
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

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As the possibility for ocean exploration increases, so do infinite cures to deadly human diseases through the development and cultivation of unique marine life. Several questions exist, however, regarding organisms found within the ocean's seabed, floor, and subsoil beyond national jurisdictions. Such organisms, called marine genetic resources ("MGRs"), were the topic of discussion and concern at the recent United Nations Informal Consultative Process on the Oceans and the Law of the Sea ("UNICPOLOS") held in New York from June 25-29, 2007 and are presently being addressed within the sixty-second session of the United Nations General Assembly. This article expands on the discussions of the UNICPOLOS meeting by exploring the substance and patentability of MGRs in international intellectual property law and by evaluating the current ownership debate within maritime law between developed and developing countries. Further, this article proposes a pragmatic solution through compulsory licensing mechanisms within international intellectual property law in order to promote research and development of essential pharmaceuticals and to provide benefits to both developed and developing countries.

Recent interest in MGRs has stemmed from the invention of new oceanographic technology, allowing scientists and researchers to collect MGR samples from deeper and more remote areas of the ocean than ever before. After minimal study, scientists have found that these areas, specifically areas surrounding hydrothermal vents, breed organisms whose unique genetic structures have the potential to counter deadly human diseases such as several kinds of cancer and HIV/AIDS. MGRs have shown 100% more potential than terrestrial organisms in curing cancers and are believed by many scientists to provide future cures, thereby generating substantial revenue to pharmaceutical companies.

Unfortunately, due to the high cost of oceanographic excavation, estimated at one billion dollars per episode, developed countries have held a monopoly on such excavation technologies and the MGRs collected there from. As many valuable MGRs have been harvested from areas beyond national jurisdictions, however, developing countries also seek ownership rights in MGRs. This article articulates the arguments of both developed and developing countries regarding

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the ownership debate and examines whether the United Nations Convention on the Law of the Sea is the proper authority to regulate MGR ownership.

Significant challenges also exist regarding patentability of MGR genetic derivatives within international and national intellectual property laws. Several national legislatures and courts, including those within the United States, have recently revised and refined the limits of gene patenting, making it more difficult to receive monopolistic rights over fragments and strands of genetic material. This article explores the depths of gene patent reform, specifically within the United States and the European Union, and suggests practical solutions to ensure patentability of MGRs.

At this moment, the settlement of MGR ownership rights is being debated in formal and informal consultations in the 62nd session of the United Nations General Assembly. Currently, a proposal is under consideration in the General Assembly, requesting that ownership of MGRs be placed beyond national jurisdictions and be shared among all countries. If this proposal is adopted however, it could severely discourage excavation of MGRs. Instead, this article proposes an alternative solution through compulsory licensing mechanisms within international intellectual property law in order to promote research and development of essential pharmaceuticals and to provide benefits to both developed and developing countries.¹

I. Introduction

Within the last thirty years, oceanographers and biologists have been able to explore the ocean and its organisms through the help of advanced oceanographic technologies. Specifically, J. Craig Venter, a pioneer in the field of bioprospecting,² recently launched the Sorcerer II Expedition to collect and culture microorganisms in hopes of discovering useful genetic materials.³ Such explorations have resulted in the discovery of several new kinds of MGRs, from which valuable genetic material has been extracted and adapted for use in the pharmaceutical, cosmetic, and bioremediation (chemical waste treatment) industries. As of 2007, more than 15,000 molecules have been isolated and described as a result of MGR exploration and collection.⁴ Due to their unique characteristics, MGRs have al-

¹ Although the following article was inspired from the World Intellectual Property Organization's role in the debate on marine genetic resources in the United Nations Informal Consultative Process on Oceans and the Law of the Sea, the ideas reflected in this paper are solely that of the author, not the World Intellectual Property Organization. Creation of this Article article began through my internship with the World Intellectual Property Organization under the supervision of Mr. S. Rama Rao.

² Implementing Rules and Regulations of Republic Act 9147, Rep. Act No. 7611, § 5(a) (May 18, 2004) (Phil.) (defining "Bioprospecting" as the research, collection and utilization of biological and genetic resources for purposes of applying the knowledge derived there from solely for commercial purposes).

³ J. Craig Venter Institute, Sorcerer II Expedition, <http://www.sorcerer2expedition.org/version1/HTML/main.htm> (last visited June 16, 2008).

⁴ The Secretary-General, *Report of the Secretary-General on Oceans and the Law of the Sea*, ¶ 127, delivered to the General Assembly at the sixty-second session, U.N. Doc. A/62/66 (Mar. 12, 2007) [hereinafter *Oceans and the Law of the Sea*].

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ready shown great potential as anti-cancer and anti-HIV/AIDS drugs and are viewed by many as organisms of significant future value.

However, obtaining the oceanographic technology, scientific expertise, and lab capacity makes extraction and cultivation of MGRs a lengthy and expensive process. Accordingly, very few countries have, thus far, produced the necessary capital, technology, and scientific expertise to obtain MGRs.

Moreover, intellectual property rights laws can create monopoly rights within countries, for companies, and scientists with extensive monetary and scientific resources. The resulting lopsided situation creates a division between developed countries and developing countries (including the least developed countries) as to who can afford to retrieve, and thus benefit from, MGR extraction.

The main point of contention between developed countries and developing countries relates to the legal ownership rights of MGRs beyond national jurisdictions. This debate was the paramount and insurmountable issue in the eighth meeting of the United Nations Open-ended Informal Consultative Process on Oceans and the Law of the Sea. Interpretation of relevant provisions of the United Nations Convention on the Law of the Sea (the Convention) was a mainstay of the UNICPOLOS proceedings. More specifically, the point of disagreement among Convention participants is whether the Convention governs MGRs, even though the term MGR is not specifically enumerated nor described within the Convention.

On one hand, developing countries adopt a broad view, stating that the Convention includes, and thus regulates, MGRs. Following such interpretation, the extraction of MGRs and the subsequent benefit from extraction would belong to the Common Heritage of Mankind (“CHM”) and would be regulated by the International Seabed Authority (“ISA”). In contrast, developed countries hold a narrow view, stating that the Convention excludes MGRs from its domain. They wish to adopt a first come, first served system; open to all countries, organizations, scientists, etc., with the technology and skill to extract and cultivate MGRs.

Despite recent negotiations in the UNICPOLOS, the MGR debate remains an unsettled, yet vital legal issue with respect to potential future pharmaceutical and monetary benefits derived from MGRs. While there appears to be a need to share the benefits derived from MGRs, the greater need is to cultivate life-saving pharmaceuticals. Thus, within the confines of international law and intellectual property law, perhaps the best solution for developed and developing countries is to focus on cultivating the pharmaceutical benefits of MGRs, and then to create compulsory licensing and benefit sharing regimes so as to maximize global profit from MGRs.

II. The Basics of Marine Genetic Resources

A. Definition of Marine Genetic Resources

Neither the Convention, nor any other international source of law has defined MGRs. However, the Convention on Biological Diversity (“CBD”) offers a definition that provides some guidance. The CBD defines “genetic resources” as,

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“genetic material of actual or potential value.”⁵ It further defines “genetic material” as, “any material of plant, animal, microbial or other origin containing functional units of heredity.”⁶ This broad definition is meant to encompass the vast potential of undiscovered MGRs.

In the recent UNICPOLOS meeting, various scientists presented their views about MGRs to aid in furthering a more specific MGR definition. Panelists represented institutions such as the Smithsonian Institute, the Woods Hole Oceanographic Institution in the United States, the Australian Institute of Marine Science, the Queensland Museum & Natural Products Discovery, Griffith University in Australia, and the French Research Institute for Exploitation of the Sea, as well as PharmaMar, a pharmaceutical company.

Panelists explained that the importance of MGRs result from the unique DNA or RNA strands that are extracted, cultured, and replicated in the laboratory. Once simplified in a laboratory, the replicated strands are then likened to other organisms to determine specific uses for the MGR derivatives. Research indicates that MGR organisms containing such valuable DNA or RNA can consist of both macro-organisms and micro-organisms, including bacteria,⁷ algae, fungi, yeasts, and viruses.⁸ Mammals, fish, invertebrates, and plants are also being considered MGRs.⁹

B. Location of Marine Genetic Resources

Although discovery of MGRs is in its infancy, several UNICPOLOS panelists reported that MGRs have been most commonly found near hydrothermal vents on the deep sea bed.¹⁰ Deep sea hydrothermal vents are also predicted to yield the majority of future MGRs.¹¹ As reported by the International Cooperation in Ridge-Crest Studies (“InterRidge”), hydrothermal vents are areas associated with

⁵ Convention on Biological Diversity, art. 2, June 5, 1992, 1760 U.N.T.S. 146, 31 I.L.M. 818 (1992).

⁶ *Id.*

⁷ Although, bacteria that are incapable of replication outside of their natural environment are not considered MGRs by some scientists.

⁸ *Oceans and Law of the Sea*, *supra* note 4, at ¶ 132.

⁹ Harlan K. Cohen, Advisor, for Ocean Governance and International Institutions at the International Union for Conservation of Nature and Natural Resources to the United Nations, statement presented at the United Nations Informal Consultative Process on Oceans and Law of the Sea: Ensuring Conservation and Sustainable Use of Marine Genetic Resources: Current and Future Challenges (June 27, 2007), abstract and presentation available at http://www.un.org/Depts/los/consultative_process/documents/8_abstract_cohen.pdf.

¹⁰ Margaret K. Tivey, Assoc. Scientist Marine Chemistry & Geochemistry of Woods Hole Oceanographic Inst., presenting work of Professor Colin Devey of InterRidge at the United Nations Informal Consultative Process on Oceans and Law of the Sea: InterRidge statement of commitment to responsible research practices at deep-sea hydrothermal vents (June 27, 2007), abstract available at http://www.un.org/Depts/los/consultative_process/documents/8_abstract%20tively_interridge.pdf, full-text of statement available at <http://www.interridge.org/irstatement> [hereinafter Devey].

¹¹ Libby Evans-Illidge, Manager Bioresources Library, Austl. Inst. of Marine Sci., statement at the United Nations Informal Consultative Process on Oceans and Law of the Sea: Towards a Practical Knowledgebase for Marine Genetic Resources (June 25, 2007), abstract available at http://www.un.org/Depts/los/consultative_process/documents/8_abstract_evans_illidge.pdf.

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tectonic and/or volcanic activity spouting from the earth's core, and are mostly found on the deep sea bed where the plates of the earth's surface continuously reform the sea-floor.¹² There are currently six main biogeographic areas within the Pacific, Atlantic, and Indian Oceans that are recognized by hydrothermal vent biologists.¹³ InterRidge predicts more hydrothermal vents will be found, specifically in the Arctic Ocean, as greater exploration progresses.¹⁴ While the possibility of hydrothermal vents shifting from inactive to active, and active to inactive, could threaten MGR life in these regions, such shifts are more likely to increase the opportunity for hydrothermal vent discovery over time across a wider geographical span.¹⁵

Due to their tectonic nature, areas of hydrothermal vents are very volatile and subject to extreme geological events such as tsunamis, volcanic eruptions and earthquakes.¹⁶ Extreme changes in temperature, pressure and hydrothermal fluid create difficult environments for sustainable life.¹⁷ Nevertheless, the majority of macro and micro-organisms living in hydrothermal vents have been able to convert hydrothermal vent fluid into useful chemical energy.¹⁸

Although many scientists do not understand how, MGRs have developed specific protectionist features to shield themselves from their harsh surroundings. Promisingly, scientists have proven that such adaptations can uniquely resist fatal human diseases.¹⁹ Genetic material extracted from MGRs have been tested for potential uses as anti-cancer drugs, anti-inflammatory drugs, anti-viral drugs, anti-leukemia drugs, anti-melanoma drugs, and many more.²⁰

C. Bioprospecting versus Biopiracy

While no definition of bioprospecting has been universally agreed upon²¹, it was defined by the Convention as, "research and development related to marine genetic resources."²² Practically speaking, bioprospecting is a search for MGRs, within or beyond the confines of national jurisdictions, of actual or potential value, often conducted by scientists (or scientific institutions) who add value to the process through their vast knowledge of general oceanographic research and marine genetic resources. At present, more than 15,000 molecules, including

¹² Devey, *supra* note 10.

¹³ *Id.*

¹⁴ *Id.*

¹⁵ *Id.*

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Oceans and the Law of the Sea*, *supra* note 4, at ¶ 164.

²¹ *Id.* at ¶ 150.

²² *Id.*

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algae and marine microbes, have been described and isolated from different marine resources.²³

Alternatively, biopiracy is bioprospecting within a foreign country's national jurisdiction without seeking permission for bioprospecting from that country's government.²⁴ Although biopiracy is a growing concern among many developing countries, this paper centers mainly on bioprospecting of MGRs beyond national jurisdictions. Even though the technology to collect MGRs exists, such technology is very expensive, estimated by UNICPOLOS panelists to cost around \$1 billion per expedition. As a result, bioprospecting occurs mostly in developed countries.

D. Multiple Uses of Marine Genetic Resources

1. *Pharmaceuticals*

The DNA and RNA derivatives extracted from MGRs have many uses such as antioxidant, antiviral, anti-inflammatory, anti-fungal, anti-HIV, antibiotic, anti-cancer, anti-tuberculosis, and anti-malarial purposes.²⁵ However, developing MGRs into patented pharmaceutical products, thus granting the patent owner temporary monopoly rights, requires that the genetic material derived from MGRs be synthesized in a lab and subjected to various testing procedures.

Before MGR derivatives are produced and sold as pharmaceuticals, they must complete preclinical testing, medicinal chemistry testing, and three phases of clinical trials: Phase I to measure safety, dose, and pharmacokinetics; Phase II to measure efficacy and tumor type; and Phase III encompassing large-scale and comparative studies.²⁶ If the test drug passes all three phases, the pharmaceutical company, through the scientist, typically applies for a patent (and/or trademark) with their national patent and trademark office. If intellectual property rights are granted, the product is then marketed by the pharmaceutical company to the public. The timeline to develop and market a new drug generally spans between fifteen and twenty years and can cost up to \$800 million dollars.²⁷ Unfortunately, after completing the entire process, the percentage of MGR derivatives that succeed to final clinical trials is less than 1%.²⁸ Overall, however, MGR

²³ *Id.* at ¶ 127.

²⁴ United Nations Univ. Inst. of Advanced Sci., *Tapping the Oceans' Treasures: Bioprospecting in the Deep Seabed*, available at <http://www.ony.unu.edu/seminars/2005/Bioprospectingoceans/Summary.doc>.

²⁵ *Oceans and the Law of the Sea*, *supra* note 4, at ¶ 164.

²⁶ Simon Munt, Medicinal Chemistry Manager, PharmaMar, presentation at the United Nations Informal Consultative Process on Oceans and the Law of the Sea: From Marine Expeditions to New Drugs in Oncology (June 26, 2007), abstract available at http://www.un.org/Depts/los/consultative_process/documents/8_abstract_munt.pdf.

²⁷ United Nations Univ. Inst. of Advanced Sci. and the United Nations Educ., Sci. and Cultural Org., report presented at the United Nations Informal Consultative Process on Oceans and the Law of the Sea: An Update on Marine Genetic Resources: Scientific Research, Commercial Uses and a Database on Marine Bioprospecting, § 4.2, (June 25, 2007), available at http://www.ias.unu.edu/resource_centre/Marine%20Genetic%20Resources%20UNU-IAS%20Report.pdf.

²⁸ Munt, *supra* note 26.

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samples show 100% greater potential, specifically as anti-cancer agents, than terrestrial samples.²⁹

Conotoxins are the most prominent MGRs to date that have been adapted into a pharmaceutical drug called Prialt.³⁰ Snail-like in form, the Conotoxin has the specific ability to kill prey using paralyzing peptides that act as potent calcium channel blockers.³¹ The Conotoxin's venom has been developed and adapted as drug treatment for intractable pain.³² Through Conotoxin's ability to target and block specific neuron channels, the drug Prialt has been adapted by scientists and pharmacists to pinpoint and suppress specific pain without altering the functions of the rest of the nervous system.³³ Thus, Prialt is used specifically by cancer patients.

In the shadow of Prialt, on the pharmaceutical horizon is an anti-cancer agent called Salinosporamide which is undergoing Phase I trials in the United States after highly successful preclinical evaluations.³⁴ Salinosporamide, derived from a species of streptomycete bacterium, called *Salinospira*, that produces small bioactive molecules, is a proven inhibitor of the human proteasome.³⁵ These molecules are able to break down the protein within cells and successfully kill cancer cells, making Salinosporamide of infinite value should it succeed past the three phases of clinical trials.

Also in the MGR pipeline are Cyanovirin and Dolastatin 10 and 15. Cyanovirin is an isolated protein from cyanobacteria, which is highly active in blocking cell entry of pathogenic viruses such as HIV and Hepatitis-C.³⁶ Dolastatin 10 and 15 are specific antitubulin molecules with great potential as anti-cancer agents, and are currently in Phase II clinical trials in the United States.³⁷

2. *Cosmetics*

Within the cosmetic industry, pigments, also derived from cyanobacteria, called Scytonemin, have been developed.³⁸ These pigments provide protection against Ultra Violet irradiation and have been considered for use, specifically in sunscreen and anti-inflammatory products.³⁹ Additionally, Pseudopterosin, de-

²⁹ *Id.* (quoting statistics from the U.S. Nat'l Cancer Inst. Estimates).

³⁰ David Rowley, Dep't. of Biomed. & Pharm. Sci., Univ. of R.I., presentation at the United Nations Informal Consultative Process on Oceans and the Law of the Sea: Services Provided by Marine Genetic Resources (June 25, 2007), abstract available at http://www.un.org/Depts/los/consultative_process/documents/8_abstract_rowley.pdf.

³¹ *Id.*

³² *Id.*

³³ Marinebiotech.org, Drugs from the Sea Index, *Ziconotide*, <http://www.marinebiotech.org/ziconotide.html> (last visited June 16, 2008).

³⁴ Rowley, *supra* note 30.

³⁵ *Oceans and the Law of the Sea*, *supra* note 4, at ¶ 164.

³⁶ *Id.*

³⁷ *Id.*

³⁸ *Id.* at ¶ 127.

³⁹ *Id.*

rived from the MGR *Pseudopterogorgia elisabethae*, commonly known as the “sea whip” plant, has been used in Estée Lauder skin care products to prevent skin irritation.⁴⁰ Pseudopterosin has also been used in the pharmaceutical arena where it has passed preclinical tests and awaits approval from the U.S. Food and Drug Administration.⁴¹

3. *Bioremediation*

Additionally, MGRs have been used in bioremediation.⁴² This concept is defined by the United Nations division to the Law of the Sea Report as “using living organisms, usually micro-organisms, for many applications in hazardous waste treatment and pollution control.”⁴³ Previously, MGRs used as industrial microbes have successfully removed dangerous chemical substances such as phenol, calcium, and chloride from the wastewater of industrial factories.⁴⁴ While industrial microbes continue to be developed from MGRs, they are currently developed at a slower rate than pharmaceutical and cosmetic developments.⁴⁵

III. The Connection between Intellectual Property and Marine Genetic Resources

International intellectual property is connected to the controversy over MGRs in several ways. Patents are the most common form of intellectual property protection discussed with regard to MGRs and will therefore be the focus of this article, however intellectual property rights conferred through trademarks could also be relevant.

With regard to MGRs, intellectual property protection provides a tool for defensive protection (strategies to prevent the acquisition of intellectual property rights by parties other than the customary custodians of the MGR DNA derivatives)⁴⁶ and positive protection of scientific and pharmacological inventions (active assertion of rights necessary to prevent undesirable use of MGR DNA derivatives by third parties).⁴⁷ According to one available source, products based on deep sea organisms have attained at least thirty-seven patents to date.⁴⁸ The

⁴⁰ Marinebiotech.org, Drugs from the Sea Index, *Pseudopterოსins*, <http://www.marinebiotech.org/pseudopterოსins.html> (last visited June 16, 2008).

⁴¹ *Id.*

⁴² *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

⁴³ *Oceans and the Law of the Sea*, *supra* note 4, at ¶ 168.

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, 11th Sess., July 3-12, 2007, *Reproduction of Document WIPO/GRTKF/IC/9/4 “The Protection of Traditional Cultural Expressions/Expressions of Folklore: Collation of Written Comments on the List of Issues”*, WIPO Doc. WIPO/GRTKF/IC/11/4(c) (Apr. 26, 2007), available at http://www.wipo.int/meetings/en/details.jsp?meeting_id=12522.

⁴⁷ *Id.*

⁴⁸ United Nations Environment Programme, Ecosystems and Biodiversity in Deep Waters and High Seas Report and Studies, No. 178, 21 (2006), http://www.iucn.org/themes/marine/pdf/unep_high_seas_130606_screen.pdf (last visited June 16, 2008).

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following sections illustrate the specific challenges of MGR DNA derivatives within current national patent regimes and within The Agreement on Trade-Related Aspects of Intellectual Property Rights, (“TRIPS”).⁴⁹

A. Patentable Subject Matter within the TRIPS Agreement

The TRIPS agreement is an international agreement administered by the World Trade Organization (“WTO”) for the protection of intellectual property rights.⁵⁰ The purpose of the TRIPS agreement is to unify national intellectual property laws to “reduce distortions and impediments to trade.”⁵¹ All members of the WTO are members of, and must comply with, the TRIPS agreement.⁵² The TRIPS agreement does not grant international patent protection, but seeks to align member states’ laws to provide clarity for inventors.

Under the TRIPS agreement, patent protection is granted for “inventions. . .in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.”⁵³ As such, mere discovery of a living organism as it exists in nature does not grant the discoverer patent protection over the organism. Thus, MGR organisms themselves cannot be patented. Additionally, it is questionable whether multi-cellular plants, or animals, or isolated and refined versions of naturally occurring DNA are patentable. Within national laws, in line with TRIPS, countries have taken various approaches to defining the patentability limits of genetic material.

1. *The United States*

Within the United States, “[w]hoever invents or discovers any new and useful . . . composition of matter, or . . . improvement thereof, may obtain a patent.”⁵⁴ The United States Supreme Court’s landmark case setting the standard for patentability of genetic material is *Diamond v. Chakrabarty*.⁵⁵ In *Chakrabarty*, a patent for a new form of microbacteria manufactured through gene combination was challenged on the grounds that microbacteria are nature, and nature is not patentable.⁵⁶ However, the Court held that the combination of naturally occurring genes into isolated and purified non-naturally occurring genes constituted a novel, useful, and non-obvious invention that met all patent require-

⁴⁹ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr.15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments – Results of the Uruguay Round, 33 I.L.M. 1125 [hereinafter *TRIPS Agreement*].

⁵⁰ *Id.* at 1197. pmb1.

⁵¹ *Id.*

⁵² There are 151 WTO members, including the United States, as of July 27, 2007. Understanding the World Trade Organization, Members, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited June 18, 2008).

⁵³ *TRIPS Agreement*, *supra* note 49, art. 27(1) at 1208.

⁵⁴ Patent Act of 1953, 35 U.S.C. §101 (West 2000).

⁵⁵ *Diamond*, *supra* note 42.

⁵⁶ *Id.* at 306.

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ments.⁵⁷ Thus, the patent in *Chakrabartry* was upheld within the meaning of §101 of the United States Patent Act.⁵⁸

Through this case, the Court also defined “utility” by requiring that invention uses be specifically stated or described, not just hypothesized.⁵⁹ Because the *Chakrabartry* microbacteria served specific bioremediation functions, it met the Court’s expanded definition of utility.⁶⁰

As *Chakrabartry* applies to MGRs, new and synthetic forms of MGR DNA are likely patentable within the United States, as long as they exist in an isolated and purified form that does not exist in nature,⁶¹ and as long as they meet the United States’ patent requirements of novelty, non-obviousness, utility, and disclosure.⁶² Further, uses of isolated and purified MGR DNA forms must be specific to receive patent protection. If granted, the patent would confer ownership rights over the new form of non-naturally occurring genetic material, however it would not confer any rights over the MGR from which the DNA was derived.

Within the United States, multi-cellular animals are also patentable providing that they do not occur in nature and that they meet all other patent requirements. A specific example is the Harvard OncoMouse, invented as a model for cancer research and study.⁶³ By inserting an “oncogene” into the genetic material of a mouse, scientists can test and identify suspected carcinogens at a faster rate than other such studies.⁶⁴ The United States Patent and Trademark office granted patent protection for the OncoMouse in 1988⁶⁵ and, to date, there have been no legal challenges regarding this patent within the United States. Thus, should scientists create a new form of multi-cellular organism derived from MGRs, this new form should receive patent protection within the United States, providing that it complies with all other patent requirements.

However, despite the many existing biotechnology and gene patents within the United States,⁶⁶ there is still substantial debate surrounding whether patents granted for isolated and refined DNA fragments actually meet all patent requirements. Before *Chakrabartry*, the United States Second Circuit upheld a patent in *Parke-Davis & Co v. H.K. Mulford & Co.* claiming protection for the naturally occurring hormone adrenaline.⁶⁷ In *Parke-Davis*, the court held that the isolated

⁵⁷ *Id.* at 309-10.

⁵⁸ *Id.*

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² 35 U.S.C.A. §§ 101, 103, 112 (West 2000).

⁶³ Case T 0315/03 – 3.3.8, *President & Fellows of Harvard College v. British Union for the Abolition of Vivisection*, Bds. of Appeal of the European Patent Office [EPO] (July 6, 2004), available at <http://legal.european-patent-office.org/dg3/pdf/t030315ex1.pdf> [hereinafter *OncoMouse*].

⁶⁴ *Id.*

⁶⁵ Leslie G. Restaino et al., *Patenting DNA-Related Inventions in the European Union, United States and Japan: A Trilateral Approach or a Study in Contrast?*, 2003 UCLA J.L. & TECH. 2 (2003).

⁶⁶ DNA patents can be researched in the DNA Patent Database. DNA Patent Database, <http://dna.patents.georgetown.edu/> (last visited on Feb. 16, 2008).

⁶⁷ *Parke-Davis & Co. v. H.K. Mulford & Co.*, 196 F. 496 (2d Cir. 1912).

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and refined version of adrenaline created a form not occurring in nature that could be used for specific medical treatments.⁶⁸ Citing *Parke-Davis* the United States Fourth Circuit also upheld a gene patent in *Merck & Co. v. Olin Mathieson Chemical Corp.* on similar grounds.⁶⁹ In *Merck*, the court upheld a patent for an isolated and purified strand of vitamin B12 stating, “[t]he fact. . . that a new and useful product is the result of processes of extraction, concentration and purification of natural materials does not defeat its patentability.”⁷⁰ While *Parke-Davis* and *Merck* are similar to *Chakrabarty* in their analysis regarding patent law interpretation, they differ in subject matter. *Parke-Davis* upheld a patent for a refined form of a naturally occurring hormone and *Merck* upheld a patent for an isolated form of a naturally occurring vitamin, whereas *Chakrabarty* involved combining genes to form a new invention of bacteria that did not occur in nature.⁷¹

As naturally occurring genetic material, isolated and purified strands and fragments of MGR DNA are most similar to the adrenaline or vitamin B12 cases. Thus, under *Parke-Davis*, *Merck*, and *Chakrabarty*, such MGR DNA derivative patents should be upheld, provided they meet all other patent requirements.

In a more recent case, however, a United States Federal Circuit Court held that substantially purified DNA fragments and strands of a naturally occurring maize protein did not satisfy the utility requirement necessary for patentability.⁷² Citing the Supreme Court’s definition of utility in *Brenner v. Manson*,⁷³ the Federal Circuit court in *In re Fisher* required that an invention have “substantial utility,” stating that, “[u]nless and until a process is refined and developed to the point – where specific⁷⁴ benefit exists in currently available form – there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.”⁷⁵ The *In re Fisher* court agreed with the patent examiner who concluded that the seven disclosed uses of purified DNA strands were generally applicable to any DNA strand or fragment, and not to these specific strands.⁷⁶ The court held that the substantially purified DNA fragments and strands of maize “act as no more than research intermediates” that may help in further experimentation, but that do not constitute specific and substantial uses and are therefore not patentable.

It is uncertain to what extent *In re Fisher* will affect patentability of isolated and purified DNA fragments and strands regarding MGRs. If applied narrowly,

⁶⁸ *Id.*

⁶⁹ *Merck & Co. v. Olin Mathieson Chemical Corp.*, 253 F.2d 156, 162 (4th Cir. 1958).

⁷⁰ *Id.* at 163.

⁷¹ Lori B. Andrews & Jordan Paradise, *Gene Patents: The Need for Bioethics Scrutiny and Change*, 5 YALE J. HEALTH POL’Y L. & ETHICS 403, 405 (2005).

⁷² *In re Fisher*, 421 F.3d 1365, 1379 (Fed. Cir. 2005).

⁷³ *Brenner v. Manson*, 383 U.S. 519 (1966).

⁷⁴ The terms “specific” and “substantial” are not further defined by the courts in *Brenner* or *In re Fisher*.

⁷⁵ *In re Fisher*, 421 F.3d at 1371.

⁷⁶ *Id.* at 1368.

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scientists might only need to distinguish specific uses of new isolated and purified MGR DNA forms from the specific uses of new maize forms to fall outside the ambit of *In re Fisher*. If applied broadly, however, the holding of *In re Fisher* could place a much greater burden of proof on scientists, requiring substantially more research and development before allowing patentability of new isolated and purified MGR DNA strands and fragments.

In a similar vein, the United States Congress addressed patentability of genetic material in the "Genomic Research and Accessibility Act."⁷⁷ This bill was introduced to the House of Representatives in February 2007, and is currently before the House Judiciary Committee.⁷⁸ The Act seeks to abolish patentability for whole or partial strands of isolated and purified DNA, although it would "grandfather-in" all existing gene patents including those not meeting the bill's new standards.⁷⁹ This legislation, like *In re Fisher*, creates uncertainty surrounding the patentability of strands and fragments of isolated and purified genetic material within the United States, suggesting a trend toward stricter patentability standards for genetic material.

However, *Chakrabartry* is still the landmark case in this field. Despite the proposed Act and *In re Fisher*, scientists who follow the *Chakrabartry* standard of gene invention, and who include a substantial and specific use for their invention, are more likely to ensure the patentability of their products over new isolated and purified MGR DNA derivatives.

2. *The European Union*

Although patentability within the European Union is similar to the United States system, important distinctions exist regarding patentability of genetic material. The Convention on the Grant of European Patents, commonly referred to as the European Patent Convention ("EPC"), is a multilateral treaty that establishes a system of law common to the Contracting States⁸⁰ for granting patents.⁸¹ While most signatories of the EPC are members of the European Union ("EU"),⁸² the EPC and EU are separate entities.

⁷⁷ A Bill to Amend title 35, United States Code, to prohibit the patenting of genetic material, H.R. 977, 110th Cong. (1st Sess. 2007).

⁷⁸ *Id.*

⁷⁹ *Id.*

⁸⁰ Under EPC Article 165, there are currently sixteen signatory states: Austria, Belgium, Switzerland, Germany, Denmark, France, United Kingdom, Greece, France, Ireland, Italy, Liechtenstein, Luxembourg, Monaco, Netherlands, Norway, and Sweden. Conference participants: signatory states plus Spain, Finland, Portugal, Turkey and Serbia. Invited states: conference participants plus Cyprus and Iceland. European Patent Convention, art. 165, Oct. 5, 1973, 1065 U.N.T.S. 303, art. 165 [hereinafter *EPC*]; European Patent Convention, art. 165, n.116, <http://www.european-patent-office.org/legal/epc/e/ar165.html> (last visited June 16, 2008) [hereinafter *EPC Online*].

⁸¹ *EPC Online*, *supra* note 80, art. 1.

⁸² For a map of the countries in the EU, see http://europa.eu/abc/european_countries/index_en.htm. The EU is a political institution of democratic European countries working together for greater international trade and cooperation. Panorama of the European Union, http://europa.eu/abc/panorama/index_en.htm (last visited June 16, 2008).

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Article 4 of the EPC establishes that the European Patent Office is responsible for granting European patents.⁸³ Similar to the United States Patent Act, “European patents shall be granted for any inventions which are susceptible of industrial application,⁸⁴ which are new,⁸⁵ and which involve an inventive step.”⁸⁶

However, unlike the United States, the EPC has strict guidelines regarding inventions contrary to societal morality. Through EPC Article 53, inventions contrary to “ordre public” are not eligible for patentability.⁸⁷ However, this Article excludes “microbiological processes or the products thereof” from the ordre public restrictions.⁸⁸ Furthermore, in 1998, the European Parliament adopted the Biotechnology Invention Directive. The Directive allows for patentability of biological material⁸⁹ that is isolated from its environment, provided that it meets all patent requirements, “even if it previously occurred in nature.”⁹⁰ The Directive requires that the inventor state specific functions of the biological material to qualify for patent protection.⁹¹ Thus, MGR DNA strands or fragments which qualify as biological material are patentable if they meet all other patent requirements of the EPC and Biotechnology Invention Directive.

The issue becomes more complex, however, regarding patentability of multicellular organisms. Article 4 of the Biotechnology Invention Directive specifically excludes plant and animal varieties from patentability.⁹² Article 6(2)(d) of the Directive also excludes from patentability any “processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal.”⁹³

The landmark case defining “animal varieties” is the Harvard OncoMouse case⁹⁴ decided by the Boards of Appeal of the European Patent Office which upheld patentability of the OncoMouse under the EPC.⁹⁵ The reasoning, however, differs from that in the United States. Here, the European Patent Office Boards of Appeal draw a patentability distinction between genus and species, stating that a plant and animal genus may be patentable, while a plant and animal species is not patentable.⁹⁶ As this case applies to MGRs, where scientists seek

⁸³ *EPC Online*, *supra* note 80, art. 4.

⁸⁴ *Id.* art. 57.

⁸⁵ *Id.* art. 54.

⁸⁶ *Id.* art. 52(1).

⁸⁷ *Id.* art. 53.

⁸⁸ *Id.*

⁸⁹ Biological material is defined by Article 2 of the EC Biotechnology Invention Directive as “any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.” Council Directive 98/44/EC, art 2, 1998 O.J. (L 213) 13 (EN).

⁹⁰ *Id.* art. 3(2).

⁹¹ *Id.* art. 3(1).

⁹² *Id.* art. 4.

⁹³ *Id.* art. 6.

⁹⁴ The facts of this case are identical to the Harvard OncoMouse case stated above for the United States. *OncoMouse*, *supra* note 63.

⁹⁵ *Id.*

⁹⁶ *Id.*

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to patent multi-cellular inventions derived from MGRs, patentability is limited to the specific genus of that plant or animal within the confines of the OncoMouse case and Article 6(2)(d) of the Directive.

Thus, within the EU, the broad difference under the EPC and Biotechnology Invention Directive, is the additional burden of *ordre public* that inventors must meet. However, unlike mounting complications and uncertainties within the United States patent reform, inventors under the EPC need only follow the specific and relatively liberal exceptions described above to meet patent requirements.

B. Exclusions from Patentability under the TRIPS Agreement

Similar to exclusions in the EPC, Article 27(3) of the TRIPS agreement states that members may exclude from patentability inventions that are contrary to morality, including the protection of human, animal or plant life or health, as well as patentability of plants and animals other than “microbiological processes or the products thereof.”⁹⁷ While it is permitted under the TRIPS agreement for Members to exclude inventions contrary to morality, this provision is not required. Thus, the TRIPS agreement generally grants each member sovereignty in determining which inventions, other than microorganisms, are contrary to morality.

Although most MGRs likely fall within the “microbiological process or the products thereof”⁹⁸ category, if MGR DNA derivatives exist in larger forms, they could be excluded from patentability by a country’s national laws in conformity with Article 27(3) of the TRIPS agreement.

C. Taxonomy

The issue of taxonomy has been raised regarding MGRs in connection with patentable subject matter and use requirements of the TRIPS agreement.⁹⁹ Article 29 of the TRIPS agreement requires that a patent applicant disclose the invention “in a manner sufficiently clear and complete.”¹⁰⁰ Generally, this requires that inventors name their creation, often by stating the proper family name, including the genus and species of the organism.

Not only does taxonomy allot a proper name to a previously unknown organism, but it also suggests the various uses of the organism, similar within each organism’s familial structure.¹⁰¹ However, because MGRs are new and provide novel uses in the field, accurate taxonomy can be problematic.¹⁰² Additionally,

⁹⁷ *TRIPS Agreement*, *supra* note 49, art. 27(3).

⁹⁸ *EPC Online*, *supra* note 80, art. 53

⁹⁹ John N.A. Hooper, Head Biodiversity & Geosciences Programs, Queensland Museum, statement presented at the United Nations Informal Consultative Process on Oceans and Law of the Sea: Maximizing benefits from ‘biodiscovery’: a Coastal State resource providers perspective (June 26, 2007), abstract available at http://www.un.org/Depts/los/consultative_process/documents/8_abstract_hooper.pdf.

¹⁰⁰ *TRIPS Agreement*, *supra* note 49, art. 29(1).

¹⁰¹ Hooper, *supra* note 99.

¹⁰² *Id.*

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the lack of trained taxonomists to adequately classify new organisms found in the deep sea and international sea bed can hinder and possibly delay patent protection.¹⁰³ Although the issue of taxonomy is not insurmountable, it is a concern to be taken into account for MGR patentability purposes.

D. Capable of Industrial Application

Another TRIPS requirement for patent protection is that the invention is useful, or capable of industrial application.¹⁰⁴ Under many national laws, including that of the United States, utility must be specifically stated and described for the inventor to qualify for protection; a hypothetical use does not meet patent requirements.¹⁰⁵ As a way of identifying uses for newly found MGRs, scientists often test the scientific names and isolated DNA of new MGRs against previously collected and tested MGRs.¹⁰⁶ Just as in taxonomy searches, the likening of one MGR to another attempts to liken their uses as well, allowing for a more directed utility study.

For example, the Australian Institute of Marine Science uses such data-mining as a technological time-saver to predict future results of MGR clinical screenings.¹⁰⁷ Elaborate databases use regional and taxonomic patterns in anti-microbial activity to show naturally occurring analogies and to identify other material with similar taxonomy, ecology, screening profile, and chemical structure.¹⁰⁸ Such databases lead to an integrated system of biodiversity data. This system helps scientists and bioprospectors to liken uses of new MGR DNA derivatives to currently existing organisms and uses, and allows for specific utility focus.

Although many MGRs have dual or multiple uses, at present, Article 27(1) of TRIPS requires that the invention be useful, but does not require disclosure of all uses.¹⁰⁹ Furthermore, as multiple uses are found through adaptations of synthesized strands and fragments of MGR DNA, scientists can obtain additional patents on such inventions so long as they meet all other patent requirements.

E. Novelty

Under the TRIPS agreement, the invention must also be novel or new.¹¹⁰ However, similar to general arguments that have been made in international opposition of patent protection for traditional knowledge and genetic resources, it is questionable whether inventions derived from marine genetic materials are novel and thus within the jurisdiction of patent protection under the TRIPS agreement.

¹⁰³ *Id.*

¹⁰⁴ *TRIPS Agreement, supra* note 49, art. 27(1).

¹⁰⁵ *Diamond, supra* note 42.

¹⁰⁶ *Evans-Illidge, supra* note 11.

¹⁰⁷ *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ *TRIPS Agreement, supra* note 49, art. 27(1).

¹¹⁰ *Id.*

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The traditional knowledge/genetic resources argument states that the traditional knowledge process with which genetic resources are used is indigenous to the culture from which it came. They say the traditional knowledge of the genetic resources has been used throughout several generations as part of tribal culture, and it is therefore not novel. This argument is similar to the argument that nature cannot be patented, as nature has existed for many years and is not new regardless of its discovery date.

However, this argument is not analogous here. Unlike traditional knowledge and genetic resources, the following debate regarding MGRs is about ownership rights in the MGRs themselves. Countries also seek ownership rights in MGR derived materials to the extent that part of the original MGR is represented in derivative materials. However, countries cannot claim ownership rights over the process of MGR cultivation. Instead, the scientists who collect and cultivate MGRs own the process by which they isolate and refine genetic material into new, useful pharmaceuticals. Therefore, if anything, countries can try to claim ownership in the specific MGR and parts of the MGR as used in derivative materials, but they cannot claim ownership over the processes used in MGR cultivation, isolation, and refinement. As such, the only issue for novelty purposes is whether the MGR derivative material is novel under the TRIPS agreement. The burden to show novelty is on the scientists and is separate from the question of MGR ownership rights, as MGRs themselves are not patentable subject matter.

F. Inventive Step

The TRIPS agreement also requires that patents are non-obvious, or include an inventive step from the viewpoint of a person skilled in the relevant art.¹¹¹ Despite current debate within several national patent offices regarding whether the “viewpoint of a person skilled in the relevant art”¹¹² is sufficient language to be used in the inventive step requirement of the TRIPS agreement, no conclusion has been reached thus far to override the current law.¹¹³

Specific to MGRs, DNA derivatives must include an inventive step¹¹⁴ in the synthetic DNA sequence, not the process of synthetic DNA construction, to be patentable.¹¹⁵ The current patent requirements also state that MGR DNA derivatives must be nonobvious to a scientist, biologist, pharmacist or any other person skilled in the relevant art¹¹⁶ of gene sequencing and drug manufacturing.

¹¹¹ *Id.* art. 29(1).

¹¹² *Id.*

¹¹³ Restaino, *supra* note 655.

¹¹⁴ *TRIPS Agreement*, *supra* note 4949, art. 27(1), n.5.

¹¹⁵ Restaino, *supra* note 65.

¹¹⁶ *TRIPS Agreement*, *supra* note 49, art. 29(1).

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G. Disclosure

The final requirement for patent protection under the TRIPS agreement is that the invention be disclosed in a publication so as to enable a person skilled in the relevant art to reproduce the invention.¹¹⁷ Additionally, under the TRIPS agreement, Members may require the applicant to indicate the best mode for carrying out the invention; however, this is not a mandatory requirement.¹¹⁸ This requirement could also include specific written descriptions, but this is at the discretion of each Member State.¹¹⁹

It is also questionable as to how far back disclosure is required. There is a current debate among the World Intellectual Property Organization's ("WIPO") Intergovernmental Committee on Genetic Resources, Traditional Knowledge, and Traditional Cultural Expressions/Folklore ("IGC") and the Standing Committee on Patents ("SCP") as well as the WTO, as to whether inventors must disclose the original source of traditional knowledge and genetic resource discoveries. This debate also addresses equitable remuneration, transfer of technology, and benefit sharing, as it stems from concerns over exploitation of indigenous peoples' traditional knowledge used in genetic resources, and ways of life.

Recently, the Convention on Biological Diversity held a conference in Canada to further establish benefit sharing procedures regarding traditional knowledge, genetic resources, and expressions of folklore of indigenous peoples. This proposal will be submitted to the 62nd session of the United Nations General Assembly. WIPO's IGC has also established a voluntary fund to address issues of benefit sharing. However, as of yet, there has been no concrete link between MGRs and traditional knowledge/genetic resources. Thus, only basic disclosure requirements must be met for patentability purposes under the TRIPS agreement.

To assist in patent disclosure, regional and national patent databases exist in several countries and are often accessible over the Internet.¹²⁰ They assist patent owners by allowing them to retain maximum protection of their invention while giving adequate notice to other inventors of relevant prior art.¹²¹ WIPO has established additional databases to assist all countries in their patent filings, through the help of the internet and several regional offices.¹²²

H. Other Intellectual Property Issues

After meeting all above requirements, if the invention is not defeated by prior art or any justifiable challenges, the inventor may receive patent protection on an

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ *See e.g.*, Section 112 of the United States Patent Act requires enablement, best mode and written description requirements. 35 U.S.C.A. §112 (1965) (West 2000).

¹²⁰ Rama Rao, Deputy Dir., World Intellectual Property Org. Office, statement at the United Nations Informal Consultative Process on Oceans and the Law of the Sea: Current Activities of WIPO (June 27, 2007).

¹²¹ *Oceans and the Law of the Sea*, *supra* note 4, at ¶ 143.

¹²² *Rao*, *supra* note 120.

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invention through national patent laws, and in accordance with the TRIPS agreement for WTO Member States.¹²³

Although there is currently no international intellectual property regime for international patent protection due to the important role of national sovereignty in intellectual property laws, WIPO has made efforts towards making the patent process easier and more accessible through the use of the Patent Cooperation Treaty (“PCT”). The PCT “makes it possible (for any national or resident of a Contracting State) to seek patent protection for an invention simultaneously in each of a large number of countries by filing an ‘international’ patent application.”¹²⁴ The PCT is open to countries party to the Paris Convention for the Protection of Industrial Property (1883).¹²⁵ Therefore, it can be of use to developed countries and developing countries alike.¹²⁶

IV. Basic Maritime Law as Related to Marine Genetic Resources

The United Nations Convention on the Law of the Sea was adopted in 1982 and came into force on November 16, 1994.¹²⁷ The Convention is an “unprecedented attempt” to regulate the law of the sea, which had previously been governed by a freedom-of-the-seas doctrine.¹²⁸ The Convention establishes guidelines in several applicable areas within and beyond areas of national jurisdiction such as guidelines for fishing on the high seas, extraction from the ocean’s seabed, floor, and subsoil, and Marine Scientific Research. However, presently, the Convention is silent with regard to the current legal classification of MGRs beyond national jurisdiction. Thus, the current controversy within UNICPOLOS questions the breadth of the Convention’s jurisdiction and whether or not the Convention should be interpreted to include and regulate MGRs.

A. Regulation within National Jurisdictions

Within a nation’s maritime jurisdiction, including a nation’s Exclusive Economic Zone (“EEZ”), a nation has control over its waters and the organisms found within them.¹²⁹ This necessarily includes all activities relating to excavation and extraction of MGRs. The Convention has clear regulations regarding national territory and a nation’s EEZ allowing sovereign rights for purposes of

¹²³ *TRIPS Agreement*, *supra* note 49, arts. 27-28.

¹²⁴ Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231 [hereinafter *PCT*].

¹²⁵ *Id.*

¹²⁶ At the UNICPOLOS meeting, Deputy Director S. Rama Rao of WIPO encouraged all countries to utilize the PCT and its databases to pursue more expansive protection for MGR DNA derivative inventions and products.

¹²⁷ United Nations Convention on the Law of the Sea, Historical Perspective, available at http://www.un.org/Depts/los/convention_agreements/convention_historical_perspective.htm#Historical%20Perspective (last visited June 16, 2008) [hereinafter *Historical Perspective*].

¹²⁸ *Id.*

¹²⁹ *Oceans and the Law of the Sea*, *supra* note 4, at ¶ 192.

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exploiting, conserving, and exploring its waters and continental shelf.¹³⁰ The continental shelf is defined as comprising of the seabed and subsoil that extend beyond the territorial sea throughout the natural prolongation of a nation's land territory to the outer edge of the continental margin, or to a distance of 200 nautical miles.¹³¹ No other country is allowed to explore or exploit another country's resources within their national jurisdiction without express permission from the coastal state.¹³² Any act contrary to this rule constitutes biopiracy.

Additionally, within areas of national jurisdiction, the CBD prevails. Its objectives are "the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources."¹³³ However, the CBD's mandate and scope, including the regulation of fair and equitable benefit sharing is limited only to areas within national jurisdiction, not beyond.¹³⁴

B. Regulation beyond National Jurisdictions

Beyond national jurisdictions, regulation by the Convention, relating to MGRs is unclear and variable. However, the Convention does currently address specific parts of the sea beyond national jurisdictions to which some countries would like to analogize MGRs.

For example, the Convention regulates the high seas.¹³⁵ The high seas include all areas beyond each nation's EEZ and beyond the territorial sea, international waters, or archipelagic waters of a nation.¹³⁶ Here, all states have freedoms *inter alia* to resources therein. For example, under Article 116 of the Convention, all States' nationals have a right to fish for profit on the high seas.¹³⁷ In such scenarios, States do have exclusive jurisdiction and responsibility over ships flying their flags on the high seas.¹³⁸ Thus, in general, commercial fishing on the high seas is open to all States on a "first come, first serve basis"¹³⁹ provided that States cooperate with the conservation and management of living resources within the high seas.¹⁴⁰

Separate from the "high seas," however, is the seabed, ocean floor, and subsoil. These regions, still beyond national jurisdiction, are referred to in the Convention as "the Area."¹⁴¹ The Area also includes "all solid, liquid, and gaseous

¹³⁰ United Nations Convention on the Law of the Sea, Dec. 10, 1982, 1933 U.N.T.S. 397, art. 77 [hereinafter *Convention on the Law of the Sea*].

¹³¹ *Id.* art. 57.

¹³² *Id.* art. 76.

¹³³ Convention on Biological Diversity, *supra* note 5, art. 1.

¹³⁴ *Id.* art. 4.

¹³⁵ *Convention on the Law of the Sea*, *supra* note 130, art. 86.

¹³⁶ *Id.*

¹³⁷ *Id.* art. 116.

¹³⁸ *Id.* art. 92.

¹³⁹ *Id.* art. 87.

¹⁴⁰ *Id.* art. 118.

¹⁴¹ *Id.* art. 1(1).

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mineral resources in situ in the Area at or beneath the seabed.”¹⁴² Unlike the regulations for commercial fishing in the high seas, no nation may assert claims or sovereignty rights over any part of the Area or its resources.¹⁴³ The Convention has devised an elaborate regime for protection of the Area. As such, the Area is currently governed by the CHM.¹⁴⁴

However, in an attempt to balance protection of the Area through the Convention and the concerns of major research States, the Convention outlines specific guidelines regarding Marine Scientific Research (“MSR”) within the Area beyond national jurisdiction.¹⁴⁵ Although not specifically defined or mentioned in the Convention, MSR is understood to encompass the study of the marine environment and its resources.¹⁴⁶ MSR intends to increase the overall knowledge of humankind through research and exploitation of resources, and is allowed solely for peaceful purposes.¹⁴⁷ With MSR, all exploration or exploitation within the Area for purposes of scientific research must be carried out for benefit of the CHM, including equitable benefit sharing.¹⁴⁸ Further, MSR and equitable benefit sharing are regulated by the International Seabed Authority (“ISA”); “an autonomous international organization that administers mineral resources in the Area.”¹⁴⁹ However, neither ISA’s mandate nor its regulation of equitable benefit sharing extends beyond mineral resources to include MGRs.

V. The Debate

A. Position of Developing Countries

Developing countries suggest that the Convention analogize MGRs to MSR, allowing the Convention and the ISA to regulate bioprospecting of MGRs through equitable benefit sharing regimes for the CHM. This point was made at the UNICPOLOS meeting specifically through the statements of Pakistan on behalf of the Group of 77 and China.¹⁵⁰ Developing countries argue that, because the specific language of the Convention does not define MSR which it now clearly regulates, the Convention should also regulate MGRs in the same breadth, as MGRs are not defined by the Convention either.¹⁵¹ Such States also noted a similarity between bioprospecting of MGRs and bioprospecting of MSR, further

¹⁴² *Id.* art 13.

¹⁴³ *Id.* art. 137.

¹⁴⁴ *Id.* pt. X.

¹⁴⁵ *Historical Perspective*, *supra* note 127.

¹⁴⁶ Devey, *supra* note 10.

¹⁴⁷ *Oceans and the Law of the Sea*, *supra* note 4, at ¶¶ 203, 205.

¹⁴⁸ *Convention on the Law of the Sea*, *supra* note 130, art. 140.

¹⁴⁹ G.A. Res. 48/263, Annex, U.N. Doc. A/RES/48/263/Annex (Aug. 17, 1994); *see also* International Seabed Authority Home Page, <http://www.isa.org.jm/en/home> (last visited June 16, 2008).

¹⁵⁰ Farukh Amil, Deputy Permanent Representative of Pakistan, on behalf of the Group of 77 and China to the United Nations, statement presented at the United Nations Informal Consultative Process on Oceans and Law of the Sea (June 25, 2007), *available at* <http://www.g77.org/statement/getstatement.php?id=070625>.

¹⁵¹ *Id.*

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likening MGRs and MSR and strengthening the argument for MGR regulation by Part XIII of the Convention.¹⁵² Many other developing countries in the UNICPOLOS meeting supported the statement of the Group of 77 and China, supporting regulation of MGRs by the Convention.

In efforts to cement their position, developing countries urged the UNICPOLOS committee to adopt language supporting MGR regulation by the Convention in their proposal to the United Nations General Assembly. Should such language be adopted, MGRs would belong to the CHM; they would be included in the ISA's scope of regulation; and benefits resulting from bioprospecting, and possibly further cultivation, of MGRs would be shared. As part of the CHM, ownership rights of extracted MGRs would not belong to any one country or bioprospector, but to all the countries of the world. As such, developing countries liken MGRs to traditional knowledge and genetic resources and look to WIPO for guidance on how to obtain *sui generis*¹⁵³ intellectual property protection and equitable benefit sharing of resources.¹⁵⁴

As addressed partially above, WIPO's IGC, currently in their eleventh session,¹⁵⁵ is focusing on developing an equitable benefit sharing system with regard to their mandate. The IGC's mandate is to discuss intellectual property issues relating to access to genetic resources and benefit sharing, traditional knowledge, and innovations; and traditional creativity and cultural expressions of folklore.¹⁵⁶ To the extent that benefit sharing of MGRs can be likened to benefit sharing of traditional knowledge or genetic resources, the IGC's progress in developing an equitable benefit sharing scheme can be useful and applicable to the MGR debate. However, no mandatory system of equitable benefit sharing currently exists through the IGC and it has never specifically addressed the issue of MGRs.

On another note, environmental groups such as the Deep Sea Conservation Coalition, Greenpeace International, the Shark Coalition and others align with the statements made by developing countries in pursuit of decreasing trafficking on the high seas. Due to the rarity of many species residing in the Area, environmental groups fear that increased boat trafficking will decrease survival rates of such MGRs through pollution.¹⁵⁷ They also fear that hasty bioprospectors will

¹⁵² *Id.*

¹⁵³ The Latin phrase *sui generis* is defined as meaning "of its own kind." A *sui generis* system is a system specifically designed to address the needs and concerns of a particular issue. World Intellectual Property Organization Glossary of Terms, <http://www.wipo.int/tk/en/glossary> (last visited June 16, 2008).

¹⁵⁴ *Id.*

¹⁵⁵ Intergovernmental Committee on Intellectual Prop. and Genetic Res., Traditional Knowledge and Folklore, 11th Sess., July 4-12, 2007, *Voluntary Fund for Accredited Indigenous and Local Communities*, WIPO Doc. WIPO/GRTKF/IC/11/INF/7 (July 6, 2007), available at http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=81733.

¹⁵⁶ WIPO General Assembly, 26th Sess., Sept. 25 – Oct. 3, 2000, *Matters Concerning Intellectual Property and Generic Resources, Traditional Knowledge and Folklore*, ¶ 20, WIPO Doc. WO/GA/26/6 (Aug. 25, 2000).

¹⁵⁷ Karen Sack, Oceans Policy Advisor for Greenpeace International, statement presented at the United Nations Informal Consultative Process on Ocean and the Law of the Sea: Statement on Deep Sea

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destroy deep seabed and international seabed ecosystems while extracting MGRs from the Area, demolishing entire habitats of MGRs.¹⁵⁸ Therefore, environmental groups support MGR regulation by the Convention in hopes of promoting an integrated, precautionary and ecosystem-based approach to high seas biodiversity protection and conservation of MGRs found within the Area.¹⁵⁹

B. Position of Developed Countries

Developed countries support the position that MGRs fall outside the scope of the Convention's regulation, and should be owned by the bioprospectors who take the initiative to collect MGRs. Developed countries support a scheme of MGR regulation analogous to the Convention's regulations regarding commercial fishing on the high seas beyond national jurisdiction: "first come, first served."

Developed countries, specifically Germany on behalf of the European Union, and the United States, argue that because MGRs are not specifically enumerated or defined in the Convention, they fall outside the scope of the Convention's jurisdiction.¹⁶⁰ In particular, the European Union added that MGRs in the Area beyond national jurisdiction cannot fall within the definition of the Area as defined by the Convention, because MGRs are not regarded as mineral resources. Thus, they argue, MGRs fall outside the mandate and equitable benefit sharing regulations of the ISA.¹⁶¹

Developed countries rely on human ingenuity and intellectual property protection, specifically patent and trademark protection, as tools in developing useful MGR DNA derivatives for pharmaceuticals, cosmetics and bioremediation products intended to have a substantial benefit for all humankind. Bioprospecting expeditions on the high seas and within the Area are difficult and expensive, as are lab technicians and other resources. However, such resources are needed to reproduce MGR DNA derivatives in a sustainable environment first, before such resources can be used and adapted for production and consumer consumption.¹⁶²

To assist other countries in the initial exploration and excavation stages, the United States delegation offered to take on board its MGR research vessels, scientists from other countries, as a capacity-building and training exercise. However, despite their hospitable offer, the United States is specifically concerned that regulation of MGRs by the Convention would hamper research initiatives to develop MGRs, as the duration required for pharmaceutical development

Genetic Resources (June 25, 2007), statement available at <http://www.greenpeace.org/usa/press-center/releases2/statement-on-deep-sea-genetic#>.

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ Press Release, U.S. Mission to the United Nations, Statement by Constance C. Arvis, U.S. Head of Delegation, on Oceans and Law of the Sea, in the General Assembly, USUN Press Release # 163(07) (June 25, 2007) available at http://www.usunnewyork.usmission.gov/press_releases/20070625_163.html.

¹⁶¹ Verena Graf von Roedern, European Union, statement at the United Nations Open-ended Informal Consultative Process on Oceans and the Law of the Sea: Statement on behalf of the European Union by the Representative of Germany (June 28, 2007).

¹⁶² See Press Release, U.S. Mission to the United Nations, *supra* note 160.

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is long and the odds of success are slim.¹⁶³ Thus, the developed countries are strongly opposed to any proposed regime that might interfere with high seas freedoms such as the freedom of navigation.¹⁶⁴

Regarding environmental concerns, there is clear agreement by both Germany on behalf of the European Union and the United States that the marine ecosystems of the high seas and within the Area be conserved and protected.¹⁶⁵ However, they argue that this is already being accomplished. The United States noted that scientists themselves have inherent incentives to protect the sites they study, thus conservation concerns of roughshod excavation and exploitation are misguided.¹⁶⁶ Additionally, further protection for MGRs in the high seas and the Area is controlled by bioprospectors, scientists, and scientific societies¹⁶⁷ who promulgate codes of conduct regulating responsible research practices, ensuring protection and conservation of marine ecosystems.¹⁶⁸

C. Negotiations of the 2007 UNICPOLOS Meeting

The format of the UNICPOLOS meeting consisted of panel presentations from various organizations and scientific institutions, including question and answer sessions by delegates and an opportunity for delegates to express their countries' positions in turn. After the conclusion of the panel presentations, delegations commenced negotiations on a draft resolution to be submitted to the General Assembly for adoption. To this end, the UNICPOLOS co-chairs, presented a document titled "Possible Elements to be Suggested to the General Assembly."¹⁶⁹ The most controversial issues of the draft centered on paragraphs ten and three.

Paragraph ten "recognize(d) that there are several aspects of intellectual property regimes relating to [MGRs] that need to be better understood, especially in relation to disclosure of source of origin of [MGRs], links to traditional knowledge, impacts on the sharing of knowledge, and on implications for access and benefit sharing."¹⁷⁰ The representative from Australia strongly opposed the list and proposed concluding the sentence after "understood," however several developing countries, including Pakistan on behalf of the Group of 77, opposed Australia's suggestion. Despite the controversy over paragraph ten, developed and developing countries reached an agreement to this paragraph in informal consultations.

¹⁶³ *Id.*

¹⁶⁴ *Id.*

¹⁶⁵ von Roedern, *supra* note 161.

¹⁶⁶ See Press Release, U.S. Mission to the United Nations, *supra* note 160.

¹⁶⁷ Devey, *supra* note 10.

¹⁶⁸ See Press Release, U.S. Mission to the United Nations, *supra* note 160.

¹⁶⁹ Eighth Meeting of the United Nations Open-ended Informal Consultative Process on Oceans and the Law of the Sea (UNICPOLOS), June 25-29, 2007, *Report on the work of the UNICPOLOS at its eighth meeting*, U.N. Doc. A/62/169/Annex (July 30, 2007).

¹⁷⁰ *Id.*

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Paragraph three was the other major issue of controversy that ultimately led to a stalemate of the negotiations. The paragraph addressed whether “the 1982 United Nations Convention on the Law of the Sea set out the legal framework within which all activities in the ocean and seas must be carried out.”¹⁷¹ As noted above, developed countries, such as the United States and Germany speaking on behalf of the European Union, strongly opposed this language while developing countries, specifically Pakistan, speaking on behalf of the Group of 77 and China, supported the language and further encouraged the language to identify MGRs as part of the CHM.

On midnight of June 29, 2007, the negotiations remained at a stalemate. Thus, the document was not accepted for submission to the General Assembly. However, the Co-Chairs have formed a new document, very similar to the first proposal, without attributing it in any manner to the delegates. At this point, this document has been presented in the General Assembly 62nd Regular Session but it has not been adopted. Delegations are also currently holding informal consultations, however the outcome of such consultations is unpredictable.

VI. Perceptions of the Debate

There is a need to balance the developing countries’ interest in sharing the ownership rights of MGRs, including all monetary benefits derived from MGR development, and the developed countries’ interest in overall extraction, exploitation and cultivation to develop MGRs into useful pharmaceuticals that have a greater potential for world-wide impact. To this end, perhaps the suggestion of the developed countries would be the best global solution, creating an incentive for bioprospecting while consciously protecting marine ecosystems within the high seas and the Area.

In this regard, even if MGRs are regulated categorically similar to commercial fishing on the high seas, developing countries would not be at a total loss. Article 31 of TRIPS regarding compulsory licensing provides an exception,¹⁷² allowing WTO Member States to temporarily use a drug “in the case of a national emergency or other circumstances of extreme urgency” without obtaining authorization from a pharmaceutical company as is normally required by Article 31(b) of TRIPS.¹⁷³ Under section (h) of this article, compulsory licensing may occur and the pharmaceutical company must be paid adequate remuneration in each case.¹⁷⁴ However, with the recent implementation of paragraph six of the Doha Declaration on the TRIPS agreement and public health, “exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f)¹⁷⁵

¹⁷¹ *Id.*

¹⁷² Although TRIPS Article 31 need not always apply.

¹⁷³ *TRIPS Agreement*, *supra* note 49, art. 31(b).

¹⁷⁴ *Id.* art. 31(h).

¹⁷⁵ *Id.* art. 31(f). (Paragraph (f) of TRIPS Article 31 restricts use of compulsory licensed materials to predominantly the domestic market of the Member authorizing the use).

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and (h)¹⁷⁶ of Article 31 of the TRIPS agreement.”¹⁷⁷ Paragraph six of the Doha Declaration also promulgates other specific requirements to be carried out in the event of national emergency or other circumstances of extreme urgency.¹⁷⁸

While this would not give developing countries a blanket right to compulsory licensing of all MGR-derived drugs, it gives developing countries a means to benefit from MGRs through humanitarian compulsory licensing measures in national emergencies. As many MGRs have shown potential as HIV/AIDS and cancer medications, development and compulsory licensing of such pharmaceuticals could serve a great need in both the developed and the developing world.

In contrast, the CHM/equitable benefit sharing approach, while possibly beneficial in the short term, has potential to do more harm than good. Despite equitable benefit sharing strategies, whether through the CBD, ISA, or WIPO's IGC, it is not clear how much revenue developing countries will actually gain from such collection and distribution mechanisms. Low pharmaceutical success rates for MGR DNA derivatives in clinical trials might yield high returns from rare blockbuster drugs, however, this is far from a steady income stream for developing countries through equitable benefit sharing mechanisms. Equitable benefit sharing funds only receive a percentage of pharmaceutical revenues which are then divided among all countries of the world, leading to unstable and limited revenue. Additionally, any deterrent effect that equitable benefit sharing may have on bioprospectors defeats the quintessential purpose for collecting precious MGRs in the first place. As the bottom line is to cultivate MGRs into life-saving uses through environmentally safe methods of bioprospecting, the most direct means toward this end should be pursued.

However, another view is to keep the status quo. Negotiations between developing countries and developed countries are in their infancy, yet all parties involved have a clear working knowledge of the debate and the impact that MGRs can have on their particular countries. Perhaps the proper regime for all parties involved is to remain in the negotiation phase, where the best regulation is no regulation at all. Accordingly, resulting from the UNICPOLOS negotiations deadlock, no resolution regarding MGR legal ownership rights seems to be in sight and the current status quo is upheld. As the status quo includes a regime where intellectual property protection is possible, as applicable, to inventions of the kind derived from MGRs, cultivation and development of MGRs continues on a first-come, first-served basis without disclosure or monetary obligations to other nations.

¹⁷⁶ *Id.* art 31(h). (Paragraph (h) of TRIPS Article 31 requires that the right holder be paid equitable remuneration in the circumstances of each case of compulsory licensing, taking into account the economic value of the authorization).

¹⁷⁷ General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Sept. 2, 2003), 43 I.L.M. 509 (2004).

¹⁷⁸ *Id.*

VII. Conclusion

Undoubtedly, regulation for MGRs, whether through intellectual property protection or maritime classification, is rapidly changing. Not only were MGRs the hot topic of the July 2007 UNICPOLOS meeting, but they continue to be discussed within the 62nd session of the United Nations General Assembly. With such heightened debate between developed and developing countries, it is unlikely that MGR ownership rights will be settled quickly. Even keeping with a status quo regime, however, both developed and developing countries can benefit from MGR derivative products through the expanded compulsory licensing mechanisms of the recent Doha Declaration. Perhaps other future solutions will include negotiations through multilateral or bilateral treaty agreements as discovery of MGRs and production of MGR DNA derivatives increases. However, given the recent stalemate during UNICPOLOS final negotiations, the certainty of ownership rights for MGRs seems to be as elusive as the organisms such rights intend to cover.