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TRIPS ON THE HIGH SEAS: INTELLECTUAL PROPERTY RIGHTS ON MARINE GENETIC RESOURCES

*Angelica Bonfanti** & *Seline Trevisanut***

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INTRODUCTION

Exploration and collection of marine genetic resources (“MGRs”) has led to the identification of more than 15,000 molecules.¹ As a result of these discoveries, the number of international claims for marine gene patents deposited between 1991 and 2009 reached 677, and dozens of products based on deep-sea organisms have been patented.² With 95% of marine gene patent claims filed after 2000, the growth of the field can be considered a recent phenomenon.³

Deep-sea marine organisms (bacteria, animals, plants, seaweeds, etc.) live in particular environments that do not have a close equivalent in terrestrial ecosystems. These organisms can resist, for example, high pressure, elevated temperature, and the absence of sunlight.⁴ Due to such unique characteristics, MGRs deriving from such organisms 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, antibiotic, anti-cancer, antituberculosis, and antimalarial uses.⁵ Major pharmaceutical firms, including Merck, Lilly, Pfizer, Hoffman-Laroche, and Bristol-Myers Squibb, have marine biology departments.⁶ At least nine companies are currently involved in research and development of biotechnology on MGRs.⁷ 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 2007.⁸ According to the results of International Census

1. Kirsten 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 LOY. U. CHI. INT'L L. REV. 151, 152 (2008) (citing U.N. Secretary-General, *Oceans and the Law of the Sea: Rep of the Secretary-General*, ¶ 127, U.N. Doc. A/62/66 (Mar. 12, 2007)).

2. Sophie Arnaud-Haond, Jesús M. Arrieta, & Carlos M. Duarte, *Global Genetic Resources: Marine Biodiversity and Gene Patents*, 331 SCIENCE 1521, 1521 (Mar. 25, 2011).

3. *Id.*

4. Sergio Beslier, *The Protection and Sustainable Exploitation of Genetic Resources of the High Seas from the European Union's Perspective*, 24 INT'L J. MARINE & COASTAL L. 335 (2009).

5. Fernando de la Calle, *Marine Genetic Resources: A Source of New Drugs: The Experience of the Biotechnology Sector*, 24 INT'L J. MARINE & COASTAL L. 209 (2009).

6. Zewers, *supra* note 1, at 156–58.

7. *Resources*, MARINEBIOTECH.ORG, <http://www.marinebiotech.org/links.html> (last visited Oct. 22, 2011).

8. Douglas Westwood Ltd., *Marine Industries Global Market Analysis*, 1 MARINE FORESIGHT SERIES 117 (2005), available at http://www.marine.ie/NR/rdonlyres/B66FBE34-3859-4FA8-9ABF-8C8558CDB15E/0/ForesightSeries1_global_market_analysis.pdf.

of Marine Microbes, “the value of the ecosystem services provided by coral reefs is estimated at more than \$5 million per square kilometer per year, in terms of revenues from genetic material and bioprospecting.”⁹ Bioprospecting refers to the “scientific investigation of living organisms for commercially valuable genetic and biochemical resources”¹⁰ and includes the research, collection, and utilization of biological and genetic resources with the aim of applying the derived knowledge for scientific and/or commercial purposes.¹¹

Despite the field’s growth, claims associated with marine genes have so far originated from only thirty-one countries in the world, and 90% of the deposited patents arise only from ten countries, with 70% from the United States, Germany, and Japan.¹² This is because scientific research related to deep seabed and high seas genetic resources is restricted to those few operators who have the necessary technological capacity and financial resources. Up to now, few countries have produced the necessary capital, technology, and scientific expertise to obtain MGRs. Due to the high costs involved, developed countries enjoy an effective monopoly on the necessary elements for research, and subsequently on the MGRs that they collect.¹³

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

9. U.N. Secretary-General, *Oceans and the Law of the Sea: Rep of the Secretary-General*, ¶ 61, U.N. Doc. A/62/66 (Mar. 12, 2007) [hereinafter U.N. Secretary-General, *Oceans Rep.*]. 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, <http://www.coml.org> (last visited Oct. 1, 2011).

10. Louise A. de La Fayette, *A New Regime for the Conservation and Sustainable Use of Marine Biodiversity and Genetic Resources Beyond the Limits of National Jurisdiction*, 24 INT’L J. MARINE & COASTAL L. 221, 228 (2009); Andree Kirchner, *Bioprospecting, Marine Scientific Research and the Patentability of Genetic Resources*, in SERVING THE RULE OF INTERNATIONAL MARITIME LAW: ESSAYS IN HONOUR OF PROFESSOR DAVID JOSEPH ATTARD 119 (Norman A. Martínez Gutiérrez ed., 2010).

11. K. TEN KATE & S.A. LAIRD, THE COMMERCIAL USE OF BIODIVERSITY 19 (1999).

12. Arnaud-Haond et al., *supra* note 2, at 1521.

13. SALVATORE ARICO & CHARLOTTE SALPIN, BIOPROSPECTING OF GENETIC RESOURCES IN THE DEEP SEABED: SCIENTIFIC, LEGAL AND POLICY ASPECTS 15 (U.N. Univ. & Inst. of Advanced Studies 2005), available at <http://www.ias.unu.edu/binaries2/DeepSeabed.pdf>; David Leary, *International Law and Genetic Resources of the Deep Sea*, in LAW, TECHNOLOGY AND SCIENCE FOR OCEANS IN GLOBALISATION 353 (Davor Vidas ed., 2010); de La Fayette, *supra* note 10, at 277.

Nations Convention on the Law of the Sea ("UNCLOS"),¹⁴ the Convention on Biological Diversity ("CBD"),¹⁵ and the Trade Related Intellectual Property Rights Agreement ("TRIPS").¹⁶ As a preliminary remark, it must be highlighted that while UNCLOS does not specifically address MGRs, it does provide that the deep seabed, as it lies beyond national jurisdiction, is subject to the common heritage of mankind regime,¹⁷ managed by the International Seabed Authority ("the Authority").¹⁸ However, the water column beyond national jurisdiction is part of the high seas regime and subject to the freedoms of the high seas, e.g., *inter alia* the freedoms of navigation and of scientific research.¹⁹ There is considerable disagreement as to whether MGRs are or should be included in the Authority's jurisdiction and whether they come under the "common heritage of mankind" regime.

Even if MGRs are not directly part of the common heritage regime, 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.

It stands to question whether the existing international regulation of intellectual property rights ("IPRs"), specifically patents, as set out by TRIPS, is compatible with these two principles and, more generally, with the complex legal regime of MGRs. According to TRIPS, the grant of patents is conditioned on technical requirements, none of which concern the prior and informed consent to access and the fair and equitable sharing of benefits. Given this lack of consistency between legal regimes, the World Trade Organization's ("WTO") Doha Ministerial Declaration charged the TRIPS Council with the task of examining the relationship

14. United Nations Convention on the Law of the Sea, *opened for signature* Dec. 10, 1982, 1833 U.N.T.S. 397 (entered into force Nov. 16, 1994) [hereinafter UNCLOS].

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

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

17. UNCLOS, *supra* note 14, art. 136.

18. *Id.* art. 137, ¶ 2.

19. *Id.* art. 87.

between TRIPS and the CBD.²⁰ A group of fifty-two WTO members seemed to have reached a compromise in July 2008 when it agreed to implement a “disclosure of origin clause,” i.e., the grant of a patent conditioned on disclosure of the source of the material upon which the invention is based, as a requirement for patent application.²¹ Such an amendment would have important implications on MGRs exploitation, since the grant of patents would be subject to the CBD principles, which are, in our view, jointly with UNCLOS ones, the principles framing the MGRs legal regime. However, the amendment’s current feasibility is definitively uncertain, due to the subsequent regression in the negotiations.

In view of these three overlapping legal regimes, any attempt at regulating the management and the exploitation of MGRs stands within the wider debate on the fragmentation of international law.²² This Article 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 interdependent relationship between UNCLOS, the CBD, and 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.²³

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

21. Trade Negotiations Comm., *Draft Modalities for TRIPS Related Issues*, T/NC/W52 (July 18, 2008).

22. On this topic, see also Int’l Law Comm’n, *Fragmentation of International Law*, U.N. Doc. A/CN.4/L.682 (Apr. 13, 2006); Eyal Benvenisti & George W. Downs, *The Empire’s New Clothes: Political Economy and the Fragmentation of International Law*, 60 STAN. L. REV. 595 (2007); Benedetto Conforti, *Unité et fragmentation du droit international: “glissez, mortels, n’appuyez pas!”* [Unity and Fragmentation of International Law: “Thus Lightly Touch and Quickly Go!”], 111 REVUE GÉNÉRALE DE DROIT INTERNATIONAL PUBLIC 5 (2007) (Fr.); Andreas Fischer-Lescano & Gunther Teubner, *Regime-Collisions: The Vain Search for Legal Unity in the Fragmentation of Global Law*, 25 MICH. J. INT’L L. 999 (2004); Duncan French, *Treaty Interpretation and the Incorporation of Extraneous Legal Rules*, 55 INT’L & COMP. L.Q. 300 (2006). See generally Symposium, *Post-ILC Debate on Fragmentation of International Law*, 17 FINNISH Y.B. INT’L L. (2006); Tullio Treves, *Fragmentation of International Law: the Judicial Perspective*, 23 COMUNICAZIONI E STUDI 821 (2007).

23. On the interdependence and theoretical debates of legal regimes, see generally Lorenzo Gradoni, *Systèmes juridiques internationaux: une esquisse* [International Legal Systems: A Sketch], in LA CIRCULATION DES CONCEPTS JURIDIQUES: LE DROIT INTERNATIONAL DE L’ENVIRONNEMENT ENTRE MONDIALISATION ET FRAGMENTATION 27 (Hélène Ruiz Fabri & Lorenzo Gradoni eds., 2009) (Fr.); Bruno Simma, *Self-Contained Regimes*, 16 NETH. Y.B. INT’L L. 111 (1985); Bruno Simma & Dirk Pyulkowski, *Of*

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. It analyzes (A) the legal status of MGRs in the light of UNCLOS, (B) the patentability of inventions derived from MGRs in the light of TRIPS, and (C) MGRs' access and commercial exploitation in the light of the CBD. It concludes that existing instruments, if considered and applied in isolation, are incomplete and inefficient to deal with MGRs. 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.

I. A LEGAL REGIME FOR MGRS: FRAGMENTATION AND COORDINATION BETWEEN EXISTING REGIMES

A. The Applicability and Limitations of UNCLOS

UNCLOS was adopted by the Third United Nations Conference on the Law of the Sea on December 10, 1982, and entered into force on November 16, 1994.²⁴ Currently, 161 states are party to UNCLOS. Considered the "Constitution for the oceans," UNCLOS, as declared by the U.N. General Assembly and repeatedly confirmed by states, "sets out the legal framework within which all activities in the oceans and seas must be carried out."²⁵ Thus, it is imperative to identify where MGRs fall under UNCLOS provisions, considering the related context and subsequent practice.²⁶

UNCLOS does not contain any provision explicitly regulating MGRs and it does not use the expression "area beyond national jurisdiction."²⁷ 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 this Part [Part VII

Planets and the Universe: Self-Contained Regimes in International Law, 17 EUR. J. INT'L L. 483 (2006).

24. UNCLOS, *supra* note 14.

25. See Oceans and the Law of the Sea, G.A. Res. 62/215, U.N. Doc. A./RES/62/215 (Dec. 22, 2008).

26. Treaties are "living instruments." See Rep. of the Int'l Law Comm'n, 60th Sess., May 5–June 6, July 7–Aug. 8, 2008, U.N. Doc. A/63/10; GAOR, 63d Sess., Supp. No. 10, Annex A, at 365 (2008).

27. See generally UNCLOS, *supra* note 14.

High Seas] apply to 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.”²⁸ High seas are the water column not included in areas submitted to coastal states’ jurisdiction²⁹ and superjacent the Area of the deep seabed and, eventually, the continental shelf.³⁰ The floor and the subsoil of the areas beyond national jurisdiction fall under the Area³¹ regulated by Part XI of UNCLOS.³² This distinction creates one of the elemental problems when applying UNCLOS 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 that 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.”³³ 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 1967.³⁴ 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.”³⁵ In those years, the optimism concerning technological developments fuelled the rise of a regime promoting a New International Economic Order³⁶ (which conveys

28. *Id.* art. 86 (emphasis added).

29. *Id.*

30. *Id.* art. 76, ¶ 1.

31. The Area is considered the floor and the subsoil of areas beyond national jurisdiction. *Id.* art. 1, ¶ 1.

32. *Id.* arts. 133–91.

33. *Id.* art. 136.

34. U.N. GAOR, 22d Sess., 1516th mtg. at 14, U.N. Doc. A/C.1/PV.1516 (Nov. 1, 1967).

35. *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).

36. In the 1960s and 1970s, the countries with newfound independence from their colonial occupier considered colonialism as an avatar of capitalism. DENIS BENN, *MULTILATERAL DIPLOMACY AND THE ECONOMICS OF CHANGE* 1–3 (2003). For this reason they claimed a new international economic order that will help solve the inequalities between developing and developed states, which translates to the difference between the new independent states and the former colonial powers. *Id.*; see also Muthucumaraswamy Sornarajah, *The New World Economic Order and Equity*, in *DYNAMICS OF INTERNATIONAL LAW IN THE NEW MILLENNIUM* 209 (R.K. Dixit & C. Jayaraj eds., 2004).

the idea of equity in economic relations).³⁷ 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.

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.³⁸

When UNCLOS was negotiated, the only resources in the Area taken into consideration were mineral resources whose economic potential, even if exaggerated,³⁹ was of great interest for both developed and developing countries.⁴⁰ The existence of living resources in the Area and their possible economic value was unknown at that time. 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.”⁴¹ This narrow definition of the resources has led some to posit that the common heritage of mankind regime does not apply to MGRs.⁴² Another reason for the nonapplication of the common heritage regime to MGRs is that the exploitation and management of the resources would be accompanied by the Authority’s position in a leading

37. Luigi Migliorino, *Sfruttamento dei fondi marini e nuovo ordine economico internazionale, trasferimento della tecnologia e controllo delle multinazionali* [Exploitation of the Seabed and New International Economic Order, Transfer of Technology and Control of Multinational Corporations], in *LO SFRUTTAMENTO DEI FONDI MARINI* 81, 82 (Tullio Treves et al. eds., 1982) (It.); Jutta Brunnée, *Common Areas, Common Heritage and Common Concern*, in *THE OXFORD HANDBOOK OF INTERNATIONAL ENVIRONMENTAL LAW* 550, 561–62 (Daniel Bodansky et al. eds., 2007).

38. UNCLOS, *supra* note 14, art. 137.

39. Lyle Glowka, *Evolving Perspectives on the International Seabed Area’s Genetic Resources: Fifteen Years after the “Deepest of Ironies,”* in *LAW, TECHNOLOGY AND SCIENCE*, *supra* note 13, at 397; DAVID LEARY, *INTERNATIONAL LAW AND THE GENETIC RESOURCES OF THE DEEP SEA* 47 (2007).

40. Migliorino, *supra* note 37, at 84–85.

41. UNCLOS, *supra* note 14, art. 133(a).

42. LEARY, *INTERNATIONAL LAW & DEEP SEA GENETIC RESOURCES*, *supra* note 39, at 47.

role, but the Authority features a composition that is potentially ill-suited for the management of MGRs.⁴³ The principal organ of the Authority, the Council, is composed of member states' representatives, in particular those states that have a leading role in the polymetallic nodules industry.⁴⁴ These groups may lack sufficient motivation or qualifications to protect MGRs and the related industry.

Despite Part XI's narrow definition of resources within the purposes of the common heritage regime, the limited language does not preclude Part XI and the Authority from governing MGRs. Applicable portions are

43. Tullio Treves, *Principles and Objectives of the Legal Regime Governing Areas Beyond Nation Jurisdiction*, in *THE INTERNATIONAL LEGAL REGIME OF AREAS BEYOND NATIONAL JURISDICTION: CURRENT AND FUTURE DEVELOPMENTS* 7, 17–18 (Erik J. Molenaar & Alex G. Oude Elferink eds., 2010) [hereinafter Treves, *Principles and Objectives*].

44. Pursuant to Article 161, ¶ 1 of UNCLOS, the Council consists of thirty-six members:

(a) four members from among those States Parties which, during the last five years for which statistics are available, have either consumed more than [2%] of total world consumption or have had net imports of more than [2%] of total world imports of the commodities produced from the categories of minerals to be derived from the Area, and in any case one State from the Eastern European (Socialist) region, as well as the largest consumer;

(b) four members from among the eight States Parties which have the largest investments in preparation for and in the conduct of activities in the Area, either directly or through their nationals, including at least one State from the Eastern European (Socialist) region;

(c) four members from among States Parties which on the basis of production in areas under their jurisdiction are major net exporters of the categories of minerals to be derived from the Area, including at least two developing States whose exports of such minerals have a substantial bearing upon their economies;

(d) six members from among developing States Parties, representing special interests. The special interests to be represented shall include those of States with large populations, States which are land-locked or geographically disadvantaged, States which are major importers of the categories of minerals to be derived from the Area, States which are potential producers of such minerals, and least developed States;

(e) eighteen members elected according to the principle of ensuring an equitable geographical distribution of seats in the Council as a whole, provided that each geographical region shall have at least one member elected under this subparagraph. For this purpose, the geographical regions shall be Africa, Asia, Eastern European (Socialist), Latin America and Western European and Others.

UNCLOS, *supra* note 14, art. 161, ¶ 1.

found in those provisions concerning marine scientific research and the preservation of the marine environment in the Area.⁴⁵ 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.”⁴⁶ No provision of UNCLOS distinguishes between marine scientific research carried out for commercial purposes on the one hand, and research that does not have direct commercial potential or is not suitable for commercial exploitation on the other.⁴⁷ 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 purposes⁴⁸—falls under the notion of “marine scientific research.”⁴⁹ 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.

. . . .

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:

(a) participating in international programmes and encouraging cooperation in marine scientific research by personnel of different countries and of the Authority;

(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 . . . ;

45. *Id.* arts. 143, 145.

46. *Id.* art. 246, ¶¶ 3, 5(a).

47. Tullio Scovazzi, *The Seabed Beyond the Limits of National Jurisdiction: General and Institutional Aspects*, in *THE INTERNATIONAL LEGAL REGIME*, *supra* note 43, at 58 [hereinafter Scovazzi, *Seabed Beyond the Limits of National Jurisdiction*].

48. KATE & LAIRD, *supra* note 11, at 19.

49. UNCLOS, *supra* note 14, art. 246.

(c) effectively disseminating the results of research and analysis when available, through the Authority or other international channels when appropriate.⁵⁰

Even if MGRs in the Area cannot be considered part of the heritage of mankind regime,⁵¹ 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 are also common because of their potential benefits to mankind.⁵² 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, as shown earlier, it is difficult to determine whether an MGR is located on the seabed or in the water column. Article 143 of UNCLOS 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 of UNCLOS 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.⁵³ In the water column, beyond national jurisdiction, all states enjoy the freedom of scientific research guaranteed by Articles 87.1(f) and 257.⁵⁴

50. *Id.* art. 143.

51. As defined in *Id.* art. 136.

52. “[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.” Tullio Scovazzi, *La notion de patrimoine culturel de l’humanité dans les instruments internationaux* [*The Notion of Cultural Heritage of Mankind in International Instruments*], in *LE PATRIMOINE CULTUREL DE L’HUMANITÉ 3* (James A. R. Nafziger & Tullio Scovazzi eds., 2008) (Fr.).

53. Article 135 of UNCLOS on the legal status of the superjacent waters and air space states that “[n]either 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.” UNCLOS, *supra* note 14, art. 135.

54. Marine scientific research consists in a multitude of disciplines (biology, geography, geology, physics etc.). UNCLOS specifically regulates marine scientific research in Part XIII. *Id.* arts. 235–65. Under UNCLOS, “[a]ll States, irrespective of their geographical location, and competent international organizations have the right to conduct marine scientific research subject to the rights and duties of other States as provided for in this Convention.” *Id.* This right is also guaranteed under Article 87 of UNCLOS, which sets forth the freedoms of the high seas, including the freedom of scientific research. *Id.* art. 87; see ROBIN R. CHURCHILL & A. VAUGHAN LOWE, *THE LAW OF THE SEA* 203 (3d ed. 1999); Marko Pavliha & Norman A. Martínez Gutiérrez, *Marine Scientific Research and*

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.”⁵⁵ The collection of samples for the creation of biotechnologies could be considered as being in the interest of the “community.”⁵⁶ 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 UNCLOS’s preamble stating that:

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.⁵⁷

These paragraphs of the Preamble encourage interpreting relevant UNCLOS 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 2749.⁵⁸ 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 IPRs over biotechnologies.

Before considering the feasibility of an amendment, the regime described above must be examined and interpreted with regard to other rel-

the 1982 United Nations Convention on the Law of the Sea, 16 OCEAN & COASTAL L.J. 115 (2010); Alfred H. Soons, *Regulation of Marine Scientific Research by the European Community and its Member States*, in 23 OCEAN DEV. & INT’L L. 259, 261 (1992); Alfred H. Soons, *The Legal Regime of Marine Scientific Research: Current Issues*, in LAW, SCIENCE AND OCEAN MANAGEMENT 139 (Myron H. Nordquist et al. eds., 2007).

55. UNCLOS, *supra* note 14, art. 241.

56. Francisco Orrego Vicuna, *Les législations nationales pour l’exploitation des fonds marins et leur incompatibilité avec le droit international* [*National Laws allowing for the Exploitation of the Seabed and their Incompatibility with International Law*], 24 ANNUAIRE FRANÇAIS DE DROIT INTERNATIONAL 810, 812 (1978) (Fr.).

57. UNCLOS, *supra* note 14, pmb., ¶¶ 5–6.

58. *See supra* note 35.

evant instruments, as required by the general rule of interpretation of treaties set forth in the Vienna Convention on the Law of Treaties (“VCLT”).⁵⁹ Moreover, UNCLOS is a product of its time. It should be applied in light of the normative evolutions that have occurred since it was adopted.⁶⁰ As numerous states are simultaneously party to UNCLOS, TRIPS, and the CBD, these two latter treaties will be analyzed both separately and jointly.

B. Finding Space for MGRs in TRIPS

1. The Legal Framework of TRIPS

TRIPS was concluded under the auspices of the WTO.⁶¹ WTO members states (and parties to the Agreement) number 153 and approximately 130 of them are also contracting parties of UNCLOS.⁶² Inventions obtained from genetic resources, including MGRs, can be patented according to Part II, Section V of TRIPS, which provides minimum standards of intellectual property protection.⁶³ TRIPS establishes that “patents shall

59. Vienna Convention on the Law of Treaties, May 23, 1969, 1155 U.N.T.S. 331, art. 31, ¶ 3(c) [hereinafter VCLT].

60. See *supra* note 26.

61. TRIPS, *supra* note 16.

62. *Understanding the WTO: Members and Observers*, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Oct. 1, 2011).

63. On TRIPS, see Carlos M. Correa, *Patents Rights, in* INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPS AGREEMENT 227 (Carlos M. Correa & Abdulkawi A. Yusuf eds., 2d ed. 2008); CARLOS M. CORREA, TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT (2007); DANIEL J. GERVAIS, L’ACCOR SUR LES ADPIC [THE TRIPS AGREEMENT] (2010) (Fr.); DANIEL J. GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS (3d ed. 2008); MITSUO MATSUSHITA, THOMAS J. SCHOENBAUM & PETROS C. MAVROIDIS, THE WORLD TRADE ORGANIZATION: LAW, PRACTICE, AND POLICY 699 (2d ed. 2006). 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 ENRICO BONADIO, SISTEMA BREVETTUALE TRIPS E RISORSE GENETICHE: ESIGENZE COMMERCIALI E INTERESSI PUBBLICI [THE TRIPS PATENT SYSTEM AND GENETIC RESOURCES: TRADE ISSUES AND PUBLIC INTEREST] (Jovene Editore S.P.A. 2008) (It.); BIOETICA E BIOTECNOLOGIE NEL DIRITTO INTERNAZIONALE E COMUNITARIO: QUESTIONI GENERALI E TUTELA DELLA PROPRIETÀ INTELLETTUALE [BIOETHICS AND BIOTECHNOLOGIES UNDER INTERNATIONAL AND EC LAW: GENERAL AND IP ISSUES] (Nerina Boschiero ed., 2006) (It.) [hereinafter BIOETICA E BIOTECNOLOGIE NEL DIRITTO INTERNAZIONALE E COMUNITARIO]; JONATHAN CURCI, THE PROTECTION OF BIODIVERSITY AND TRADITIONAL KNOWLEDGE IN INTERNATIONAL LAW OF INTELLECTUAL

be 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 of industrial application.”⁶⁴ Therefore, patents can be granted on inventions based on MGRs if these three essential conditions are simultaneously fulfilled. Moreover, as a necessary condition, applications shall contain invention descriptions sufficiently clear and complete for the invention to be carried out by a person skilled in the art.⁶⁵ According to Article 28 of TRIPS, a patent confers on its owner a series of exclusive rights, including the 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.⁶⁶

Given the patentability of inventions derived from MGRs—such as pharmaceutical products or processes—which are novel, original, industrial and properly described, the exceptions established by Article 27 of TRIPS acquire importance in this field. Firstly, Paragraph 2 provides that member states are allowed to exclude from patentability “inventions the commercial exploitation of which is necessary to protect *ordre public* or morality.”⁶⁷ *Ordre public* and morality are composed of mandatory rules, the application of which cannot be neglected.⁶⁸ *ordre public* refers to those basic values prevailing in society and is meant to include public

PROPERTY 30 (2010); BIOTECHNOLOGY AND INTERNATIONAL LAW (Francesco Francioni & Tullio Scovazzi eds., 2006); BIODIVERSITY AND THE LAW: INTELLECTUAL PROPERTY, BIOTECHNOLOGY AND TRADITIONAL KNOWLEDGE (Charles R. McManis ed., 2007); INTELLECTUAL PROPERTY AND BIOLOGICAL RESOURCES (Burton Ong ed., 2004); RICCARDO PAVONI, BIODIVERSITÀ E BIOTECNOLOGIE NEL DIRITTO INTERNAZIONALE E COMUNITARIO [BIODIVERSITY AND BIOTECHNOLOGY IN INTERNATIONAL AND EC LAW] (2004) (It.) [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.

64. TRIPS, *supra* note 16, art. 27, ¶ 1.

65. *Id.* art. 29.

66. *Id.* art. 33.

67. Correa, *Patents Rights*, *supra* note 63, at 229.

68. According to Pierre-Marie Dupuy: “L’indérogeabilité est un attribut conféré à une norme en raison de son caractère d’ordre public, qu’aucune volonté individuelle ne saurait transcender sans porter du même coup atteinte à la sécurité de l’ensemble du système et des intérêts collectifs de la société qu’il a à charge de réguler.” Pierre-Marie Dupuy, *L’unité de l’ordre juridique international: Cours général de droit international public* [The Unity of International Law: General Course on Public International Law], in 297 RECUEIL DES COURS. COLLECTED COURSES OF THE HAGUE ACADEMY OF INTERNATIONAL LAW 282 (2002) (Neth.).

safety, the physical integrity of individuals, and the protection of the environment; morality instead is based on ethical norms accepted and deeply rooted in a particular culture.⁶⁹ Secondly, pursuant to Paragraph 3(a), members may consider diagnostic, therapeutic, and surgical methods for the treatment of humans and animals as nonpatentable subject matter.⁷⁰ On the contrary, given the nature of MGRs and the techniques employed, biotech inventions from MGRs are not affected by Article 27.3(b), which provides for exceptions to patents on “plants and animals other than micro-organisms”—i.e. a category to which MGRs should not be ascribed—“and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes”—i.e. techniques different from biotechnologies.⁷¹

As mentioned above, TRIPS, like other treaties, must be interpreted in the light of the general principles on treaty interpretation enshrined in the VCLT.⁷² This is important, as it pertains to the grant of patents on inventions based on MGRs, considering that 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”⁷³ and the principles provided in Articles 31 and 32 of the VCLT⁷⁴ have attained status of customary international law in the WTO Appellate Body’s reports.⁷⁵

Thus, according to Article 31.1 of the 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.”⁷⁶ Reference should then be made to Article 7, which sets out objectives and establishes that the protection and enforcement of IPRs: “should con-

69. See Angelica Bonfanti, *Environmental Risk in Biotech Patent Disputes: Which Role for Ordre Public before the European Patent Office?*, EUR. J. OF RISK REG. (forthcoming); E. Richard Gold, *The Ethics of Biotechnological Intellectual Property*, in BIOTECHNOLOGY, IP & ETHICS 15 (E. Richard Gold & Bartha Maria Knoppers eds., 2009); OLIVER MILLS, BIOTECHNOLOGICAL INVENTIONS: MORAL RESTRAINTS AND PATENT LAW (2010).

70. Correa, *Patents Rights*, *supra* note 63, at 231.

71. TRIPS, *supra* note 16, art. 27, ¶ 3(b); PAVONI, BIODIVERSITÀ E BIOTECNOLOGIE, *supra* note 63, at 110.

72. Isabelle Van Damme, *Treaty Interpretation by the WTO Appellate Body*, 21 EUR. J. INT’L L. 605, 620 (2010).

73. 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].

74. VCLT, *supra* note 59, arts. 31–32.

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

76. VCLT, *supra* note 59, art. 31, ¶ 1; Van Damme, *supra* note 72, at 631.

tribute 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.”⁷⁷

Moreover, pursuant to Article 31.2 of the VCLT,⁷⁸ TRIPS shall be interpreted in the context⁷⁹ of the preambulatory 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 . . . needs and concerns at different levels of economic development.”⁸⁰

Finally, as clarified by the Appellate Body, the WTO Agreements shall not be interpreted in “clinical isolation.”⁸¹ On the contrary, they should be read through the lens of subsequent practice,⁸² and of “any relevant

77. TRIPS, *supra* note 16, art. 7.

78. VCLT, *supra* note 59, art. 31, ¶ 2.

79. See generally MARK VILLIGER, COMMENTARY ON THE 1969 VIENNA CONVENTION ON THE LAW OF TREATIES 415, 427–29 (2009) [hereinafter VILLIGER, VIENNA CONVENTION COMMENTARY]; see also, Mark E. 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 9, 113–34 (2009) (Neth.).

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

81. The expression was used by the Appellate Body in the case *United States – Standards for Reformulated and Conventional Gasoline*, *supra* note 75, ¶ 14. On the relationship between WTO agreements and international law, see Gabrielle Marceau, *Fragmentation in International Law: The Relationship between WTO Law and General International Law - A Few Comments from a WTO Perspective*, 17 FINNISH Y.B. INT’L L. 5 (2006); Gabrielle Marceau, *Conflict of Norms and Conflicts of Jurisdiction: The Relationship between the WTO Agreement and MEAs and Other Treaties*, 35 J. WORLD TRADE 1081 (2001); Gabrielle Marceau & Anastosios Tomazos, *Comments on Joost Pauwelyn’s Paper: ‘How to Win a WTO Dispute Based on Non-WTO Law?’*, in 8 AT THE CROSSROADS: THE WORLD TRADING SYSTEM AND THE DOHA ROUND 54, 56 (Stefan Grillier ed., 2008); JOOST PAUWELYN, CONFLICT OF NORMS IN PUBLIC INTERNATIONAL LAW: HOW WTO LAW RELATES TO OTHER RULES OF INTERNATIONAL LAW 25, 35 (2003); Joost Pauwelyn, *The Application of Non-WTO Rules of International Law in WTO Dispute Settlement*, in THE WORLD TRADE ORGANIZATION: LEGAL, ECONOMIC AND POLITICAL ANALYSIS 1405 (Patrick F. J. Macrory ed., 2005); see also Isabelle Van Damme, *Treaty Interpretation by the WTO Appellate Body*, *supra* note 72; Int’l Law Comm’n, *supra* note 26, paras. 165, 345; Isabelle 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 Y.B. INT’L L. 21 (2006).

82. VCLT, *supra* note 59, art. 31, ¶ 3(b); Georg Nolte, *Subsequent Practice as a Means of Interpretation in the Jurisprudence of the WTO Appellate Body*, in THE LAW OF TREATIES BEYOND THE VIENNA CONVENTION 138, 140–41 (Enzo Cannizzaro ed., 2011); VILLIGER, VIENNA CONVENTION COMMENTARY, *supra* note 79, at 431.

rules of international law applicable in the relations between the parties.”⁸³ Applying Article 31.3(c) of the VCLT to the WTO Agreements may require consideration of other international law provisions, either customary or conventional, which are both binding on the parties and simultaneously applicable to the issue at stake.⁸⁴ When dealing with the grant of patents on inventions from MGRs, relevant provisions of international law can be found in UNCLOS 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, UNCLOS and CBD provisions could be considered rules of international law relevant to the grant of patents on inventions derived from them. In light of the analysis undertaken on interpreting TRIPS, a discussion of its relationships to UNCLOS and the CBD can now follow.

2. The Compatibility of IPRs and MGRs

To some extent, the standards provided by TRIPS, and even the attribution of exclusive rights to private individuals through the grant of patents, may be considered incompatible with some provisions set out by UNCLOS. Indeed, as underscored by the Secretary General report on Oceans and Law of the Sea:

[t]he following questions may arise and require further consideration:
whether filing a patent application is considered as a claim to part of

83. VCLT, *supra* note 59, art. 31, ¶ 3(c); VILLIGER, VIENNA CONVENTION COMMENTARY, *supra* note 79, at 432.

84. The notion of “parties” as provided by art. 31, ¶ 3(c) of the VCLT, is controversial. See Ulf Linderfalk, *Who Are ‘The Parties’? Article 31, Paragraph 3(c) of the 1969 Vienna Convention and the ‘Principle of Systemic Integration’ Revisited*, 55 NETH. INT’L L. REV. 343, 347 (2008). 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*, ¶ 7.70, WT/DS291/R, WT/DS292/R, WT/DS293/R (Sept. 29, 2006); see also Margaret Young, *The WTO’s Use of Relevant Rules of International Law: An Analysis of the Biotech Case*, 56 INT’L & COMP. L. Q. 907, 914–15 (2007); Benn 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 J. WORLD TRADE 589, 614 (2008); Ernst-Ulrich Petersmann, *The WTO Dispute over Genetically Modified Organisms: Interface Problems of International Trade Law, Environmental Law and Biotechnology Law*, in BIOTECHNOLOGY AND INTERNATIONAL LAW, *supra* note 63, at 173; Andrew Thomison, *A New Controversial Mandate for the SPS Agreement: The WTO Panel’s Interim Report in the E.C. – Biotech Dispute*, 32 COLUM. J. ENVTL. L. 287, 307 (2007).

the marine environment or its resources; whether the rights conferred by a patent are likely to interfere with the right to carry out marine scientific research; and whether the degree of confidentiality required prior to the filing for patents in order to safeguard the novel character of an invention is compatible with the requirement for dissemination and publication of data and research results.⁸⁵

Firstly, according to some of the essential principles on which it is based, the Area is a commons.⁸⁶ As such, it is not subject to appropriation by individual states or persons, natural, or juridical.⁸⁷ Activities in the Area must be carried out for the benefit of mankind as a whole and proceeds must be equitably shared among all parties.⁸⁸ As demonstrated above, even if MGRs are not directly encompassed in the common heritage regime regulated by Part XI of UNCLOS, they constitute common concerns submitted to common use. Therefore, granting patents or inventions obtained from MGRs could be considered as incompatible with the nature of commons—it would provide the holder an exclusive right to use and commercially exploit the invention and, to some extent, also the natural resources on which it is based, without requiring that activities on MGRs are carried out for the benefit of mankind or that economic benefits arising from them are equitably shared among all states.⁸⁹

Secondly, Article 241 of UNCLOS addresses the “non-recognition of marine scientific research activities as the legal basis for claims.”⁹⁰ This article implies that scientific research and bioprospection on MGRs shall not constitute the legal basis for claims either of ownership or of exclusive use of the resources. To correctly understand the meaning of Article 241, consideration should be given to the preparatory works. These reveal that the Article was adopted to preclude research being used as the basis for claims of “exploitation rights or any other rights in areas beyond national jurisdiction.”⁹¹ As underlined by some, the grant of patents on inventions derived from MGRs, as far as they attribute to their holder the exclusive rights to use and commercially exploit the covered inven-

85. U.N. Secretary-General, *Oceans and the Law of the Sea: Rep. of the Secretary General—Addendum*, ¶ 241, U.N. Doc. A/62/66/Add.2 (Sept. 10, 2007).

86. *See supra* p. 192–98.

87. UNCLOS, *supra* note 14, art. 137. Vladimir-Djuro Degan, *The Common Heritage of Mankind in the Present Law of the Sea*, in I LIBER AMICORUM JUDGE SHIGERU ODA, 1363, 1375 (Nisuke Ando et al. eds., 2002).

88. UNCLOS, *supra* note 14, art. 140.

89. Kirchner, *supra* note 10, at 126–27.

90. UNCLOS, *supra* note 14, art. 241; de La Fayette, *supra* note 10, at 271.

91. *See UNITED NATIONS CONFERENCE OF THE LAW OF THE SEA 1982: A COMMENTARY* 464 (Myron H. Nordquist et al. ed., 1991).

tions, could be considered contrary to Article 241.⁹² Indeed, patents imply a concurrent restriction of third parties' rights to use and exploit MGRs located beyond national jurisdiction, which is exactly the effect that Article 241 attempts to prevent.⁹³

Finally, according to Article 244 of UNCLOS, states shall publicize and disseminate research results, knowledge, scientific data, and information.⁹⁴ The same is required of scientific research undertaken in the Area, articulated in Article 143, which states that scientific results, when available, shall be duly disseminated to state parties.⁹⁵ Pursuant to Article 246.3, marine scientific research shall be carried out "in order to increase scientific knowledge of the marine environment for the benefit of all mankind."⁹⁶ Moreover, according to these provisions, the dissemination of scientific results and knowledge shall favor developing countries, which shall be given the chance to increase their autonomous scientific and professional skill.⁹⁷ In light of these objectives, the grant of patents on marine scientific research results could be seen, at least in the short term, as contrary to UNCLOS,⁹⁸ unless the description of the invention, disclosing the coverage and best mode for carrying out the invention, can be considered as fulfilling UNCLOS provisions and guaranteeing the compliance of IPRs with UNCLOS requirements.

C. Protecting Biological Diversity beyond National Jurisdiction

1. The CBD Legal Framework

The CBD was concluded in Rio de Janeiro on June 5, 1992, and entered into force on December 29, 1993.⁹⁹ It has currently been ratified by 193 states. 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 ap-

92. Charlotte Salpin & Valentina Germani, *Patenting of Research Results Related to Genetic Resources from Areas Beyond National Jurisdiction: The Crossroad of the Law of the Sea and Intellectual Property Law*, 16 REV. EUR. CMTY & INT'L ENVTL. L. 12, 20–22 (2007).

93. de La Fayette, *supra* note 10, at 271.

94. UNCLOS, *supra* note 14, art. 244; de La Fayette, *supra* note 10, at 271.

95. UNCLOS, *supra* note 14, art. 143, ¶ 3(c)

96. *Id.* art. 246, ¶ 3.

97. *Id.* art. 244, art. 143, ¶ 3(b).

98. de La Fayette, *supra* note 10, at 278.

99. CBD, *supra* note 15.

propriate transfer of relevant technologies.”¹⁰⁰ Pursuant to the CBD, states have the sovereign right to exploit their own natural resources¹⁰¹ and the authority to regulate foreign states public institutions, and private institutions’ access to them.¹⁰²

Two mandatory principles govern access to these 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 the jurisdiction of which the resource is located.¹⁰³ Second, the terms that authorize access are agreed upon between the provider state and the user.¹⁰⁴ 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.¹⁰⁵ 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

100. *Id.* art. 1. On the application of the CBD’s principles to genetic resources, see Michael I. Jeffery, *Bioprospecting: Access to Genetic Resources and Benefit-Sharing under the Convention on Biodiversity and the Bonn Guidelines*, 6 SING. J. INT’L & COMP. L. 747, 749 (2002); Charles Lawson, *Biodiversity Conservation Access and Benefit-Sharing Contracts and the Role and Place of Patents*, 33 EUR. INTELL. PROP. REV. 135, 137 (2011). *See also* WILLIAM LESSER, SUSTAINABLE USE OF GENETIC RESOURCES UNDER THE CONVENTION ON BIOLOGICAL DIVERSITY: EXPLORING ACCESS AND BENEFIT SHARING ISSUES (1998); McManis, *supra* note 63; Jean-Frédéric Morin, *Les accords de bioprospection favorisent-ils la conservation des ressources génétiques? [Do Bioprospecting Agreements Favor the Conservation of Genetic Resources?]*, 34 REVUE DE DROIT DE L’UNIVERSITÉ DE SHERBROOKE 307 (2003) (Can.); PAVONI, BIODIVERSITÀ E BIOTECNOLOGIE, *supra* note 63, at 119; PATRICIA BIRNIE, ALAN BOYLE & CATHERINE REDGWELL, INTERNATIONAL LAW AND THE ENVIRONMENT 612 (3d ed. 2009); *see generally* PHILIPPE SANDS, PRINCIPLES OF INTERNATIONAL ENVIRONMENTAL LAW 435 (2d ed. 2003); Aphrodite Smagadi, *Analysis of the Objectives of the Convention on Biological Diversity: Their Interrelation and Implementation Guidance for Access and Benefit Sharing*, 31 COLUM. J. ENVTL. L. 243 (2006); Aphrodite Smagadi, *The Impact of the Convention on Biological Diversity on the Utilization of Plant Genetic Resources and Benefit Sharing*, 6 Y.B. EUR. ENVTL. L. 119 (2006); Zakir Thomas, *Common Heritage to Common Concern. Preserving a Heritage and Sharing Knowledge*, 8 J. WORLD INTELL. PROP. 248 (2005).

101. CBD, *supra* note 15, art. 3.

102. *Id.* art. 15.

103. *Id.* art. 15, ¶ 5.

104. *Id.* art. 15, ¶ 4.

105. *Id.* art. 15, ¶ 7.

an objective cannot be easily reached. Indeed, practice demonstrates that the corresponding obligation is seldom fulfilled.¹⁰⁶

Given the practical difficulties faced by states and private operators with regard to sharing, in 2002 the 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”).¹⁰⁷ This nonbinding instrument aims at facilitating access to genetic resources and ensuring that benefits of any commercialization are duly shared with provider states.¹⁰⁸ 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 a legal formula according to which they should be concretely fulfilled.

Additionally, the CBD framework was recently expanded with the adoption of the Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization (“Nagoya Protocol”).¹⁰⁹ After lengthy negotiations,¹¹⁰ the Protocol was adopt-

106. Nerina Boschiero, *Le biotecnologie tra etica e principi generali del diritto internazionale* [Biotechnologies between Ethics and General Principles of International Law], in *BIOETICA E BIOTECNOLOGIE NEL DIRITTO INTERNAZIONALE E COMUNITARIO*, *supra* note 63, at 70–71; Jonathan Carr, *Agreements That Divide: TRIPs vs. CBD and Proposals for Mandatory Disclosure of Source and Origin of Genetic Resources in Patent Applications*, 18 *J. TRANSNAT'L L. & POL'Y* 131, 134 (2008); James S. Miller, *Impact of the Convention on Biological Diversity: The Lessons of Ten Years of Experience with Models for Equitable Sharing of Benefits*, in *BIODIVERSITY AND THE LAW: INTELLECTUAL PROPERTY, BIOTECHNOLOGY & TRADITIONAL KNOWLEDGE*, *supra* note 63, at 58, 65–66; Morin, *supra* note 100, at 307.

107. 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 [hereinafter *Bonn Guidelines*], available at <http://www.cbd.int/decision/cop/?id=7198>; see generally W. Bradnee Chambers, *Emerging International Rules on the Commercialization of Genetic Resources: The FAO International Plant Genetic Treaty and the CBD Bonn Guidelines*, 6 *J. WORLD INTELL. PROP.* 311 (2003); Jeffery *supra* note 100, at 747; Stephan Tully, *The Bonn Guidelines on Access to Genetic Resources and Benefit Sharing*, 12 *REV. EUR. CMTY & INT'L ENVTL. L.* 84, 84 (2003).

108. Chambers, *supra* note 107, at 314; Jeffery, *supra* note 100, at 747; Tully, *supra* note 107, at 84.

109. 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 [hereinafter *Nagoya Protocol*], available at <http://www.cbd.int/abs/text/>.

ed on October 29, 2010, by the Conference of the parties of the CBD. It will remain open for signature until February 1, 2012, and it will enter into force after the fiftieth instrument of ratification is deposited.¹¹¹

2. Do MGRs Fall Under the CBD?

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 scope¹¹² and the bilateral nature of the exploitation scheme.¹¹³ To the contrary, MGRs can fall within the reach of the CBD. However, given that the drafters of UNCLOS kept in mind the possibility of future normative developments,¹¹⁴ the CBD must firstly be interpreted consistently with UNCLOS when it comes to marine biodiversity before any application to MGRs can be made.

UNCLOS provides an important set of rules for the protection of the marine environment in Part XII.¹¹⁵ These provisions do not apply exclusively in the sense that Part XII is a sort of "umbrella" agreement for the protection of marine environment.¹¹⁶ This role of UNCLOS Part XII is performed by the integration mechanism set out in Article 237, which provides:

110. Negotiations were conducted by the Ad Hoc Open Ended Working Group on Access and Benefit-Sharing of the CBD ("ABS Working Group"). *Background, CONVENTION ON BIOLOGICAL DIVERSITY*, <http://www.cbd.int/abs/background> (last visited Oct. 1, 2011). The ABS Working Group was originally given in 2004 the task of drafting a new legal instrument, called the International Regime on Access to Genetic Resources and the Fair and Equitable Sharing of the Benefits Arising from Their Use. *Id.* The negotiations for such an instrument lead to the drafting of the Protocol. *Id.* For information concerning activities carried out by the ABS Working Group, see *CONVENTION ON BIOLOGICAL DIVERSITY*, <http://www.cbd.int/abs/> (last visited Oct. 1, 2011).

111. *Nagoya Protocol*, *supra* note 109, arts. 26–27.

112. CBD, *supra* note 15, art. 4.

113. Nele Matz-Lück, *The Concept of the Common Heritage of Mankind: Its Viability as a Management Tool for Deep-Sea Genetic Resources*, in *THE INTERNATIONAL LEGAL REGIME*, *supra* note 43, at 63.

114. Article 237 in fact requires that subsequent instruments be uniformly applied with UNCLOS. UNCLOS, *supra* note 14, art. 237.

115. *Id.* arts. 192–237.

116. UNITED NATIONS CONFERENCE OF THE LAW OF THE SEA 1982: A COMMENTARY, *supra* note 91, at 423. See also Tullio Treves, *Réflexions sur quelques conséquences de l'entrée en vigueur de la Convention des Nations Unies sur le droit de la mer* [*Reflections on a Number of Consequences of the Entry into Force of the United Nations Convention on the Law of the Sea*], 1994 ANNUAIRE FRANÇAIS DE DROIT INTERNATIONAL 849, 853–54 (Fr.), in which the author affirms: "Cet article [l'art. 237] vise à permettre à la Partie XII de la Convention de mieux fonctionner comme convention-cadre vis-à-vis des autres conventions qui portent sur la protection de l'environnement."

1. The provisions of this Part are *without 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*.

2. 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.¹¹⁷

This provision highlights how UNCLOS has an interdependent relationship with the existing instruments in the field of marine environment.¹¹⁸ This must be kept in mind when turning to the relevant provisions of the CBD, namely Article 4, which provides:

Subject to the rights of other States, and except as otherwise expressly provided in this Convention, the provisions of this Convention apply, 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.¹¹⁹

Some believe that Article 4(b) of the CBD precludes direct application to MGRs in the water column of the high seas or on the deep seabed,¹²⁰ while others authors suggest that “the State parties may only regulate the activities of their own nationals to achieve the objectives of the CBD. So far no state has implemented measures specifically regulating activities of their nationals.”¹²¹ The latter view is contestable in the light of existing regulations, both national and international, concerning activities carried out on the high seas. For example, the freedom of high seas, a rule beloved by states and approaching dogma, does not mean that states can

117. UNCLOS, *supra* note 14, art. 237 (emphasis added).

118. Seline Trevisanut, *La Convention des Nations Unies sur le droit de la mer et le droit de l'environnement: développement intrasystémique et renvoi intersystémique* [*The United Nations Convention on the Law of the Sea and Environmental Law: Intrasystemic Development and Intersystemic Cross-Reference*], in *LA CIRCULATION DES CONCEPTS JURIDIQUES*, *supra* note 23, at 415 (Fr.).

119. CBD, *supra* note 15, art. 4 (emphasis added).

120. Matz-Lück, *supra* note 113, at 63.

121. LEARY, *INTERNATIONAL LAW & DEEP SEA GENETIC RESOURCES*, *supra* note 39, at 52.

do anything they want. Rather, the freedom of high seas is well regulated both by customary and treaty law.¹²² This freedom encompasses, *inter alia*, the freedom of navigation, the freedom to construct artificial islands and installations, and the freedom of scientific research,¹²³ which “shall be exercised by all States with due regard for the interests of other States in their exercise of the freedom of the high seas, and also with due regard for the rights under this Convention with respect to activities in the Area.”¹²⁴

The fundamental condition for enjoying these freedoms is the nationality of vessels. States enjoy freedoms that their nationals can likewise enjoy.¹²⁵ Thus any vessel exercising an activity in the high seas has to be linked with a state, exhibited by the flying of the flag.¹²⁶ Such vessels are subject to the exclusive jurisdiction of the flag state,¹²⁷ which has to exercise “its jurisdiction and control” over it.¹²⁸ Unfortunately, not all flag states are willing to exercise effectively their control on vessels.¹²⁹ Consequently the implementation of the above mentioned CBD principles is hampered.

However, it may then be asked whether other states might act under Article 4(b) CBD. Processes or activities concerning MGRs can presumably be carried out or funded by a private actor, a research institute, or a pharmaceutical company, which controls the activity or process. Private actors have a nationality in conformity with international law criteria.¹³⁰

122. UNCLOS, *supra* note 14, art. 87, ¶ 1(f); CHURCHILL & LOWE, *supra* note 54, at 203.

123. UNCLOS, *supra* note 14, art. 87, ¶ 1(a), (d), (f).

124. *Id.* art. 87, ¶ 2.

125. *Id.* arts. 90–91; CHURCHILL & LOWE, *supra* note 54, at 166.

126. UNCLOS, *supra* note 14, arts. 91–92.

127. *Id.* art. 92, ¶ 1.

128. *Id.* art. 94.

129. See Dr. Ademuni-Odeke, *An Examination of Bareboat Charter Registries and Flag of Convenience Registries in International Law*, 36 OCEAN DEV. & INT'L L. 339, 341 (2005); JOHN N. K. MANSELL, FLAG STATE RESPONSIBILITY: HISTORICAL DEVELOPMENT AND CONTEMPORARY ISSUES, AN ANALYSIS OF FLAG STATE RESPONSIBILITY FROM A HISTORICAL PERSPECTIVE 140–41 (2009); Djamchid Montaz, *La Convention des Nations Unies sur les conditions d'immatriculation des navires* [*The United Nations Convention on Conditions for Registration of Ships*], 1986 ANNUAIRE FRANÇAIS DE DROIT INTERNATIONAL 715 (Fr.); Tullio Treves, *Flags of Convenience before the Law of the Sea Tribunal*, 6 SAN DIEGO INT'L L.J. 179 (2004).

130. As far as the nationality of legal persons is concerned, the main international law criteria were stated by the International Court of Justice in the *Barcelona Traction, Light and Power Company, Limited* (Belg. v. Spain), Judgment, 1970 I.C.J. Rep 3 (Feb. 5). Comments on this case can be found in Rosalyn Higgins, *Aspects of the Case Concerning the Barcelona Traction Company*, 11 VA. J. INT'L L. 327 (1971); Richard B. Lillich, *Two*

States are bound to exercise due diligence¹³¹ towards private actors and activities carried out on their territory or under their jurisdiction.¹³² It is debatable whether such an obligation exists with regard to private actors' behavior outside the national state, i.e. if their activities abroad fall under the national state's jurisdiction.¹³³ However, even if the existence of such a general obligation is doubted, states must pay due diligence in specific sectors. For instance, UNCLOS provides that states "shall keep under surveillance the effects of *any activities which they permit or in which they engage* in order to determine whether these activities are likely to pollute the marine environment."¹³⁴ Reading Article 4(b) CBD in combination with this provision suggests that the state of nationality of private actors or even the state sponsoring the private activity does have a role to

Perspectives on the Barcelona Traction Case, 65 AM. J. INT'L L. 522 (1971); Francis A. Mann, *The Protection of Shareholders' Interests in the Light of the Barcelona Traction Case*, 67 AM. J. INT'L L. 259 (1973); Brigitte Stern, *La protection diplomatique des investissements internationaux. De Barcelona Traction à Elettronica Sicula ou les glissements progressifs de l'analyse* [*The Diplomatic Protection of International Investments. From the Barcelona Traction to Elettronica Sicula and the Progressive Shifts in Analysis*], 117 JOURNAL DU DROIT INTERNATIONAL 897 (1990) (Fr.). On the attribution of nationality to legal persons, see also Rep. of the Int'l Law Comm'n, 61st Sess., May 1–June 9, July 3–Aug. 11, 2006, U.N. Doc. A/61/10, Supp. No. 10, at 13 (2006).

131. United States Diplomatic and Consular Staff in Tehran (U.S. v. Iran), Judgment, 1980 I.C.J. 3 (May 24).

132. RICCARDO PISILLO MAZZESCHI, "DUE DILIGENCE" E RESPONSABILITÀ INTERNAZIONALE DEGLI STATI ["DUE DILIGENCE" AND INTERNATIONAL RESPONSIBILITY OF THE STATES], 234–36 (1989) (It.). On this issue see U.S. v. Iran, 1980 I.C.J. at 3; Luigi Condorelli, *L'imputation à l'Etat d'un fait internationalement illicite: solutions classiques et nouvelles tendances* [*The Attribution of Internationally Wrongful Acts to States: Classical Solutions and New Trends*], 189 RECUEIL DES COURS. COLLECTED COURSES OF THE HAGUE ACADEMY OF INTERNATIONAL LAW 19, 95 (1984) (Neth.).

133. The extraterritorial application of the due diligence obligation is an on-going and everlasting debate in international law literature and international legal practice. The analysis of such a topic goes far beyond the scope of the present contribution. See generally IAN BROWNLIE, PRINCIPLES OF PUBLIC INTERNATIONAL LAW 308 (7th ed. 2008); A. Vaughn Lowe, *Jurisdiction*, in INTERNATIONAL LAW 341–42 (Malcolm D. Evans ed., 2d ed. 2008); Francis A. Mann, *The Doctrine of International Jurisdiction Revisited after Twenty Years*, 186 RECUEIL DES COURS. COLLECTED COURSES OF THE HAGUE ACADEMY OF INTERNATIONAL LAW 19 (1984) (Neth.); EXTRATERRITORIAL JURISDICTION IN THEORY AND PRACTICE (Karl Matthias Meessen ed., 1996); François Rigaux, *Le concept de territorialité: un fantasme en quête de réalité* [*The Concept of Territoriality: A Fantasy in Search of Reality*], in LIBER AMICORUM JUDGE MOHAMMED BEDJAOU 211 (Emile Yapok & Tahar Boumedra eds., 1999) (Fr.); Brigitte Stern, *Quelques observations sur les règles internationales relatives à l'application extraterritoriale du droit* [*Some Observations on International Rules Concerning the Extraterritorial Application of Law*], 32 ANNUAIRE FRANÇAIS DE DROIT INTERNATIONAL 7 (1986).

134. UNCLOS, *supra* note 14, art. 204 (emphasis added).

play,¹³⁵ the state, if is a party to the CBD, would be bound by it in regards to activities and processes concerning MGRs beyond national jurisdiction.

This interpretation would be in line with the recommendation of the Subsidiary Body on Scientific, Technical and Technological Advice of the CBD (“SBSTTA”):¹³⁶

(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 vulner-

135. Under the regime set in Part XI, a state can sponsor the application of a private actor carrying out activities of exploration and exploitation of the Area. UNCLOS, *supra* note 14, art. 153. Considering the possible application of the Area regime concerning the exploitation of MGRs, the sponsoring by a state system can be taken into consideration for the MGRs regime. A potential sponsoring state could be encompassed in the scope of application of Article 4(b) CBD. UNCLOS does not precisely define the degree of control exercised by the sponsoring state on the private actor and on the activities. The delegation of Nauru submitted such a proposal to the Council of the Authority, which then submitted a request for advisory opinion to the Seabed Disputes Chamber of ITLOS. Delegation of Nauru, Proposal presented to the Int'l Seabed Auth. Council, 16th Sess., Apr. 26–May 7, 2010, ISBA/16/C/6 (Mar. 5 2010); Responsibilities and Obligations of States Sponsoring Persons and Entities with Respect to Activities in the Area, ¶ 78, Case No. 17, Seabed Disputes Chamber Advisory Opinion of Feb. 1, 2011, http://www.itlos.org/fileadmin/itlos/documents/cases/case_no_17/adv_op_010211.pdf, stating that:

[a]s the Convention [UNCLOS] does not consider the links of nationality and effective control sufficient to obtain the result that the contractor conforms with the Convention and related instruments, it requires a specific act emanating from the will of the State or States of nationality and of effective control. Such act consists in the decision to sponsor.

From this voluntary act follows an obligation of due diligence for the sponsoring state concerning the activities carried out by the sponsored private actors. *Id.* ¶ 116. Sponsorship might be considered as a confirmation of the existence of effective control and, consequently, confirm the application of Article 4(b) of the CBD.

136. Article 25 of the CBD establishes an open-ended intergovernmental scientific advisory body known as the Subsidiary Body on Scientific, Technical and Technological Advice (“SBSTTA”) to provide the Conference of the Parties (“COP”) and its other subsidiary bodies, with timely advice relating to the implementation of the Convention. CBD, *supra* note 15, art. 25. Its functions include providing assessments of the status of biological diversity, providing assessments of the types of measures taken in accordance with the provisions of the Convention, and responding to questions that the COP may put to the body. *Id.*

able deep seabed ecosystems with a view to the conservation and sustainable use of resources, and report on measures taken as part of the national reporting process.¹³⁷

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 parties of the CBD are called to play in the shaping of a regime for MGRs.¹³⁸ Moreover, the recently adopted Nagoya Protocol¹³⁹ recognizes the need of finding an “innovative solution,” addressing “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.”¹⁴⁰ This carefully worded expression seems to target genetic resources, such as MGRs, that do not fall under the jurisdiction of any state. This phrasing thus supports the view that the CBD applies to MGRs in areas beyond national jurisdiction.

II. A LEGAL REGIME FOR MGRS: FEASIBLE SOLUTIONS

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. Indeed, it is evident that a “national state” cannot be identified when dealing with MGRs in areas beyond national jurisdiction.

Generally, from developed nations’ perspectives, intellectual property is an essential incentive to invent and produce biotech products,¹⁴¹ the usefulness of which cannot be denied. As far as the G77 countries are concerned, the grant of patents for MGRs-based inventions gives rise to economic benefits that need to be equitably shared among the patent holder and the international community, with special consideration for the needs of developing countries.¹⁴²

137. 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*, ¶ 4(c) (2005), available at <http://www.cbd.int/recommendation/sbstta/?id=10967>.

138. 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*, ¶ 3 (2006).

139. See *supra* note 109.

140. *Nagoya Protocol*, *supra* note 109, pmb1.

141. LEARY, INTERNATIONAL LAW & DEEP SEA GENETIC RESOURCES, *supra* note 39, at 175.

142. *Id.*

Given the present unbalanced condition in the current legal regimes, 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.”¹⁴³ 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.”¹⁴⁴

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. Four legal solutions are identified in the first section (A): (1) the application of the Bonn Guidelines; (2) the hopeful entry into force of the Nagoya Protocol to the CBD; (3) the adoption of a disclosure of origin clause to be inserted in TRIPS; and (4) the adoption of a legal model inspired to the United Nations Food and Agriculture Organization (“FAO”) International Treaty on Plant Genetic Resources for Food and

143. Robert J. McLaughlin, *Exploiting Marine Genetic Resources beyond National Jurisdiction and the International Protection of Intellectual Property Rights: Can They Coexist?*, in LAW, TECHNOLOGY AND SCIENCE, *supra* note 13, at 379.

144. 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.

Scovazzi, *Seabed beyond the Limits of National Jurisdiction*, *supra* note 47, at 57. See also Salvatore Arico, *Marine Genetic Resources in Areas beyond National Jurisdiction and Intellectual Property Rights*, in LAW, TECHNOLOGY AND SCIENCE, *supra* note 13, at 385.

Agriculture.¹⁴⁵ Section (B) explores two institutional scenarios: (1) the attribution of a primary role to the Authority and (2) the creation of a new international institution.

A. Possible Legal Frameworks

1. 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.¹⁴⁶ 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.¹⁴⁷ Pursuant to the Guidelines, these terms should be agreed to on a case-by-case basis.¹⁴⁸ Mechanisms for benefit sharing should vary depending upon the type of benefits, the specificity of the resource at issue, the specific conditions in the country, and the stakeholders involved.¹⁴⁹ The National Focal Points should also develop framework agreements, as well as standardize material transfer agreements and benefit-sharing arrangements.¹⁵⁰ Pursuant to Paragraph 48, benefits should be fairly and equitably shared with all identifiable contributors to the resource management and to its scientific and commercial exploitation¹⁵¹ The latter “may include governmental, nongovernmental or academic institutions, as well as indigenous and local communities.”¹⁵² Moreover, “[b]enefits should be directed in such a way as to promote conservation and sustainable use

145. International Treaty on Plant Genetic Resources for Food and Agriculture, Nov. 3, 2001, 2400 U.N.T.S. 303 [hereinafter ITPGRFA].

146. Chambers, *supra* note 107, at 316; Jeffery, *supra* note 100, at 747; Thomas, *supra* note 100, at 250; Tully, *supra* note 107, at 84.

147. *Bonn Guidelines*, *supra* note 107, ¶ 13.

148. *Id.* ¶ 41.

149. *Id.* ¶ 42.

150. *Id.* ¶ 42(b)(iii)–(iv).

151. *Id.* ¶ 48.

152. *Id.*

of biological diversity.”¹⁵³ Likewise, pursuant to Paragraph 43(a), ethical concerns of parties and stakeholders should be taken into consideration in drafting the mutually agreed-on terms.¹⁵⁴ Parties and stakeholders should define the conditions, obligations, procedures, types, timing, distribution, and mechanisms upon which benefits should be shared.¹⁵⁵ These will vary depending on what is regarded as fair and equitable in light of the circumstances. Near-term, medium-term, and long-term benefits should be considered and monetary and nonmonetary benefits may be agreed upon.¹⁵⁶ 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 these means are 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.¹⁵⁷ Finally, notable among Bonn’s suggested means is the payment of royalties,¹⁵⁸ which could be considered to be in line with the system provided for by Article 82 of UNCLOS.

This latter provision sets in place a mechanism for an international royalty to be levied for the exploitation of nonliving resources of the continental shelf beyond 200 nautical miles.¹⁵⁹ Article 82 UNCLOS provides that coastal states shall make payments or contributions in respect of their exploitation and establishes the rate and the formula according to which the amount shall be calculated.¹⁶⁰ Moreover, it provides that pay-

153. *Id.*

154. *Id.* ¶ 43(a).

155. *Id.* ¶ 45.

156. 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, ¶ 1. The list of nonmonetary 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, ¶ 2.

157. *Id.* ¶¶ 43–50.

158. *Id.* app. II, ¶ 1(d).

159. UNCLOS, *supra* note 14, art. 82.

160. *Id.*

ments shall be made through the Authority, which shall distribute them to parties, on the basis of equitable sharing criteria and with special regard to the needs of developing states, least developed states, and land-locked countries.¹⁶¹

As to the application of such a mechanism, it has been noted that “this revenue-sharing formula was developed with the unique characteristics of offshore oil and gas production in mind, but there is no reason why an appropriate formula could not also be found for revenues from commercialization of MGRs,” which at that time were not yet discovered.¹⁶² In our view, the definition of formulas and rates according to which benefits should be shared represents an interesting and useful compromise between intellectual property protection and equity needs claimed by developing countries. Unfortunately, when applied to MGRs, such a method ineluctably faces difficulties due to the lack of an authority competent to manage their utilization, to authorize and discipline their exploitation and, consequently, to receive the amount of money deriving from the sharing of the economic benefits accrued. Should an institution gain such competences in the future, this solution could be taken into consideration.

2. MGRs and the Nagoya Protocol

The possible approaches outlined in the Bonn Guidelines could be further strengthened by the Nagoya Protocol’s entry into force. 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. The content of many of its articles is either directly inspired or influenced by the Bonn Guidelines.

As far as MGRs are specifically concerned, after long debates, the negotiating parties agreed to introduce a provision—Article 10—dealing expressly with sharing of benefits that arise from the utilization of genetic resources in transboundary situations or from uses for which it is not possible to grant or obtain prior informed consent.¹⁶³ Therefore, notwithstanding the fact that many parties opposed the inclusion of MGRs in the application of the Protocol, it eventually applies also to their exploitation.¹⁶⁴

161. *Id.* art. 82, ¶ 4.

162. McLaughlin, *supra* note 143, at 381.

163. *Nagoya Protocol*, *supra* note 109, art. 10.

164. Int’l Institute for Sustainable Dev., *Summary of the Resumed Ninth Meeting of the Working Group on Access and Benefit-Sharing of the Convention on Biological Diversity: 10-16 July 2010*, in 9 IISD REPORTING SERIES 257, at 4–5 (July 19, 2010), available at www.iisd.ca/biodiv/rabs9.

The relationship between the Protocol and other international instruments is one of the most controversial points that arose during the negotiations.¹⁶⁵ The parties agreed on the final draft of Article 4, which has a complex structure that breaks into four paragraphs. The first paragraph is directly inspired by the coordination clause provided in Article 22 of the CBD and establishes that the present instrument “shall not affect the rights and obligations of any party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity.”¹⁶⁶ Further paragraphs provide for the Nagoya Protocol’s implementation in a “mutually supportive manner” with other relevant international instruments and, in particular, with those specialized on access and benefit sharing.¹⁶⁷ In this regard they follow the Cartagena Protocol on Biosafety¹⁶⁸—the first Protocol to the CBD—in demanding mutual support as a tool of interpretation.¹⁶⁹ However, the Nagoya Protocol differs by giving the provision on mutual support a broader ambit and an expressly binding character, as it is not limited to a general and preambulatory statement. Moreover, according to Paragraph 3, “useful and relevant ongoing work or practices under international instruments and relevant organizations” deserve due regard in implementing the Protocol.¹⁷⁰ The only situation in which the Nagoya Protocol is explicitly subjected to the application of other international instruments is set forth in Paragraph 4; namely, the Protocol shall not apply to states which are at the same time parties to another international instrument providing for the access and benefit-sharing regime of a specific genetic resource, when this latter instrument is consistent with the letter and purpose of the CBD and the Nagoya Protocol.¹⁷¹ Therefore, the formulation of Article 4 gives the parties discretion as to how they wish to deal with the management of MGRs, either through the application of already existing and consistent legal instru-

165. *Id.*

166. *Nagoya Protocol*, *supra* note 109, art. 4, ¶ 1.

167. *Id.* ¶¶ 2–3.

168. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, 2226 U.N.T.S. 208 [hereinafter *Cartagena Protocol*].

169. On this topic, see Laurence Boisson de Chazournes & Makane Moïse Mbengue, *A propos du principe du soutien mutuel: Les relations entre le Protocole de Cartagena et les accords de l'OMC [The Principle of Mutual Support: The Relation between the Cartagena Protocol and the WTO Agreements]*, 111 REVUE GÉNÉRALE DE DROIT INTERNATIONAL PUBLIC 829 (2007) (Fr.).

170. *Nagoya Protocol*, *supra* note 109, art. 4, ¶ 3.

171. *Id.* art. 4, ¶ 4.

ments, or by way of the future adoption of a specific and consistent one.¹⁷²

The Nagoya Protocol goes further than the Bonn Guidelines in establishing the issuance of internationally recognized certificates by the competent national authorities.¹⁷³ It also provides for their notification to the Access and Benefit-Sharing Clearing House, a mechanism established by the Protocol as part of the Clearing House mechanism set out in Article 18.3 CBD.¹⁷⁴ Such certificates shall show that the genetic resource has been obtained, accessed, and used in accordance with prior informed consent, and that mutually agreed-upon terms have been entered into.¹⁷⁵ The certificates shall contain minimum information, such as the identities of the issuing national authority, the provider, and the user. Moreover, they shall specify the subject matter covered and the geographic location of the access activity, the uses permitted and the correspondent restrictions, as well as the conditions of transfer to third parties.¹⁷⁶ Lastly, the certificates shall contain a link to the mutually agreed-on terms regulating the benefit sharing.¹⁷⁷

The Protocol provides that parties shall establish clear rules and procedures for mutually agreed-on terms.¹⁷⁸ 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.¹⁷⁹ Accordingly, parties shall encourage the development, update, and use of model contractual clauses for mutually agreed-upon 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.¹⁸⁰ The Protocol likewise provides that parties shall take measures to monitor the utilization of genetic resources, for instance, by establishing checkpoints and disclosure requirements.¹⁸¹

The Nagoya Protocol addresses the specific cases in which access and benefit sharing of genetic resources occur in transboundary situations or

172. *Id.* art. 4, ¶¶ 1, 2, 4.

173. *Id.* art. 6, ¶ 3(e), art. 13, ¶ 2, art. 17, ¶¶ 2–4.

174. *Id.* art. 6, ¶ 3(e), art. 14, ¶ 2(c).

175. *Id.*

176. *Id.* art. 17, ¶ 4.

177. *Id.*

178. *Id.* art. 5, art. 6, ¶ 3(g), art. 18.

179. *Id.* annex.

180. *Nagoya Protocol, supra* note 109, arts. 19–20.

181. *Id.* art. 17.

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.¹⁸² The parties agree to further develop its functional modalities according to their needs.¹⁸³ 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.¹⁸⁴

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 to be 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 Mechanism and the issuance of internationally recognized certificates.¹⁸⁵ 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 internationally recognized certificates would certainly contribute to guaranteeing their correct administration and to avoiding abuses.

3. 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 TRIPS relevant provisions.¹⁸⁶ Negotiations are still underway since the topic gives rise to strong debates between developed and developing countries.¹⁸⁷ Up to now, the main outcome of such negotiations is a

182. *Id.* art. 10.

183. *Id.*

184. *Id.*

185. *Id.*

186. Doha Declaration, *supra* note 20, ¶ 19.

187. 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

proposition to insert a “disclosure of origin clause” within 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 provider countries.¹⁸⁸ However, as we will see below, negotiations are still ongoing and show a certain unpredictability with regard to the formulation and the actual insertion of the clause.¹⁸⁹

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.¹⁹⁰ Others, in particular developing countries, pushed in favor of amending TRIPS, in order to insert a disclosure of origin clause.¹⁹¹ As we will see, some other WTO member countries have since significantly modified their positions.¹⁹² 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),¹⁹³ and Switzerland, who supported the insertion of a disclosure of origin clause in the Patent Cooperation Treaty,¹⁹⁴ out of the WTO forum.¹⁹⁵

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*].

188. On the insertion of a disclosure of origin clause, see BONADIO, *supra* note 63; Graham Dutfield, *Sharing the Benefits of Biodiversity: Is there a Role for the Patent System?*, in *THE WTO, TRADE, AND THE ENVIRONMENT* 511 (Gary Sampson & John Whalley eds., 2005); Martin 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 *J. WORLD INTELL. PROP.* 451 (2004); Michael I. Jeffery, *Intellectual Property Rights and Biodiversity Conservation: Reconciling the Incompatibilities of the TRIPS Agreement and the Convention on Biological Diversity*, in *INTELLECTUAL PROPERTY AND BIOLOGICAL RESOURCES*, *supra* note 63, at 186–87. See generally Jacques de Werra, *Fighting against Biopiracy: Does the Obligation to Disclose in Patent Applications Truly Help?*, 42 *VAND. J. TRANSNAT’L L.* 143, 146–50 (2009).

189. See *supra* note 187.

190. See *TRIPS Agreement & Biological Diversity Convention*, *supra* note 187.

191. *Id.*

192. *Id.*

193. *Id.*

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

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").¹⁹⁶ The sponsoring states proposed to amend TRIPS through the insertion in the text of a mandatory disclosure of origin requirement.¹⁹⁷ According to the DMT, in order to comply with the latter requirement, either the provider country or the source of the genetic resources shall be disclosed in patent applications.¹⁹⁸

The insertion of the fourth mandatory requirement for patentability (additional to novelty, inventive step, and industrial application) 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,¹⁹⁹ and it would avoid burdensome opposition and revocation procedures being eventually perceived as the only means for obtaining, even if *ex post*, that patents comply with the essential requirements and the fundamental values guaranteed under the *ordre public* exception.²⁰⁰

However, due to the vagueness of DMT, the following consultations "have not created convergence [but] have certainly shed light on the divergences."²⁰¹ 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. Additional-

195. See *TRIPs Agreement & Biological Diversity Convention*, *supra* note 187.

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

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

198. *Id.*

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

200. See Bonfanti, *supra* note 69; Gold, *supra* note 69, at 15; MILLS, *supra* note 69; M.B. RAO & MANJULA GURU, BIOTECHNOLOGY, IPRs AND BIODIVERSITY 211-14 (2007); LI WESTERLUND, BIOTECH PATENTS: EQUIVALENCE AND EXCLUSIONS UNDER EUROPEAN AND U.S. PATENT LAW (2002).

201. 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.

ly, debates include the legal character and enforcement possibilities of a national based approach.²⁰² Each of the debated points is crucial for patents on MGRs. Indeed, a provision with a narrow definition of “misappropriation” (e.g., taking into account only illegal or illegitimate acts on those genetic resources which are located under the national jurisdiction of states) would clearly render the disclosure of origin clause unsuitable for MGRs. Moreover, the additional administrative costs deriving from incorporating the mandatory disclosure requirement might be excessively detrimental for investment and research development. This would clearly discourage states from insisting on its insertion as a requirement for patentability. Finally, should alternative solutions (such as national-based mechanisms or contract-based measures) be considered as more effective and less costly, the possibility of inserting a disclosure of origin clause would probably be put aside.

The debate has not yet been settled and the situation has not yet concretely evolved after the adoption of the Nagoya Protocol.²⁰³ The Doha Round is still open and new consultations have begun. 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 benefits. However, in the unlikely event that such an outcome is reached, it could be very useful for the management of MGRs. Indeed, it would ensure the enforcement of the CBD’s obligations when patent applications on MGRs are filed by requiring mutually agreed-on terms on access and fair and equitable benefit-sharing. Nonetheless, it appears clear that in order for a disclosure of origin clause to be implemented and function properly, a centralized institution on the international level would have to be implemented and have the ability to enforce the patentability requirements.

4. 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

202. See *Report on the Extension of the Protection of Geographical Indications*, *supra* note 187.

203. *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.

("ITPGRFA").²⁰⁴ 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.²⁰⁵

The treaty establishes the Multilateral System, set forth in Article 10,²⁰⁶ which aims at facilitating access to genetic resources and providing for the fair and equitable sharing of the benefits arising from their use.²⁰⁷ Pursuant to Article 12, 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.²⁰⁸ Recipients cannot claim any intellectual property or other rights that limit

204. ITPGRFA, *supra* note 145. The ITPGRFA contracting parties number 123; neither Japan nor the United States have ratified it, even though the United States is a signatory as of 2002. *Id.* For more information on the ITPGRFA, see Chambers, *supra* note 107; see also Carlos 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 WORLD INTELL. PROP. 795 (2003); Luigi 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 NON-COMPLIANCE PROCEDURES AND MECHANISMS AND THE EFFECTIVENESS OF INTERNATIONAL ENVIRONMENTAL AGREEMENTS 137, 137–52 (Tullio Treves et al. eds., 2009); Christine Frison, Tom Dedeurwaerdere & Michael 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. 1 (2010); Christiane 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 J. WORLD INTELL. PROP. 259 (2007); Muriel Lightbourne, *The FAO Multilateral System for Plant Genetic Resources for Food and Agriculture: Better than Bilateralism?*, 30 WASH. U. J.L. & POL'Y 465, 467–71 (2009); Riccardo Pavoni, *Accesso alle risorse fitogenetiche e diritti di proprietà intellettuale dopo il trattato della FAO del 2001 [Access to Plant Genetic Resources and Intellectual Property Rights after the FAO Treaty in 2001]*, 58 LA COMUNITÀ INTERNAZIONALE 369 (2003) (It.).

205. ITPGRFA, *supra* note 145, art. 1, ¶ 1.

206. *Id.* art. 10.

207. *Id.* art. 10, ¶ 2. The ITPGRFA covers the resources listed in Annex I, which are under the control of the contracting parties and in the public domain, as well as those genetic resources held in the *ex situ* collections of the International Agricultural Research Centers of the Consultative Group of the International Agricultural Research. *See id.* annex I. The Multilateral System can also apply, on a voluntary basis, to plant genetic resources for food and agriculture held by natural and legal persons within the jurisdiction of the contracting parties, and to those held by international institutions, other than the Centers, with which the Governing Body for the International Treaty will have concluded agreements for the purposes of the Treaty. *See id.*

208. *Id.* art. 12, ¶ 3(a).

access to the resources from the Multilateral System, or their genetic parts or components.²⁰⁹

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”).²¹⁰ The content of the SMTA complies with the ITPGRFA’s relevant provisions. Indeed, it states that the provider shall accord access to genetic resources expeditiously. On the other hand, the recipient shall undertake that the resources accessed be used or conserved only for the purposes allowed by ITPGRFA. SMTA also 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),²¹¹ or according to alternative payment schemes defined within the SMTA.²¹² Articles 13 of ITPGRFA and 6.9 of SMTA set forth additional terms, including but not limited to, such requirements that the recipient: make all nonconfidential information that results from research and development carried out on the resources supplied available to the Multilateral System; share nonmonetary benefits that result from such research and development; and facilitate access to technologies for conservation and use of genetic resources.²¹³

209. *Id.* art. 12, ¶ 3(d). According to Chambers:

This question was one of the main sticking points between the United States and developing countries in the Plant Genetic Treaty negotiations. The United States did not want to preclude the possibility of its companies isolating a gene—such as a reagent, a cell line or DNA sequencing—or a microbe from genetic material and patenting it.

Chambers, *supra* note 107, at 319.

210. *Id.* art. 12, ¶ 4. 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) [hereinafter SMTA], available at <ftp://ftp.fao.org/ag/agp/planttreaty/agreements/smta/SMTAe.pdf>. See Claudio Chiarolla, *Plant Patenting, Benefit Sharing and the Law Applicable to the Food and Agriculture Organisation Standard Material Transfer Agreement*, 11 J. WORLD INTELL. PROP. 1 (2008); Charles Lawson, *Intellectual Property and the Material Transfer Agreement under the International Treaty on Plant Genetic Resources for Food and Agriculture*, 31 EUR. INTELL. PROP. REV. 244, 244–45 (2009).

211. ITPGRFA, *supra* note 145, art. 19, ¶ 3(f), art. 6, ¶¶ 7, 8; SMTA, *supra* note 210, annex 2.

212. SMTA, *supra* note 210, art. 6, ¶ 11, annexes 3–4.

213. ITPGRFA, *supra* note 145, art. 13.

Therefore, the ITPGRFA provides a workable model for MGRs and a useful compromise for the drafting of a specific legal regime.²¹⁴ 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-upon 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 authority supervision, such as the Governing Body, would ensure that equitable results are obtained.²¹⁵ 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,”²¹⁶ a “trust fund” for payments received could be instituted as a means for guaranteeing the enforcement of the benefit-sharing obligation.

214. 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, ¶¶ 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. Working Group, *EU Intervention on Agenda Item 5.g, supra* note 144, 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 85, ¶¶ 112–13.

215. ITPGRFA, *supra* note 145, art. 12, ¶ 4.

216. LEARY, INTERNATIONAL LAW & DEEP SEA GENETIC RESOURCES, *supra* note 39, at 176.

B. Institutional Solutions

1. Attributing a Primary Role to the Authority

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. Some suggest that the Authority should be the governing international body for MGRs.²¹⁷

Due to the fact that the commercial value of MGRs was unknown by UNCLOS negotiators and that in 1970 the U.N. General Assembly declared all the Area the common heritage of mankind beyond its mineral resources, MGRs can thus fall within the common heritage regime.²¹⁸ This “dynamic” interpretation of UNCLOS 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 create 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 UNCLOS text as far as the mandate of the Authority is concerned has been suggested.²¹⁹ As it stands, the composition of the Authority is oriented towards the mineral industry.²²⁰ A change in the Authority’s makeup has to be decided either by amendment or through a second agreement for the implementation of Part XI.²²¹ This would demand an unlikely diplomatic effort in light of the contrasting positions supported by UNCLOS states parties and the above mentioned

217. Louise A. de La Fayette, Commentary, *Institutional Arrangements for the Legal Regime Governing Areas Beyond National Jurisdiction – Commentary on Tullio Scovazzi*, in *THE INTERNATIONAL LEGAL REGIME*, *supra* note 43, at 79.

218. *Id.*

219. “Nothing prevents States from expanding the mining focus of the ISA and granting to it some broader management competences within the Area.” See Scovazzi, *Seabed Beyond the Limits of National Jurisdiction*, *supra* note 47, at 59.

220. Treves, *supra* note 43, at 13–14.

221. 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 July 28, 1994, 1896 U.N.T.S. 41 (140 UNCLOS states parties are also parties to this Agreement).

doctrinal debates on MGRs' legal status. Moreover, such a solution would also exclude states that are not parties to UNCLOS, but who still have an interest in MGRs. Conversely, it might induce nonparties to ratify the convention. In terms of institutional economics, this solution is interesting because it builds on an existing system and an existing structure.

However, the Authority is not party to the CBD and cannot become one; according to Article 34, only states and regional economic integration organizations can become parties.²²² 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."²²³ However, the Authority 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.²²⁴ Stakeholders interested in the exploitation of such resources (both states and private actors) should support the involvement of the Authority in the concrete management of the MGRs, which by default implies its involvement in the broader debate.²²⁵ The Authority, with its competences and co-operative role,²²⁶ 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*."²²⁷ 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 Authority.²²⁸

222. CBD, *supra* note 15, art. 34, ¶ 1.

223. UNCLOS, *supra* note 14, art. 145.

224. Tullio Scovazzi, *Mining, Protection of the Environment, Scientific Research and Bioprospecting: Some Considerations on the Role of the International Sea-Bed Authority*, 19 INT'L J. MARINE & COASTAL L. 383 (2004) [hereinafter Scovazzi, *Mining, Protection of the Environment, Scientific Research and Bioprospecting*].

225. Matz-Lück, *supra* note 113, at 72; Scovazzi, *supra* note 224, at 399–407.

226. Scovazzi, *Mining, Protection of the Environment, Scientific Research and Bioprospecting*, *supra* note 224, at 407–08.

227. *Nagoya Protocol*, *supra* note 109, art. 4, ¶ 3 (emphasis added).

228. *Id.* 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, UNCLOS, or TRIPS). An inter-systemic approach and a systemic interpretation of the relevant provisions might then be the solution.

2. Implementation Agreements or Management Convention Alternatives

Two alternative options exist in which the Authority 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”).²²⁹ 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.”²³⁰ A specialized instrument might contain such a mechanism and would likewise be consistent with the Nagoya Protocol.²³¹

(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.²³² Both regimes are *leges speciales* in respect to the high seas general regime in the sense

229. 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 Dec. 11, 2001) [hereinafter Straddling Stocks Agreement]. Seventy-seven UNCLOS parties have also ratified the Straddling Stocks Agreement. See *Chronological Lists of Ratifications of, Accessions and Successions to the Convention and the Related Agreements as at June 3, 2011*, U.N., http://www.un.org/depts/los/reference_files/chronological_lists_of_ratifications.htm (last updated June 3, 2011).

230. *Nagoya Protocol*, *supra* note 109, art. 10.

231. *Id.* art. 4, ¶¶ 2–4.

232. Treves, *supra* note 43, at 13–15.

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 interest. 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,²³³ 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.²³⁴

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 "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 rele-

233. SBSTTA, *supra* note 137. 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.

234. SBSTTA, *supra* note 137, ¶4(f).

vant 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 UNCLOS 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 Authority but open to representation by other interests.

The creation of a centralized body by the ad hoc agreement would establish an authority 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 and 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, UNCLOS, 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 meetings of the others.

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.²³⁵ As it stands, the law of the sea plays the role of “equalizer” among maritime nations of the world.²³⁶ UNCLOS specifically creates mechanisms for balancing interests and sometimes redistributing benefits deriving from maritime economic activities.²³⁷ 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 fair and equitable benefit sharing. It might in the end indeed be suitable to have a “common heritage without mentioning it.”²³⁸

235. 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 LEARY, *INTERNATIONAL LAW & DEEP SEA GENETIC RESOURCES*, *supra* note 39, at 100.

236. Jay L Batongbacal, *The Law of the Sea, Marine Technology and Global Social Justice*, in *THE FUTURE OF OCEAN REGIME-BUILDING, ESSAYS IN TRIBUTE TO DOUGLAS M. JOHNSTON* 105, 116 (Aldo Chircop et al. eds., 2009).

237. See also UNCLOS, *supra* note 14, arts. 87, 124–91, speaking to 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.

238. See Treves, *Principles and Objectives*, *supra* note 43, at 23.