Regulating marine biodiscovery in sea areas under coastal state jurisdiction

Regulating Marine Biodiscovery in Sea Areas Under Coastal State Jurisdiction

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Abstract

Marine biodiscovery is the examination of marine biological material for features that may be of value for commercial purposes. These features may include chemical compounds, genes and their products or, in some cases, the physical properties of the material in question. One of the principal attributes of biodiscovery is the commercialisation of the research or the intellectual property derived from the research. As it stands, many coastal States maintain an open access approach to marine biodiscovery. That is to say, no attempt is made to exclude the access of others or to control the collection and the subsequent use of material for the purpose of biodiscovery. There is some evidence however to support the view that biodiscovery will be most effective when governed by a range of international and national laws. Accordingly, the purpose of this paper is to identify the principal legal elements in the 1982 United Nations Law of the Sea Convention that are applicable to marine biodiscovery. The paper explores the key challenges and recommendations for the establishment of an appropriate governance framework governing biodiscovery activities in sea areas under the jurisdiction of a coastal Member State of the European Union.

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Introduction

The ocean is the largest habitat on earth and the biodiversity of the sea is extraordinary with 34 of the 37 phyla of life represented in the ocean. This may be contrasted with the 17 phyla that occur on land. Thus it is unsurprising that the relentless quest for new scientific knowledge coupled with the rapid development of new deep-ocean exploration technology has placed the spotlight on the legal regime governing the conduct of scientific research in the marine environment. This is particularly the case in relation to scientific activities that entail the collection of biological and geo-chemical material from the ocean and the subsequent screening of this material for information and features that may be of value for commercial purposes. These features may include chemical compounds, genes and their products or, in some instances, the physical properties of the material in question.

This type of research is sometimes referred to as "chemical prospecting", "pharmaceutical prospecting", or "genetic prospecting" in the scientific literature.[2] As will be seen below, there is now a tendency to refer to this type of research as simply "bioprospection" or "biodiscovery". In recent years much of the debate on this subject has focused on the legal status of marine genetic resources in sea areas beyond national jurisdiction with particular emphasis on the regime that ought to

[2]"Chemical prospecting" was defined by Reid *et al*. in 1993 as "the exploration of biodiversity for commercially valuable genetic and biochemical resources", see W. V. Reid, Laird SA, Meyer CA, Gámez R, Sittenfeld A, Janzen DH, Gollin MA and Juma C (eds.) (1993) A new lease on life. In: Biodiversity Prospecting: Using Genetic Resources for Sustainable Development, pp 1–52. World Resources Institute, USA. On the use of the terms "pharmaceutical prospecting" and "genetic prospecting" see *inter alia*: Aylward BA (1993) The Economic Value of Pharmaceutical Prospecting and its Role in Biodiversity Conservation London Environmental Economics Centre, London, Discussion Paper DP 93-05, IIED; Krattiger AF and Lesser WH (1995) The 'Facilitator': proposing a new mechanism to strengthen the equitable and sustainable use of biodiversity. Environmental Conservation 22(3): 211–215

apply to deep ocean hydrothermal vent sites, cold water seeps, deep-water corals and seamounts.[3] In contrast, there has been little discussion of the legal regime that ought to apply to similar activity in sea areas under coastal State jurisdiction.[4] This is surprising because much of the material that has yielded valuable genetic and biochemical information has been taken from the coastal environment. In many instances, access to this material is unregulated and little reward is derived by the coastal State when commercial products are developed from marine biodiversity.

Accordingly, the aim of this paper is to identify the key challenges and recommendations for the establishment of an appropriate governance framework governing biodiscovery activities in sea areas under the jurisdiction of a coastal Member State of the European Union. The paper begins by presenting some background information on biodiscovery in general. This is followed by a review of some important definitions and an assessment as to whether it is possible to distinguish biodiscovery from the more traditional forms of scientific research such as taxonomy. The paper concludes by looking at some of the key issues that need to be addressed in designing a framework for biodiscovery in the sea area of a coastal member State of the European Union, namely Ireland.

[3]See Y. Tanaka, "Reflections on the Conservation and Sustainable Use of Genetic Resources in the Deep Seabed Beyond the Limits of National Jurisdiction" in (2007) *Ocean Development and International Law* Vol. 39(2) (in press) The term "genetic resources" is defined in Article 2 of the Convention on Biological Diversity as "genetic material of actual or potential value", and in turn defines the term "genetic material" as "any material of plant, animal, microbial or other origin containing functional units of heredity".

[4]Coastal State jurisdiction is defined as: internal waters, the territorial sea, the Exclusive Economic Zone and the continental shelf where that extends to distance greater than 200 miles measured from the baselines. Coastal State jurisdiction also applies to archipelagic waters in the case of archipelagic States under Part IV of the 1982 LOS Convention.

The contextual background

Before delving into the legal regime that ought to apply to biodiscovery activities in sea areas under coastal State jurisdiction it may be appropriate to provide some background information on the rapid development of biodiscovery as a distinctive field of scientific inquiry. One of the best examples from an early research programme (albeit a terrestrial programme) was the discovery of two anti-cancer agents (vincristine and vinblastine) in the Madagascar Rosy Periwinkle plant (*Catharanthus roseus*) by scientists from the pharmaceutical firm Eli Lilly & Co in the late 1950s.[5] These agents became standard medicines in the treatment of childhood leukemia and Hodgkin's disease. Similarly, the discovery of the antibiotic Ertthromycin and the development of the Cyclosporin A anti-rejection drug which was isolated from a soil fungus sample (*Tolypocladium inflatum*) collected in the Hardangarvidda National Park in 1969 had a major impact on organ transplants and is now used in the treatment of AIDS.[6] Significantly, at the time that the original samples of the source material were collected in Madagascar and Norway, neither country had a benefit sharing agreements in place and thus derived no direct commercial benefit from the discoveries.

There were also some remarkable finds in the marine environment in the 1950s and 1960s.[7] An early success was the discovery of the new

[5]Juma C. (1989) The Gene Hunters. Biotechnology and the Scramble for Seeds. Zed Books; London Princeton University Press, Princeton.

[6]See, *inter alia*: Thali M (1995) Cyclosporins: immunosuppressive drugs with anti-HIV-1 activity. Molecular Medicine Today 1(1): 287–291; H. Varstad, H. Chr. Bugge, S. Dhillion "From Norway to Novartis: cyclosporin from *Tolypocladium inflatum* in an open access bioprospecting regime" in *Biodiversity and Conservation* 9: 1521–1541, 2000.

[7]See F. Flam, "Chemical Prospectors Scour the Sea for Promising Drugs", 266 *Science* 1324 (1994) Also see the authorities cited by P. Feist in "A Tale from the Sea to Ara–C" at www.pfeist.net/ALL/arac/ (accessed July 15, 2007). These include, *inter alia*: D. J. Newman, G. M. Cragg (2004), Advanced Preclinical and Clinical Trials of Natural Products and Related Compounds from Marine Sources, *Current Medicinal Chemistry*,

compound spongothymidine in a species of marine sponge (*Cryptotethia crypta*) which grew in coastal waters Florida and the subsequent development of the Ara–C (*cytosine arabinoside*) oncology drug from this compound in the 1950s.[8] This drug is still used to treat cancer and there is some support in the scientific that spongothymidine is one of the precursors of all nucleoside drugs.[9] Many of pioneering marine biodiscovery programmes in the United States and elsewhere focused on sea anemones. More recently, much study has been undertaken on invertebrates, algae and marine microbes. This study is greatly facilitated by automated screening techniques, new scientific disciplines such as bioinformatics as well as advances in genomic research. In 1982, for example, a methane producing marine microorganism (*Methanococcus jannaschii*) was fully sequenced by scientists. Less than half of the organism's genome shared similarities to the genomes of previously studied prokaryotes (bacteria) and eukaryotes (fungi, plants and animals), which comprise the two other major branches of life. This meant that a large proportion of the microbe's genome was new to science. In 1996, researchers at The Institute for Genomic Research confirmed that the Archaea represented a third major branch of life on Earth. Today much of

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July 2004, vol. 11, no. 13. pp. 1693-1713 (21); A. M. S. Mayer, "Marine Pharmacology in 1998: "Antitumor and Cytotoxic Compounds", *The Pharmacologist*, Vol. 41, No. 4, 1999, p. 159; Modern Drug Discovery, on the web, *ACS Publications*, Nature's pharma sea, MDD lab, Jan. 2002, vol. 5, no. 1, pp. 32-38; S. S. Yang, G. M. Cragg. D. J. Newman, and J. P. Bader, Natural Product-Based Anti-HIV Drug Discovery and Development Facilitated by the NCI Developmental Therapeutics Program, *Journal of Natural Products*, 200, vol. 64, no. 2; G. Schwartsmann, A. Brondani da Rocha, R. GS Berlinck and J. Jimeno, "Marine organisms as a source of new anticancer agents", *Lancet Oncol* 2001; 2: 221-5; A.J.S. Ray. Online on The Scientist.com, Oceans: Medicine Chests of the Future?, *The Scientist* 13 [19]1, Sep. 27, 1999; A. Kijjoa and P. Sawangwong Marine drugs review article on the web, Drugs and Cosmetics from the Sea, *Mar. Drugs* 2004, 2.

[8]See S.S. Cohen, "Sponges, Cancer, Cellular Aging", *Perspectives in Biology and Medicine*, Winter (1963) 6(2):215–227.

[9]Suckling, C. J. Chemical approaches to the Discovery of New Drugs. Sci. Prog. 1991, 75, 323-359.

the research focuses on a broad range of macro and micro-organisms including bacteria, archae, fungi, yeasts and viruses. In 2007, the Report of the Secretary–General of the United Nations on the Oceans and the Law of the Sea noted that proteins and in particular enzymes (biochemical cataclysts) are prime candidates for biodiscovery. New marine species are regularly being discovered under international research programmes such as the Census of Marine Life. These include shrimp and other life forms living in extreme environments including at hydrothermal vent sites where temperatures have been recorded at 407°C, the hottest marine temperature ever recorded. Zooplankton have been discovered 5 km below the surface of the Sargossa Sea and a single litre of common seawater taken from the Atlantic was found to have over 20,000 kinds of bacteria floating in it.[10]

Many of these discoveries have led to the development of new commercial products.[11] The range of applications varies enormously from fibre–optic cables to cosmetic and skin care products. Some of the most exciting developments are in the medical domain where considerable research has been undertaken by specialist institutes in the United States.[12] Much of the research has focused on the identification of anti–cancer compounds as well as compounds to treat Alzheimer's disease, asthma, pain, and viral infections. As mentioned above, many of the early research programmes were focused on shallow tropical water mainly because of ease of access. More recently, the focus has shifted towards the exploration of the continental shelf and the deep–ocean floor where various forms of life live in extreme environments.[13] The main

[10]See www.comlr.org
[11]US Dept of Commerce/NOAA, Discovering Earth's Final Frontier: A US Strategy for Ocean Exploration. The Report of the President's Panel on Ocean Exploration 43 (2000).
[12]The National Cancer Institute in the USA, the Centre for Marine Biotechnology and Biomedicine at Scripps Institution of Oceanography, and at the Division of Biomedical Marine Research at Harbor Branch Oceanographic Institution in Florida.
[13]See B. Moore "A U.S. perspective on Global marine science in *Recent Developments in the Law of the Sea and China* (Martinus Nijhoff, Leiden/Boston, 2006), pp. 293-316.

characteristic of deep-ocean species is their tolerance to extreme conditions and their very peculiar physiology. Levels of endemism in the deep-ocean habitats are very high (more than 90 per cent in the case of hydrothermal vent sites). There appears to be no general rule regarding which marine organisms are most likely to be the focus of biodiscovery programmes. However, there is some support for the view that:

> *The majority of marine-derived compounds are obtained from either microorganisms or stationary organisms such as corals, sponges, and tunicates. Because stationary organisms cannot evade predators through movement, they rely heavily on chemical defense mechanisms to protect themselves.* [14] *These mechanisms generate compounds that frequently show significant bioactivity, or effects on living cells or organisms, such as those which cause human ailments.*[15]

It should also be borne in mind that microbes can be collected more quickly and more cost-effectively than larger organisms. Their removal has little impact on the natural environment and in most instances they can be cultured in large quantities. However, few countries (other than Japan, The Russian Federation, the USA and France) have the technical expertise to undertake manned exploration of the deep-ocean with a view to collecting samples from extreme environments such as hydrothermal vents. Other countries such as Ireland, will be depend on unmanned exploration (ROV) which do not require such levels of technical expertise. Furthermore as noted by two of the leading experts, "when it comes to investigation of the samples and then particularly the further development to a drug, there is only one country, the USA, where

[14]Faulkner, JD. 2002. Marine natural products. *Natural Products Review* 19: 1-48.
[15]Mill S. *et al*., *Medicines from the Deep, The Importance of Protecting the High Seas from Bottom Trawling* (Natural Resources Defense Council, issue paper: March 2005) Available at http://www.nrdc.org/water/oceans/medicines/medicines.pdf

the government funds materials through to clinical trials (and then only in the case of cancer and AIDS). In all other cases, industrial involvement is necessary and, again, only a few groups can go all the way without involving others."[16]

One final point that is relevant in this context is that product development entails very high costs over an attenuated period. In the case of new drugs this may be up to USD 1.7 billion and it may take up to 15 years to produce results.[17] Furthermore, only 1 to 2 per cent of preclinical candidates actually reach the market place.[18] Neither is it possible to be definitive on how long it will take to make the initial discovery because the testing of old samples with new technology sometimes demonstrates scientific potential that was not evident when the sample was initially screened for activity.[19] Unsurprisingly, the advent of metagenomic libraries, genome shotgun sequencing, as well as rapid advances in deep-ocean exploration technology have all accelerated the discovery process. Accordingly, technical expertise, industry lead partnerships, cost, and the long lead-in-time before commercialisation are important factors to be taken into consideration in establishing an appropriate governance programme.

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[16]See J. Newman and G.M. Cragg, "Political, legal, scientific and financial aspects of marine biodiscoery programmes" in Deep Sea 2003: Conference on the Governance and Management of Deep-sea Fisheries. Part 2: Conference poster papers and workshop papers, (Rome, FAO, 2006) pp. 447-454.

[17]The United Nations estimates that the cost of research and development of a new drug (not necessarily one related to marine biotechnology) presently range between USD 231 / USD 500 million to USD 800 million / USD 1.7 billion. See para. 108 of the Addendum to the Report of the Secretary-General to the United Nations General Assembly on the Oceans and the Law of the Sea, 15 July 2005, AD /60/63/Add.1.

[18]*Ibid.*

[19]See, *inter alia*: Shu, Y.-Z. Recent Natural Products Based Drug Development: A Pharmaceutical Industry Perspective. *J. Nat. Prod.* 1998, 61, 1053-1071; Young, R. N. Importance of Biodiversity to the Modern Pharmaceutical Industry. *Pure Appl. Chem*., 1999, 71, 1655-1661.

Little consensus on definitions

One of the first problems for the lawyers is that there is no universal definition of the terms "biodiscovery" "or "bioprospection" in international or European law. Neither term is mentioned in the 1982 LOS Convention or in the 1992 Convention on Biological Diversity. This omission is compounded by the tendency of scientists and lawyers to use the terms interchangeably. Accordingly, both terms merit further consideration here.

The term "biodiscovery" is a hybrid term and is a combination of the words "biological" and "discovery". The term is used in the domestic law on a number of States which have specific legislation aimed at controlling the use of biodiversity for the purpose of commercial research.[20] A notable example is the Biodiscovery Act 2004 of Queensland, Australia, which defines "biodiscovery" to mean: "biodiscovery research; or the commercialisation of native biological material or a product of biodiscovery research".[21] "Biodiscovery research" in turn is defined in the same Act to mean "the analysis of molecular, biochemical or genetic information about native biological material for the

[20]Diversity is a measure of difference and marine biodiversity may thus be understood as a measure of biological difference in the marine environment including both ecological and genetic diversity. The classical definition of "biological diversity" as a term of art is provided in the 1992 Convention on Biological Diversity which defines the term in Article 2 to mean "the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems" see M. Lodge, "Improving International Governance in the Deep Sea", 19 *International Journal of Marine and Coastal Law* 299-316 (2004) at p.302, n.12.

[21]Schedule, Biodiscovery Act 2004. For an excellent analysis of the legal framework governing and the law in a number of coastal States including Australia (and the Biodiscovery Bill 2003), see D. Owen, "A Study into the Legal Framework for Marine Biotechnology Development in the United Kingdom", Foresight Marine Panel (Report: FMP MBG–01 2004), available at: http://www.defra.gov.uk/science/project_data/DocumentLibrary/ME1403/ME1403_1275_FRP.pdf

purpose of commercialising the material".[22] One key component in this definition is that "native biological resource" is limited in scope to "non-human living organism or virus indigenous to Australia and sourced from State land or Queensland waters; or a living or non-living sample of the organism or virus."[23] In other words, the application of the legislation is limited to resources that are only found in Australia. The term "commercialisation" of native biological material is defined in the Act as "using the material or property in any way for gain".[24] The term does not include using the material to obtain financial assistance from a State or the Commonwealth, including, for example, a government grant (for research purposes).[25]

Similar to the word "biodiscovery", the term "bioprospecting" is a combination of the two words "biological" and "prospecting".[26] The term appears in the domestic law of several States that have enacted legislation to implement the 1992 Convention on Biological Diversity. A good example is the law in the Philippines which defines "bioprospecting or prospecting" to mean "the research, collection and utilization of biological and genetic resources for the purposes of applying the knowledge derived therefrom for scientific and/or commercial purposes".[27] Similarly, there are many references to the term "bioprospecting" in the specialist literature on genetic resources. In 2003, for example, the Subsidiary Body on Scientific, Technical and Technological Advice of CBD defined "bioprospecting" to mean "the exploration of biodiversity for

[22] *Ibid*.
[23] *Id.*
[24] *Id*
[25] *Id*.
[26] E. Asebey, J. Kempenaar, "The Intellectual Property Perspective on Biodiversity: Biodiversity Prospecting: Fulfilling the Mandate of the Biodiversity Convention" (1995) 28 Vanderbilt Journal of Transnational Law 703.
[27] Department Administrative Order No.96-20. These regulations contain a very broad list of definitions for terms such as: "academic research agreement", "benefit sharing", "biological diversity", "commercial research agreement", "genetic material", "genetic resources", "prior informed consent" and "sustainable use".

commercially valuable genetic and biochemical resources" and as "the process of gathering information from the biosphere on the molecular composition of genetic resources for the development of new commercial products".[28]

We can make a number of very general points about these definitions:

Firstly, "marine biodiscovery" refers to the examination of marine biological resources (e.g. plants, animals, micro-organisms) for features that may be of value for commercial development.[29] These features may include chemical compounds, genes and their products or, in some cases, the physical properties of the material in question.[30]

Secondly, the precise range of activities covered by biodiscovery may be wide-ranging and extend from the initial sampling of organisms in the marine environment to its subsequent investigation in the laboratory.[31] The initial phase of research is more often than not undertaken at sea by scientists embarked on research vessels that may be deployed in sea areas under foreign state jurisdiction or in areas beyond national jurisdiction. In other cases it may involve the initial harvesting of organisms from the

[28]This definition is important because it is provided in their study on the relationship between the CBD and the 1982 LOS Convention with regard to the conservation and sustainable use of genetic resources on the deep sea-bed. See Doc. UNEP/CBD/SBSTTA/8/INF/3/Rev. 1 of 22 February 2003, para. 49.

[29]See "Bioprospecting in New Zealand - Discussing the Options". Available at: www.med.govt.nz/ers/nat-res/bioprospecting/

[30]*Ibid.*

[31]See D. Owen, "A Study into the Legal Framework for Marine Biotechnology Development in the United Kingdom", Foresight Marine Panel (Report: FMP MBG–01 2004), available at: http://www.defra.gov.uk/science/project_data/DocumentLibrary/ME1403/ME1403_1275_FRP.pdf

marine environment and their culture in the laboratory for the purpose of further investigation or for commercial production.[32]

Thirdly, the means of collection may vary and include the collection of samples by means of a submersible.[33] Marine biodiscovery may be the focus of a particular research programme which aims to obtain a particular organism for analysis or it may be more exploratory and involve the screening of a wide range of organisms for unusual features or properties. In some instances, organisms may be sought exclusively for their genetic information and in other cases they may be sought for a biochemical or molecular process that has a commercial application.[34]

Fourthly, many contemporary definitions of biodiscovery place emphasis on the search of biodiversity for valuable genetic and biochemical *information* found in wild plants, animals and micro-organisms (emphasis added).[35] Accordingly it is the *information* that is important and not the source material *per se*.

Fifthly, a principal attribute of biodiscovery is the commercialisation of the research or the intellectual property derived from the research. This characteristic is emphasized in a number of authoritative reports on the subject of marine genetic resources.[36]

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[32]*Ibid.*
[33]*Id.*
[34]*Id.*
[35]See W. Reid *et al*, "A New Lease on Life" in W. Reid *et al*, eds., *Biodiversity Prospecting: Using Genetic Resources for Sustainable Development*, (Washington, DC, World Resources Institute, 1993).
[36]For example, the *United Nations University–Institute of Advanced Studies Report on Bioprospecting of Genetic Resources in the Deep Seabed: Scientific, Legal and Policy Aspects* states that "bioprospection" involves research for commercial purposes" at p.15. This study goes on to suggest that the possible elements of a definition of bioprospecting include: the systematic search, collection, gathering or sampling of biological resources for the purposes of *commercial* or industrial exploitation; the screening, isolation, characterization of *commercially* useful compounds; the testing and trials; and further

Essentially, commercialization entails converting the results of research projects into marketable products or services. In nearly all instances this takes place long after the original source material was acquired or after the material has been stored in a culture collection or reference library. Moreover, many scientific breakthroughs are serendipitous and have not come about as a result of targeted research programmes. However with advances in biotechnology, genomics, bioinformatics, as well as other scientific disciplines, biodiscovery is now ensuring that the commercialisation of marine products is happening more rapidly. Commercialisation has important legal consequences as it clearly distinguishes biodiscovery from the more traditional forms of marine scientific research (examined below) such as taxonomy which is the systematic identification and classification of living organisms according to their genetic and morphological characteristics. On this point, it is important to keep in mind that there is a fundamental link between biodiscovery and taxonomy as the former is very much dependent on the reliable classification of marine living organisms in the first instance. Indeed, one impediment to the successful implementation of biodiscovery programmes at an international level is the shortage of suitably qualified taxonomists capable of correctly identifying and classifying marine organisms for research purposes.[37] Moreover, one of the direct benefits of biodiscovery is the enhancement of knowledge about marine biodiversity generally and about marine organisms in particular.

Sixthly, it is clear from the specialist literature that there is no consensus on the precise meaning of the terms "biodiscovery "or

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application and development of isolated compounds for *commercial* purposes, including large–scale collection, development of large scale culture techniques, and conduct of trials for approval for *commercial* sale (emphasis added).

[37]See Report of the work of the United Nations Open-ended Informal Consultative Process on Oceans and Law of the Sea at its eight meeting, UN General Assembly A/62/169, 30 July 2007, para.101. Available at: http://www.un.org/Depts/los/consultative_process/consultative_process.htm

"bioprospection". On the one hand, they may be understood as describing the entire research and development process from sample extraction in the marine environment through to the full scale commercialisation and marketing of a new product or process.[38] One expert, on the other hand, has made the interesting distinction that the phase of initial research and gathering of information could be referred to as "biodiscovery", while the term "bioprospecting" could cover the subsequent phases of collection of the resources for purposes of further investigation and eventual commercial application.[39] Irrespective of whether one accepts this distinction or not, it is clearly evident that both terms embrace a very broad range of disciplines including ecology, biology, biochemistry, organic chemistry and pharmacology, as well as the subsequent commercial process of taking the new product or process to the market place.

Finally and solely for the purpose of this paper, "biodiscovery" is understood to refer to the collection of small amounts of marine biological material and their subsequent screening to identify bioactive compounds that may be used for commercial purposes. This definition has three key features: it entails the collection and use of *small* amounts of biological/geochemical material, its *subsequent* screening, and the application of knowledge for *commercial purposes* (emphasis added).

[38]See United Nations University, An Update on Marine Genetic Resources: Scientific Research, Commercial Uses and a Database on Marine Bioprospection, United Nations Informal Consultative Process on Oceans and the Law of the Sea, 8th Meeting, United Nations, New York, 25-29 June 2007.

[39]See paper by D. J. Newmann Deep Sea 2003, an International Conference on Governance and Management of Deep-sea Fisheries, Fisheries Report No. 772, (Rome, Food and Agriculture Organization of the United Nations, 2005); D. J. Newman, G. M. Cragg and K. M. Snader, "Natural products as sources of new drugs over the period 1981-2002", Journal of Natural Products, vol. 66, No. 7 (2003).

Relevant provisions in the 1982 LOS Convention

The 1982 LOS Convention does not refer expressly to biodiscovery or bioprospection. There are however extensive provisions on MSR in the Convention which are set out in Part XIII and are summarised in Table 1 below. [40]

[40]For detailed analysis of negotiation of the MSR provisions in the 1982 LOS Convention, see Myron H. Nordquist, Shabtai Rosenne and Alexander Yankov, *United Nations Convention on the Law of the Sea 1982: A Commentary*, Vol. IV (Dordrecht: Nijhoff, 1991). The first major monograph on the subject was undertaken by Professor Soons at the Netherlands Institute on the Law of the Sea, Utrecht University and published the same year the Convention was signed (1982) and twelve years before the Convention came into force in 1994. See, A. Soons, *Marine Scientific Research and the Law of the Sea* (Deventer, Netherlands: Kluwer Law, 1982). Subsequently, a useful summary of the principal provisions in the Convention was published by Alexander Yankov, a member of USSR delegation and since a Judge at the International Tribunal on the Law of the Sea, and who as Chairperson of the Third Committee had first–hand knowledge of the negotiations of the MSR provisions in the Convention, see A. Yankov, "A General Review of the New Convention on the Law of the Sea: Marine Science and its Application," 4 *Ocean Yearbook* 150-175 (1983). In 1991, the United Nations published a useful guide which is now somewhat dated, see United Nations, *Guide for the Implementation of the Relevant Provisions of the UN Convention on the Law of the Sea* (United Nations, Office for Ocean Affairs and the Law of the Sea, New York, 1991). There have also been a number of insightful journal articles including *inter alia*: P. Birnie, "Law of the Sea and Ocean resources: Implications for Marine Scientific Research," 10(2) *International Journal of Marine and Coastal Law* 229-251 (1995); J. Ashley Roach, "Marine Scientific Research and the New Law of the Sea," 27 *Ocean Development and International Law* 59-72 (1996). Also see, R.R. Churchill and A.V. Lowe, *The Law of the Sea* (3rd ed., Manchester University Press, Manchester, 1999), pp. 400–420; In recent years, two comprehensive works have been completed on MSR by Montserrat Gorina-Ysern, *An International Regime for Marine Scientific Research* (Ardsley, NY: Transnational Publishers, 2003); and by Florian H.Th. Wegelein, *Marine Scientific Research: The Operation and Status of Research Vessels and other Platforms in International Law* (Leiden: Nijhoff, 2005). In Ireland, see, C. R. Symmons, P. Gardiner, 1983. "Marine Scientific Research in Offshore Areas, Ireland and the Law of the Sea Convention". *Marine Policy,* 7(4), 291–231; C. Symmons, *Ireland and the Law of the Sea* (2nd. ed., Dublin, Round Hall Sweet and Maxwell, 2000),391-406; R. Long, *Marine Resource Law* (Dublin, Thomson Round Hall, 2007), 684–722.

Table 1: Provisions on MSR in Part XIII 1982 LOS Convention[41]

Article	*Subject*
Article 245	Marine scientific research in the territorial sea
Article 246	Marine scientific research in the EEZ and on the continental shelf
Article 247	Marine scientific research projects undertaken by or under the auspices of international organisations
Article 248	Duty to provide information to the coastal State
Article 249	Duty to comply with certain conditions
Article 250	Communications concerning marine scientific research projects
Article 251	General criteria and conditions
Article 252	Implied consent
Article 253	Suspension or cessation of marine scientific research activities
Article 254	Rights of neighbouring land-locked and geographically disadvantaged states
Article 255	Measures to facilitate marine scientific research and assist research vessels
Article 256	Marine scientific research in the Area
Article 257	Marine scientific research in the water column beyond the EEZ

There are a number of general points that may be made about Part XIII. Firstly, it should be noted that all States and competent international organisation (irrespective of their geographical location) have the right to

[41]Reproduced from R. Long, *Marine Resource Law* (Dublin, Thomson Round Hall, 2007), 684–722.

conduct MSR subject to the rights and duties of other States as provided for in the 1982 LOS Convention.[42] Indeed, the Convention places an express duty on states and international organisations to promote and facilitate the development and conduct of MSR.[43] Several principles apply under the Convention to the conduct of MSR including the requirement that it is conducted exclusively for peaceful purposes, with appropriate scientific methods and means compatible with the Convention.[44] In addition, it must not unjustifiably interfere with other legitimate uses of the sea that are compatible with the Convention and must be duly respected in the course of such uses.[45] MSR must be conducted in compliance with all relevant regulations adopted in conformity with the Convention including those for the protection and preservation of the marine environment.[46] Importantly in the context of designing a framework for marine biodiscovery activities, MSR must not constitute the legal basis for any claim to any part of the marine environment or its resources.[47]

The Convention aims to promote international cooperation and create favourable conditions for the conduct of MSR and calls for the conclusion of bilateral and multilateral agreements with a view to integrating the efforts of scientists in studying the essence of phenomena and processes occurring in the marine environment and the interrelations between them.[48] Surprisingly, there is little evidence of state practice in this regard since the coming into force of the Convention in 1994. Apart from a number of memoranda of understanding that have been concluded between scientific institutes there appears to be few bilateral or multilateral agreements aimed at creating favourable conditions for MSR.

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[42] 1982 LOS Convention, Art.238.
[43] *Ibid.,* Art.239.
[44] These principles are set out in Art.240(a) to (d).
[45] *Ibid.*
[46] *Id.*
[47] Art.241.
[48] Art.243.

The rights and duties of all States and international organisations vary in the different maritime jurisdiction zones that come under the sovereignty and jurisdiction of a coastal State. In the case of Ireland, these zones include internal waters, the territorial sea, the Exclusive Economic Zone, and the continental shelf. The rules that apply to foreign MSR are relatively straight forward and are briefly reviewed here.[49]

In the exercise of sovereignty, the coastal State has the exclusive right to conduct, authorise and regulate MSR in the territorial sea.[50] Although the Convention is silent on the matter, the coastal State has the exclusive right to conduct, authorise and regulate MSR in "internal waters" and this includes in the sea area on the landwards side of straight baselines. MSR may only be conducted by foreign research vessels in the territorial sea/internal waters with the express consent of the coastal State.

Seaward of the territorial sea, the coastal State has jurisdiction over MSR and this includes the right to conduct, authorise and regulate MSR in the EEZ and on the continental shelf subject to the standards and qualifications set down by the 1982 LOS Convention.[51] Essentially, the Convention differentiates between two types of research—the first type relates to research carried out exclusively for peaceful purposes and in order to increase scientific knowledge of the marine environment for the benefit of all mankind. For this type, the coastal State must in normal circumstances grant consent for MSR projects by other states or competent international organizations in the EEZ or on the continental shelf.[52] The coastal State is also obliged to establish rules and procedures ensuring that such consent will not be delayed or denied unreasonably.[53] In practice, few states have specific legislation governing MSR and the general preference appears to be for the establishment of administrative

[49]See R. Long, *Marine Resource Law* (Dublin, Thomson Round Hall, 2007), pp. 684–722.
[50]1982 LOS Convention, Art.245.
[51]*Ibid.,* Arts 246–255.
[52]*Id.* Art.246(3).
[53]*Ibid.*

schemes for controlling foreign MSR in sea areas under national jurisdiction.[54] The second type relates to research on natural resources in the EEZ or on the continental shelf. For the second type, the costal State has discretion to withhold consent if: the research project is of direct significance for the exploration and exploitation of the living or non-living resources;[55] involves drilling into the continental shelf; involves the use of explosives or the introduction of harmful substances into the marine environment; or entails the use of artificial islands, installations, or structures.[56] In certain circumstances, the coastal State may deny consent if the researching State has not provided accurate information or has outstanding obligations in relation to previous research projects.[57] Consent is also granted subject to a number of conditions including the coastal State's right under the Convention to participate in the project, to have access to data and samples and to assistance in the interpretation of data and results, and to have the results of the research project internationally available as soon as practicable.[58] This is without prejudice to the conditions established by the laws and regulations of the coastal State for the exercise of its discretion to grant or withhold consent including requiring prior agreement for making internationally available the research results of a project of direct significance for the exploration and exploitation of natural resources.

Slightly different rules apply to MSR on the outer continental shelf, that is to say on the part of the shelf that extends beyond 200 miles

[54]See replies to Advisory Body of Experts on the Law of the Sea (IOC/ABE-LOS) questionnaire no. 3. Available at http://ioc3.unesco.org/abelos/index.php?option=com_content&task=view&id=45&Itemid=56

[55]Under Art.246(6), coastal States may only withhold their consent in relation to this ground in areas of the continental shelf beyond 200 miles that are publicly designated as areas in which exploitation or detailed exploratory operations focused on those areas are occurring or will occur within a reasonable period of time.

[56]*Ibid.,* Art.246(5)(a)–(c).

[57]*Ibid.,* Art.246(5)(d).

[58]*Ibid.,* Art.249.

measured from the baselines. In such areas, the coastal State may not exercise its discretion to withhold consent in respect of MSR projects outside of those specific areas which are publicly designated as areas in which exploitation or detailed exploratory operations focused on those areas are occurring or will occur within a reasonable period of time.[59] Coastal States must give reasonable notice of the designation of such areas, as well as any modifications thereto, but shall not be obliged to give details of the operations therein.

The 1982 LOS Convention sets down a number of general and specific duties on both the coastal State and the researching State. Thus, for example, MSR activities must not unjustifiably interfere with activities undertaken by coastal States in the exercise of their sovereign rights and jurisdiction provided for in the 1982 LOS Convention. The researching State or States and competent international organizations which intend to undertake the MSR must provide considerable information when requesting consent to undertake research in the EEZ or continental shelf. This information must include a full description of:

(a) the nature and objectives of the project;
(b) the method and means to be used, including name, tonnage, type and class of vessels and a description of scientific equipment;
(c) the precise geographical areas in which the project is to be conducted;
(d) the expected date of first appearance and final departure of the research vessels, or deployment of the equipment and its removal, as appropriate;
(e) the name of the sponsoring institution, its director, and the person in charge of the project; and

[59] Art.246(6)

(f) the extent to which it is considered that the coastal State should be able to participate or to be represented in the project.

MSR beyond the limits of national jurisdiction is a high seas freedom. The specific issues associated with biodiscovery on the high seas are beyond the scope of this paper. The different rules that apply to MSR in these zones under the Convention are briefly summarised in Table 2 below.

Biodiscovery projects may be undertaken by or under the auspices of international organisations that have competence in marine scientific research. There are a number of reasons for this including the cost of undertaking deep–ocean science as well as the limited number of institutions worldwide who own or operate vehicles that are able to reach areas deeper than 1,000 metres below the oceans' surface and can therefore be actively involved in deep seabed research. There is a specific provision (Article 247) in the 1982 LOS Convention dealing with MSR projects undertaken by or under the auspices of international organizations.[60] This article provides that a coastal State which is a member of or has a bilateral agreement with an international organization, and in whose EEZ or on whose continental shelf that organization wants to carry out a MSR project, directly or under its auspices, shall be deemed to have authorized the project to be carried out in conformity with the agreed specifications if that State approved the detailed project when the decision was made by the organization for the undertaking of the project, or is willing to participate in it, and has not expressed any objection within four months of notification of the project by the organization to the coastal

[60]See *inter alia*: B. H. Oxman, "The Third United Nations Conference on the Law of the Sea: The 1977 New York Session" (1978) *American Journal of International Law*, pp. 57–83, at 77–78; United Nations, *Guide for the Implementation of the Relevant Provisions of the UN Convention on the Law of the Sea* (United Nations, Office for Ocean Affairs and the Law of the Sea, New York, 1991), pp. 14-15.

State. Essentially, this article foresees the establishment of a special consent regime for projects undertaken by or under the auspices of international organizations when such projects can only be executed meaningfully when access is available to the EEZs of several coastal States. In particular, it foresees a simplified and less bureaucratic procedure for projects which involve regional or global intergovernmental organisations. The procedure envisaged by Article 247 is aimed at enabling long–term planning by scientists and could be used by any international organisation with competence in marine scientific research.[61] At the time of writing, only one international organisation, the Intergovernmental Oceanographic Commission has adopted an internal procedure for the implementation of Article 247. The procedure has been described as quite cumbersome and it has been questioned by one leading expert in the field who played a major role in its drafting whether it will be ever implemented by the IOC.[62]

Importantly, states and competent international organisations are responsible for ensuring that MSR, whether undertaken by them or on their behalf, is conducted in accordance with the 1982 LOS Convention.[63] In this context, they are responsible and liable for any measure they take in contravention of the 1982 LOS Convention with respect to research by other states, their natural or juridical persons, or by competent international organisations and are obliged to provide compensation for damage resulting from such measures.[64] They are also liable for damage caused by pollution of the marine environment arising out of MSR.[65]

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[61]*Ibid.*
[62]See A. Soons, "The Legal Regime of Marine Scientific Research: Current Issues" in M. Nordquist, R. Long, T. Heidar, J. Norton Moore eds., *Law, Science and Ocean Management* (Leiden/Boston, Martinus Nijhoff, 2007), p.158.
[63]*Ibid.,* Art.263(1).
[64]*Ibid.,* Art.263(2).
[65]*Ibid.,*, Art.235.

Table 2: Rights in relation to MSR in the various maritime jurisdictional zones

Maritime Jurisdictional Zone	*Rights in relation to MSR*
Internal waters / territorial sea	Coastal States have the exclusive right to regulate, authorise and conduct MSR including biodiscovery
Exclusive Economic Zone/ continental shelf (within 200 miles)	Coastal States have the exclusive right to regulate, authorise and conduct MSR including biodiscovery. ➢ Must grant consent in normal circumstances to other states and competent international organisations for MSR projects that are carried out in accordance with the Convention exclusively for peaceful purposes and in order to increase scientific knowledge of the marine environment for the benefit of all mankind. ➢ Have discretion to withhold their consent to the conduct of MSR of another state or competent international organisation if the project is *inter alia* of direct significance for the exploration and exploitation of natural resources whether living or non-living.
Outer continental shelf (beyond 200 miles from the baselines)	Right of the coastal State to authorise and regulate MSR in the specific areas which it may publicly designate as areas in which exploitation or detailed

	exploratory operations focused on those areas are occurring or will occur within a reasonable period of time.
Water column beyond the EEZ/ International seabed area	All States and competent international organisations have the right to conduct MSR

Can we distinguish biodiscovery from the more traditional forms of marine scientific research?

As mentioned previously, the term "marine scientific research" is not defined in the 1982 United Nations Convention on the Law of the Sea and there is considerable debate at an international level as to the precise range of activities that may be considered as MSR for the purpose of the Convention. In particular, different views have been expressed on whether routine operational oceanography data collection and hydrography come within the scope of the provisions in the Convention on MSR.[66]

Broadly speaking, MSR involves gathering information, data, or samples and their subsequent analysis. In many instances it may not initially be undertaken with a view to economic gain, although the research results generated may be commercially valuable. MSR may involve cooperation between participating scientists, dissemination of data, exchange of publicly and privately owned samples between researchers, as well as the publication of research results. Some commentators have drawn a distinction between *fundamental* scientific research which is undertaken exclusively for peaceful purposes and in order to increase scientific knowledge of the marine environment for the benefit of all mankind and *applied* marine scientific research which is

[66]See A. Roach "Defining Scientific Research: Marine Data Collection", *Law, Science and Ocean Management* (Leiden/Boston, Martinus Nijhoff Publishers, 2007), 541–573.

undertaken on natural resources for commercial purposes.[67] There is also some support for this view in the expert reports on the subject of marine genetic resources. For example, the report undertaken by the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) of the Parties of the Convention on Biological Diversity points out that:

> *Marine scientific research activities are characterized by their transparency and openness, the obligation to disseminate information and data obtained therefrom, as well as the subsequent publication of results of the research. Marine scientific research has, therefore, to be distinguished from other investigative marine activities with any kind of commercial component, such as prospecting, exploration, or fish stock assessment, which may involve confidentiality or proprietary rights. Under the United Nations Convention on the Law of the Sea, marine scientific research is primarily aimed at furthering mankind's knowledge of the marine environment, its resources and various phenomena, and is not a vehicle for searching for natural resources for commercial purpose.*[68]

Elsewhere in this report it is suggested that:

> *In the absence of a formal definition, marine scientific research could be defined as an activity that involves collection and analysis of information, data or samples aimed at increasing mankind's knowledge of the environment, and is not under-taken with the intent of economic gain. Since the object is the enhancement of knowledge, marine scientific research is characterized by openness, dissemination of data, exchange of samples, as*

[67]Arts 246(3) and 246(5), 1982 LOS Convention. On this point see, R.R. Churchill and A.V. Lowe, *The Law of the Sea* (3rd ed., Manchester University Press, Manchester 1999), p.405.

[68]SBSTTA Report, Doc. UNEP/CBD/SBSTTA/8/INF/3/Rev. 1 of 22 February 2003, para. 39,

> *well as publication and dissemination of research results as provided for in Part XIII.*[69]

There are many problems associated with this somewhat theoretical distinction between pure and applied research. Indeed it may be argued that this distinction is more illusory than real because in many cases the source material used in biodiscovery may have been obtained and analysed as part of a marine scientific research project which was not undertaken exclusively for economic gain. In some cases, it may only become apparent at a much later stage that the knowledge, information and useful materials collected during such projects have a commercial application. It should also be noted that government and European Union sponsored research programmes often encourage marine researchers to pass organisms and related discoveries to industry as a form of technology transfer. Even where this is not required, organisms and environmental samples, such as water and sediment samples may be passed to industry by marine scientific researchers under material transfer agreements. At a practical level, it is often difficult to draw a firm line between fundamental research and research that may at some point be significant in terms of the commercial development of a product. Indeed, primary research and sampling in the marine environment will often be the first step in the long process that ultimately leads to product development and commercialization. As noted in the UN Secretary–Generals Report on the Oceans and the Law of the Sea, the difference between scientific research and biodiscovery/bioprospecting therefore seems to lie in the use of knowledge and results of such activities, rather than in the practical nature of the activities themselves.[70]

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[69]*Ibid.,* para.47. Professor Scovazzi has argued that the SBSTTA provides not a definition, but an interpretation of the notion of marine scientific research as used in the 1982 LOSC.

[70]Report of the Secretary–General on the Oceans and the Law of the Sea, A/60/63/Add.1. para. 202.

In summary, marine biodiscovery, if it is resource related, requires the express consent of the coastal State and this consent may be withheld at the discretion of the coastal State if the research is of direct significance for the exploration and exploitation of natural resources. In this context, it is important to recall that under the Convention, MSR must not constitute the legal basis for *any* claim to any part of the marine environment *or its resources* (emphasis added).[71] Indeed, one commentator has pointed out that the current international regime for MSR under the Convention does not deal with proprietary title over MSR data results.[72] Results made available to the public often lead to developments of new marine products or processes which require protection as an intellectual property right. Such rights are regulated by private agreements rather than under international regulation and may thus constitute a "claim" under Article 241. Therefore it would seem prudent that this issue is addressed by coastal State authorities prior to granting consent for foreign MSR activity in sea areas under national jurisdiction. In particular, consent for applied marine scientific research could be made subject to specific provisions addressing the commercialisation of the research. Furthermore, the coastal State ought to seek consultation and precise information regarding any proposals for the patent protection of inventions concerning micro-organisms, micro-biological and non-biological processes.

Are the provisions in the Convention on "natural resources" applicable to biodiscovery?

The search and collection of macro-organisms plants, animals, fungi or micro–organisms may constitute natural resource exploration and exploitation if it is accepted that the organisms which are the focus of biodiscovery are covered by the term "natural resources" as used in the

[71]Art. 241 of the 1982 LOS Convention.
[72]See Y. Montserrat Gorina-Ysern, *An International Regime for Marine Scientific Research* (Ardsley, NY: Transnational Publishers, 2003), pp. 353-460 *passim*.

Convention. This term has four separate meanings under the Convention depending in which maritime jurisdictional zone the resources are found.[73]

Importantly, under the provisions on the EEZ, the coastal State has sovereign rights for the purpose of exploring, exploiting, conserving and managing natural resources, whether living or non-living, of the waters superjacent to the seabed and of the seabed and its subsoil.[74] In this context, the term "natural resources" undoubtedly includes macro-organisms plants, animals, fungi or micro–organisms found in the EEZ. Similarly, the natural resources governed by the provisions on the continental shelf are the "mineral and other non-living resources of the seabed together with sedentary species, that is to say, organisms which, at the harvestable stage, either are immobile on or under the seabed or are unable to move except in constant physical contact with the seabed or the subsoil".[75] The meaning of the phrase "...living resources belonging to sedentary species..." is not free from controversy.[76] The rationale for the inclusion of the sedentary species in the provisions dealing with continental shelf in the Convention is apparently their attachment to the seabed, expressed in terms of limited mobility at the harvestable stage. Clearly, it may be argued that sedentary species includes the biotic

[73]See A. Roach, "Defining Scientific Research, Marine Data Collection" in M. Nordquist, R. Long, T. Heidar, and J, Norton Moore (eds.) *Law, Science and Ocean Management* (Leiden/ Boston, Martinus Nijhoff Publishers, 2007), p. 545.
[74]1982 LOS Convention, Art. 56(1)(a)
[75]1982 LOS Convention, Art. 77(4)
[76]See *inter alia*: R.R. Churchill and A.V. Lowe, *The Law of the Sea* (3rd ed., Manchester University Press, Manchester 1999),p.152.; D. Attard, *The Exclusive Economic Zone in International Law* (Clarendon Press, Oxford, 1987), pp.190–191; B. Kwiatkowska, *The 200 Mile Exclusive Economic Zone in the New Law of the Sea* (Martinus Nijhoff Publishers, Dordrecht, 1989),pp.74-78; S.V. Scott, "The Inclusion of Sedentary Fisheries within the Continental Shelf Doctrine" (1992) 41 I.C.L.Q. 788, V. Prescott, "Resources of the Continental Margin and International Law" in *Continental Shelf Limits: The Scientific and Legal Interface* (Peter J. Cook and Chris M. Carleton, eds., Oxford University Press, Oxford, 2000), pp. 64–83 . On sedentary species in areas beyond national jurisdiction see, F. M. Armas Pfirter, *The Management of Seabed Living Resources in "The Area" under UNCLOS* (Report completed for the Tenth Session of International Seabed Authority, 24th May-4th June 2004).

components associated with the benthic species, as well as the fauna and flora of the continental shelf.[77] Accordingly, the coastal State may exercise sovereign rights for the purpose of exploring and exploiting the natural resources of the continental shelf.[78]

Both within and beyond the Exclusive Economic Zone (EEZ) limits, the rights of the State over the continental shelf resources are exclusive in the sense that no one may exploit these resources without the consent of the State.[79] Moreover, under international law, continental shelf rights are not dependent on occupation, effective or notional, or on any express proclamation.[80] In the case of fishery resources, however, Ireland similar to other Member States of the European Union has ceded certain powers to manage, conserve and allocate these resources to the EC under the common fisheries policy (CFP). The same is not true in relation to the deepwater ecological resources such as deep-water corals to the west of Ireland.[81] These are not European resources for the purpose of management or the allocation of user-related rights, or indeed for undertaking marine scientific research without the express and prior consent of the Irish government. [82] In sea areas within the EEZ limits, the coastal State has a duty to manage and conserve these resources. Beyond the EEZ, the State may authorise the exploration and exploitation of these resources as far as the outer limits of the continental shelf.[83] Accordingly, whether an organism on the continental shelf beyond 200 miles is sedentary or not will have important legal consequences since the State's sovereign rights are limited to biological resources that satisfy this requirement, if they do not they are subject to the regime of the high seas.

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[77]On this point see See R. Long, *Marine Resource Law*, paras 3–98 to 3–103.
[78]1982 LOS Convention, Art. 77(1).
[79]Art.77(2) of the 1982 LOS Convention.
[80]*Ibid.,* Art.77(3).
[81]On the protection of deep–water coral see R. Long, *Marine Resource Law*, paras 10–143 to 10–151.
[82]See R. Long, *Marine Resource Law*, paras 11–24 to 11–38.
[83]Art. 77(1) of the 1982 LOS Convention

This will always entail both a factual and legal analysis on whether these resources satisfy the sedentary species test. As noted in one authoritative study on this subject:

> *…the application of the sedentary species test to microfauna is at best problematic and at the worst farcical. Moreover, allocating conservation and management authority on a species–by–species basis, according to which organisms meet the sedentary species test, will almost certainly preclude an ecosystem management approach….*[84]

The third category of natural resources mentioned in the Convention are the natural resources of the deep seabed beyond the limits of national jurisdiction which is simply referred to as the Area. The regime of the Area is governed according to Part XI of the 1982 LOS Convention and by the 1994 Implementation Agreement relating to the Implementation of Part XI of the United Nations Law of the Sea Convention of the December 1982.[85] The resources of the Area are defined by the 1982 Convention as "solid, liquid or gaseous *mineral resources* in situ in the Area at or beneath the seabed including

[84]See C. Allen, "Protecting the Oceanic Garden of Eden: International Law issues in Deep–Sea Vent Resource Conservation and Management" in 16 *Georgetown International Environmental Law Review* 563 at 659.

[85]The Agreement relating to the Implementation of Part XI of the United Nations Law of the Sea Convention of the December 1982 was adopted in 1994. Under this Agreement, the original provisions of Part XI of the 1982 Convention relating to the setting of production levels and for the transfer of technology to developing States do not apply. Ireland ratified the 1994 Implementation Agreement in 1996. At the time of writing Ireland has not adopted any regulatory measures pertaining to the "Area". On Ireland's approach to the negotiation of the provisions in the 1982 LOS Convention, see 309 *Dáil Debates* Col.1574. For a comprehensive review of the 1982 LOS Convention and the 1994 Agreement, see S.N. Nandan, M. Lodge and S. Rosenne, *United Nations Convention on the Law of the Sea 1982 A Commentary* (Martinus Nijhoff Publishers, The Hague/London/New York, 2002) Vol. VI.

polymetallic nodules".[86] Resources, when recovered from the Area, are referred to as 'minerals'".[87] Clearly, living resources are not mineral resources and do not come within the scope of the resource definition in Part XI of the Convention. However, it should also be noted that under the Convention the ISA has the authority and the duty in some instances to prevent any damage to the marine flora and fauna which may arise from activities in the Area. The functions of the Authority extend in a limited extent to environmental protection and marine scientific research in the Area.

The fourth category of "natural resources" is the provisions in the Convention concerning the "living resources of the high seas".[88] In the main, these provisions deal with fisheries and marine mammals. Although the Convention lacks specific provisions on marine genetic resources, living resources of the high seas by definition includes genetic material extracted from fish, marine mammals and from microbes in the water column. In this context, as noted above, it is important to bear in mind that marine genetic material is often collected from fish and a broad range of other vertebrates and invertebrates including squid, sea snails etc**.** As a matter of practice, marine genetic research will normally only require small quantities of samples for laboratory analysis and may thus be distinguished from fishing which is always aimed maximising the catch. There is however some evidence in the specialist literature that this is not always the case. For instance, the report of the UN Secretary General on the Oceans and the Law of the Sea cites the example of 2,400 kg of sponge yielding less than 1 mg of spongistatin.[89] It should also be noted that a number of scholars have pointed that it would be illogical to apply

[86]Art.133(a), 1982 LOS Convention.
[87]Art.133(b), 1982 LOS Convention.
[88]Arts 116 to 120, 1982 LOS Convention.
[89]See "Recent Trends in Biological Prospecting," Information Paper submitted to the 29th meeting of the Antarctic Treaty Consultative Meeting, Document IP116 cited in UN Doc. A/62/ p.35. On the use of spongistatin as a marine natural product, see, *Molecular Pharmacology*, Volume 44, Issue 4, pp. 757-766, 10/01/1993.

the rules of the LOSC relating to fishing and conservation and management of the living resources of the high seas (Arts. 116 to 120) to activities directed at the acquisition of genetic material from organisms or microbes found in the sea.[90] Nevertheless, it should not be forgotten that some of the most successful forms of biodiscovery have been targeted at higher forms of marine life such as tooth fish in the Southern Ocean.[91] For this reason, it may not be that easy to draw a distinction between fishing activity and biodiscovery. It should also be noted that the domestic law of several common law countries such as Ireland define "fish" and "fishing" rather broadly and this term could include the collection of fish species for biodiscovery.[92]

For convenience Table 3 below presents a brief summary of the law which applies to the exploration and exploitation of natural resources in sea areas under coastal State jurisdiction.

[90]See, for example, T. Scovazzi, "Mining, Protection of the Environment, Scientific Research and Bioprospecting: Some Considerations on the Role of the International Seabed-Authority" 19 *International Journal of Marine and Coastal Law* pp.383-409 at p.400.

[91]For example, Arctic/Antarctic fish have antifreeze properties which are of interest to marine scientists. One commentator has also pointed out that genetic material may be extracted from fish and marine mammals, see D. Owen, "A Study into the Legal Framework for Marine Biotechnology Development in the United Kingdom", UK Fore*sight* Marine Panel Report: FMP MBG – 01, January 2004, p. 113.

[92]See, for example, s.6 of the Sea-Fisheries and Maritime Jurisdiction Act 2006 in Ireland which defines "fish" and "sea-fish" to include "anadromous and catadromous species and all crustaceans and mollusks found in the sea and the brood and spawn of fish, and references to a fish are to be read as including references to part of that fish".

Table 3: Consent regime that applies to the exploration of natural resources in sea areas under coastal State jurisdiction

Maritime Jurisdictional Zone	***Rights of coastal State in relation to resources under the 1982 LOS Convention***
Internal waters / territorial sea	Sovereignty over all natural resources
Exclusive Economic Zone	Sovereign rights for the purpose of exploring and exploiting, conserving and managing the natural resources, whether living or non-living, of the waters column and seabed.
Continental shelf (both within and beyond 200 miles)	Sovereign rights for the purpose of exploring it and exploiting its natural resources. The natural resources consist of the mineral and other non-living resources of the seabed and subsoil together with living organisms belonging to sedentary species, that is to say, organisms which, at the harvestable stage, either are immobile on or under the seabed or are unable to move except in constant physical contact with the seabed or the subsoil.
High seas	In principle high seas freedom
International seabed area	Common heritage of mankind

Case study: regulating marine biodiscovery in sea areas under Ireland's jurisdiction.

Ireland is a useful case study where it may be possible to establish a governance framework for marine biodiscovery. There are several reasons why it may be prudent to establish such a framework. Firstly, Ireland is an island on the Atlantic margin of the Europe Union with a broad continental shelf and abundant biodiversity. The marine sector in Ireland is worth approximately EUR3 billion per annum to the economy. Ireland has a dynamic and well-resourced marine scientific research community which grown rapidly over the last decade. This growth is set to continue under the national development plan with a targeted investment of EUR600 million in the marine sector over the period 2007 to 2011. A key component in this plan is the development of a marine biodiscovery/biotechnology research programme. This is significant because it will move Ireland from its current position of a coastal State where research is carried out by scientists embarked on foreign flagged research vessels to a State which will have primary interest in its own national biodiscovery programme. In addition, Ireland has its own ocean-going research vessel and Irish scientists are very much part of the broader community of European scientists.

The second reason why it may be prudent to establish a legislative framework for biodiscovery relates to the large number of foreign research vessels which undertake research in sea areas under Irish jurisdiction.[93] For example, there were over 500 foreign MSR vessels which undertook research in this area during the period 1992 to 2007. The origin of these vessels varies considerably with over 260 visits by vessels flying the flag of the United Kingdom, and several visits by vessels from the other Member States of the European Union, the United States, The Russian Federation and Norway. Although the majority of the research cruises are

[93]For a detailed of the law applicable to MSR in Ireland, see R. Long, *Marine Resource Law*, chapter 1, pp. 684-723.

focused on fisheries research, there is also a considerable number of cruises that collect samples and data on the fauna and flora of the seabed. The consent process for foreign research vessels is essentially an administrative exercise. At the time of writing, it generally takes a number of weeks (sometimes less than 6) to process a foreign research vessel cruise application form. Ireland does not have a rigorous system of oversight regarding the activities of foreign research vessels with scientific observers participate in approximately 3 cruises per annum. Up until relatively recently, Ireland had no facilities for sample storage and little effort was made to evaluate if foreign research projects were being undertaken for commercial purposes.

In designing a framework governing foreign biodiscovery, a key challenge for Ireland is to continue to work within the normative framework established by the 1982 Law of the Sea Convention and to uphold its duty to promote and facilitate MSR. One of the key issues to be resolved in relation to foreign MSR is to ensure that the acquisition of samples does not become a covert claim to resources in sea areas under national jurisdiction. In this context, it is important to recall that Ireland has considerable discretion under the Convention regarding the conditions that may be applied to foreign research vessels if their activity is of direct significance for the exploration and exploitation of natural resources in sea areas under national jurisdiction.[94]

There are several methods which may be used in designing a governance framework for foreign MSR. The most obvious one relates to the enactment of specific regulatory measures protecting the marine bio-resource and implementing in domestic law the provisions codified in the 1982 LOS Convention. Any such regulation should have specific provisions dealing with ownership of MSR data, samples and the results of MSR. Alternatively, it is also possible to adopt measures for the establishment of marine protected areas. Ireland already has such

[94]Arts 246, 248 and 249 of the 1982 LOS Convention.

measures in place for the protection of deep-water coral in the EEZ. Similarly, Canada and Portugal have established MPAs for the protection of hydrothermal vent sites. The designation of areas as MPAs facilitates the adoption of codes of practice governing MSR. In the European context, considerable work has been undertaken in this regard within the framework of the 1992 Convention for the Protection of the Marine Environment of the North-East Atlantic.

The principle difficulty regarding the establishment of a specific governance regime for biodiscovery is how to reconcile the various rights and duties that arise under international treaties including *inter alia*: the 1982 LOS Convention, the 1992 Convention on Biological Diversity, the Convention on International Trade in Endangered Species of Wild Flora and Fauna, as well as the Agreement on Trade Related Aspects of Intellectual Property, Including Trade in Counterfeit Goods. This task is compounded by the many aspects of European law that are relevant to such a framework. Nevertheless, such a framework should aim to: promote and facilitate MSR; respect the balance between coastal State rights and researching State/international organisations interests; retain favourable conditions for the acquisition of data and the collection of samples from the marine environment. The framework should also place an emphasis on the monitoring of research perhaps through the establishment of a database and the registering of all biodiscovery related activities including the patenting of inventions.

Although MSR should not form the basis of any claim to the marine environment or its resources, this risk should not be over-emphasised or used as a reason to curtail MSR. Indeed, in order to address concerns regarding property rights it may be prudent to address this issue through the medium of intellectual property law at the point of commercialisation. In Ireland, one of the issues to be resolved in this context is whether there should be the same regime in place for nationals and non-nationals. Clearly in the context of European law any future

measures cannot discriminate on the grounds of nationality in relation to scientists from other Member States of the European Union.

Conclusion

The MSR provisions in the 1982 LOS Convention have served the international community well since the Convention has come into force over two decades ago. In Ireland, the implementation of these provisions by means of an administrative system has not posed any particular problem. Nevertheless, with advances in ocean science and with the development of a national marine biodiscovery programme it may be prudent for Ireland to bring forward national legislation to implement Part XIII of the 1982 LOS Convention. Apart from conforming with international & European law, any such legislation should aim to provide a transparent and stable regime governing the conservation, mapping, sampling and utilisation of biodiversity. Only such an approach will ensure clarity and certainty for all.