, protection regimes could become unduly fragmented. Compliance with and enforcement of international obligations would be entrusted to a regional or sub-regional body through the conclusion of an agreement by the interested states. The powers given to this body can vary in strength and the means allocated likewise can vary in efficiency for guaranteeing the protection of MGRs. This possible fragmentation of protection could undermine the

[93] SBSTTA, *Recommendation XI/8* cit. Part of the role of the SBSTTA as an advisory board is to provide the Conference of the Parties of the CBD and its other subsidiary bodies with timely advice relating to the implementation of the Convention in the form of recommendations.

"common" dimension of MGRs management and exploitation in areas beyond national jurisdiction.

(b) Creating a Convention for the Management and Protection of MGRs

Another possibility is the creation of a unified regime for MGRs beyond national borders by an ad hoc agreement that regulates all the relevant aspects (protection, management, and exploitation). This agreement would also create an institution, such as an international organization, to take charge of enforcement. This new agreement would be a sort of "CBD for MGRs." It would complement the actual CBD and LOSC by providing a unique regime for MGRs, independent of their location in the water column or on the Area, and by guaranteeing machinery similar to the ISA but open to representation by other interests.

The creation of a centralized body by the ad hoc agreement would establish an ISA in charge of granting access to and managing the benefit-sharing among states and private actors interested in activities beyond national jurisdiction. This new institution could be a Multilateral System for MGRs, inspired by the FAO example mentioned above. The main difference with the FAO Multilateral System would be that this new institution would also be party to agreements regulating the activities concluded with states party or private investors. Thus, all contracts should have a "public" dimension in the interest of including the participation of this institution. Accordingly, the new machinery should be closer to the Area regime than the FAO Multilateral System concerning the contractual aspects.

The creation of a centralized body has the advantage of guaranteeing uniform protection and uniform standards for the exploitation of MGRs. In theory, it would guarantee a "common" management of the MGRs, less influenced by particular or regional interests. The establishment of such an institution and machinery would, however, come at an economical cost for state parties. The conclusion of such an agreement would be reached only after a determination of the commercial worth of biotech products deriving from MGRs. Only then is it likely that states would be keen to regulate

their protection and management, to determine their legal status and common use.

It is also necessary to consider that this agreement would be situated in an already crowded legal environment; its links and relationships with the other instruments would have to be discussed and regulated. In particular, it would be useful to create links with the CBD, LOSC, and TRIPS, to create "legal gateways" between the texts (compatibility clauses and, eventually, recalls of the existing agreements in the new one) and links between the regimes. The latter suggestion could consist, for example, of a system for the exchange of information and data between the technical organs of each regime or in a mechanism for the participation of technical organs of one regime in the meeting of the others.

4. Concluding remarks

The first part demonstrates how several legal instruments overlap when it comes to the governance of MGRs. While they stand in a relationship of interdependence, also of complementarity and mutual support, they manage MGRs inadequately and inefficiently. That is the reason why an ad hoc regime for the management and exploitation of MGRs should be adopted.

To the extent that MGRs are considered to be global commons (if not part of the common heritage of mankind) ethical and moral concerns cannot be left out and ought to be taken into consideration in the creation of a regulatory framework for MGRs and their exploitation.[94] As it stands, the law of the sea plays the role of "equalizer" among maritime nations of the world.[95] LOSC specifically creates mechanisms for balancing interests and sometimes redistributing benefits deriving from maritime economic activities.[96]

[94] Leary, on the contrary, prefers to leave the debate behind, fearing the delay in the creation of a new legal regime by focusing on pointless debates. See D. LEARY, *International Law & Deep Sea* cit., at 100.

[95] J. L. BATONGBACAL, *The Law of the Sea, Marine Technology and Global Social Justice*, in A. CHIRCOP ET AL. (eds.), *The Future of Ocean Regime-Building, Essays in Tribute to Douglas M. Johnston*, Leiden, 2009, at 116.

[96] See also arts. 87, 124–91 LOSC on the freedoms of the high seas, the right of access of land-locked states to and from the sea and freedom of transit, the regime of the Area.

Therefore, any future legal regime for MGRs cannot ignore the role of the law of the sea.

Each solution explored above brings with it useful features for putting together the future regime. One main conclusion can be drawn: a compromise between IPRs' protection and MGRs' management can only be realized via a new instrument, either a protocol or an annex to an existing instrument, or an ad hoc agreement, creating an institutional machinery for guaranteeing prior and informed access to MGRs and the fair and equitable benefit sharing. It might in the end indeed be suitable to have a "common heritage without mentioning it".[97]

[97] T. TREVES, *Principles and Objectives* cit., at 23.