

UNU-IAS Report

Bioprospecting of Genetic Resources in the Deep Seabed: Scientific, Legal and Policy Aspects



This report was written by

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Abbreviations

AIMS Australian Institute of Marine Science ATS Antarctic Treaty System CCAMLR Convention on the Conservation of Antarctic Marine Living Resources CRAMRA Convention on the Regulation of Antarctic Mineral Resources Activities CBD Convention on Biological Diversity CNRS French National Scientific Research Center CoML Census of Marine Life COP Conference of the Parties DSRV Deep Submergence Research Vehicle **EEZ Exclusive Economic Zone** EIA Environmental impact assessment FAO Food and Agriculture Organization of the United Nations GEOSS Global Earth Observing System of Systems **HBOI Harbor Branch Oceanographic Institution** ICP (also UNICPOLOS) United Nations Informal Consultative Process on the Law of the Sea **IDA International Depositary Authorities** IFREMER French Research Institute for the Exploitation of the Sea IGC WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore **INSERM French National Institute of Health and Medical Research** IOC Intergovernmental Oceanographic Commission IPRs Intellectual Property Rights ISA International Seabed Authority JAMSTEC Japan Agency for Marine-Earth Science and Technology LTC ISA's Legal and Technical Commission MA Millennium Ecosystem Assessment MAP Mediterranean Action Plan MarBEC Marine Bioproducts Engineering Center MATs Mutually agreed terms MPA Marine protected area MSR Marine scientific research **NCI US National Cancer Institute** NOAA US National Oceanic and Atmospheric Administration **NSF US National Science Foundation** OSPAR Organization for the Protection of the Marine Environment of the North-East Atlantic PIC Prior informed consent R&D Research & development **ROV Remote Operation Vehicles** SBSTTA Subsidiary Body on Scientific Technical and Technological Advice TRIPS Agreement on Trade-Related Aspects of Intellectual Property Rights UNCLOS United Nations Convention on the Law of the Sea UNDOALOS United Nations Division for Ocean Affairs and the Law of the Sea UNEP United Nations Environment Programme WIPO World Intellectual Property Organization WSSD World Summit on Sustainable Development WTO World Trade Organization XBR Extremobiosphere Research Center of JAMSTEC

Foreword

The growing commercial interest in deep seabed research and the use of the unique genetic resources that this research has discovered raises key policy, ethical and moral questions. For example, who owns these resources, how should they be used and how should the benefits of this research be distributed, are just some of the issues that need attention.

Although some aspects of this type of use are adequately addressed by existing policies, there is uncertainty about the rules governing the use of these genetic resources.

The absence of clear rules governing the use of deep seabed genetic resources restricts use of these resources, and this affects stakeholders in significant ways. For industry, the uncertainty about the use and ownership of samples inhibits their support and involvement for this type research. For scientists, a lack of clear protocols for exchanging information arising from commercial activities inhibits their ability to work with companies and adapt to the changing nature of basic research around the world. For governments, it has proven difficult to decide about the need for, and modalities of, conservation measures for the deep seabed environment and also to negotiate how benefits of commercially orientated research are adequately shared.

The debate so far has indicated a strong need for more information and analysis. It is important that this information and analysis be neutral, balanced and accurate. This study aims to provide a factual review of the scientific, legal and policy aspects related to bioprospecting in seabed areas beyond national jurisdiction.

The United Nations University Institute of Advanced Studies (UNU-IAS) was established in 1996 as a research and training centre of UNU to undertake research and postgraduate education on emerging issues of strategic importance for the United Nations and its Member States. Pursuant to its Statute, UNU-IAS undertakes its work in an independent, neutral and objective manner. A key purpose of the Institute is to promote interaction between the UN System and other bodies. Development of this report is part of the wider programme on biodiversity at the Institute. The programme is also looking at bioprospecting in the Antarctica, certificates of origin for genetic resources and training for developing country officials.

I hope that this study will contribute to filling a gap in knowledge regarding deep seabed bioprospecting, thereby helping further advance policy debates on the issue.

A.H. Zakri Director, UNU-IAS May 2005

Executive Summary

Governments and international policy-makers are increasingly requesting information on various aspects of activities carried out in remote areas beyond the limits of national jurisdiction. This study focuses on deep seabed bioprospecting, loosely defined as the search for, and exploitation of, valuable compounds from genetic resources of the seabed beyond national jurisdiction. It provides an overview of the scientific, legal and policy aspects related to the issue, and explores various policy options that exist to address deep seabed bioprospecting at the international level.

A more detailed overview of the study is provided in Section 7, which outlines the report's main findings and possible approaches to addressing deep seabed bioprospecting.

Scientific research related to deep seabed genetic resources, whether purely academic or commercially-oriented, is restricted to a very few, who own the necessary technological capacity and the financial resources to access these remote areas. This raises development and ethical issues, among others, since the potential applications of deep seabed genetic resources to various sectors, including the health and food sectors, are manifold but the legal status of these resources is still uncertain.

Deep seabed ecosystems and associated genetic resources offer great opportunities in terms of bioprospecting and scientific interest. Seamounts are host to an extremely rich macrofauna, while hydrothermal vents provide valuable information with regard to the adaptation of life to extreme conditions. More generally, the study highlights the importance of deep seabed ecosystems and associated genetic resources from the ecological, scientific, economic, and ethical points of view.

The study demonstrates that bioprospecting for deep seabed genetic resources is taking place and that related commercial applications are being marketed. Deep seabed bioprospecting is placed within the broader context of the biotechnology sector, as well as bioprospecting for marine resources and for extremophiles. The study notes a shift from conventional techniques for the screening of potentiallyvaluable molecules to genomics and bioinformatics-driven approaches. These latter approaches provide an opportunity to link access and benefit-sharing arrangements regarding deep seabed genetic resources.

Deep seabed ecosystems and microorganisms attract the interest of marine scientists and bioprospectors alike. In this respect, partnerships between public and private research organizations are common, if not the norm. These partnerships and joint ventures have been fundamental in expanding the scope of original oceanographic research to more practical research, including prospecting. Without public-private partnerships, the potential of deep seabed ecosystems and resources would remain unexplored and unexploited.

A lack of availability of information regarding the specific terms of public-private partnerships, including access to deep seabed genetic resources and benefit-sharing arrangements, is noted. Shortcomings are also highlighted with regard to the limited availability and disclosure of information regarding the practical applications of deep seabed genetic resources, as well as the current patent classification system, which does not allow easy identification of patents based on the use of deep seabed genetic resources.

The study shows that there is currently a legal lacuna with regard to commercially-oriented activities targeting the biodiversity of seabed areas beyond the limits of national jurisdiction. The current international legal framework, composed of provisions to be found in several instruments, including the United Nations Convention on the Law of the Sea (UNCLOS), the Convention on Biological Diversity (CBD), intellectual property rights instruments, and regional marinerelated instruments, does not address, in an exhaustive and integrated manner, the conservation of, access to, and benefit-sharing related to, deep seabed resources.

Some of the legal gaps highlighted by the study relate to, *inter alia*:

- the uncertain legal status of deep seabed genetic resources, which are excluded from the regime of the Area, defined under UNCLOS as the seabed and ocean floor and its subsoil beyond the limits of national jurisdiction, and are therefore not considered as common heritage of humankind;
- whether, on the basis of the distinction between sedentary and non-sedentary species, deep seabed genetic resources fall under the regime of living resources in the High Seas under UNCLOS;
- the lack of an international definition of bioprospecting, which is difficult to distinguish, in practice, from pure marine scientific research – for which an internationallyagreed definition is also required;
- issues raised by the uncertain delineation of the Area;
- treatment of information and research results, as well as possible conflicts between the provisions of UNCLOS addressing treatment of research results from marine scientific research and those of intellectual property rights instruments;
- the legitimacy of asserting intellectual property rights over resources deemed of public interest, and what constitutes a patentable invention with regard to genetic resources; and
- the principle for, and modalities of, sharing of ensuing benefits, including through technology transfer, capacity building, information sharing and disclosure requirements within patent applications.

The study presents examples illustrating that uncertainty over access to marine biota can act as a deterrent to investment in research, thereby hampering the potential for benefits to both private companies and society as a whole. Marine research and bioprospecting undertakings are most effective when supported by clear and practical rules.

The study concludes by weighing the advantages and disadvantages of various possible options to address deep seabed bioprospecting. These non-mutually exclusive options include: retaining the *status quo*; using regional frameworks; the adoption of guidelines by the United Nations General Assembly, complemented by a voluntary code of conduct; using the framework of the CBD; and bringing deep seabed genetic resources within the regime of the Area.

1 Introduction

Oceans are experiencing rapid and, in many cases, dramatic changes as a result of human activity. Data indicate that at the global level, the abundance of large fish species has declined by ninety percent as compared to pre-fishery levels. Because the world's oceans remain a source of livelihood for hundreds of millions of people, their sustainable and equitable use must continue to be promoted.

Over the last twenty to twenty-five years, new uses of the oceans and their resources have emerged. Most of these changes have been driven by technological developments and knowledge acquired as a result of scientific explorations of previously unknown oceanic areas. An example of new use of the oceans is bioprospecting, i.e. the search for, and commercial development of, valuable natural compounds. More particularly, marine scientists and bioprospectors have paid increasing attention to species which have developed unique biological and physiological properties to survive in extreme environmental conditions. These species, called extremophiles, are found in areas such as Antarctica and the deep seabed. In the absence of an internationally-agreed definition of the term "deep seabed," this report uses the term to designate the seabed and ocean floor and its subsoil beyond the limits of national jurisdiction. Under the United Nations Convention on the Law of the Sea, this is also called the "Area."

As technology develops and becomes more widely available, scientific research in these extreme environments is likely to increase. Not only will this allow expanding our knowledge of extreme ocean ecosystems in order to improve their conservation and sustainable use, but this will also provide opportunities to discover valuable resources and compounds of potential application to the food, industrial and pharmaceutical sectors, among others.

There is currently no specific international regime addressing bioprospecting in the deep seabed, and in recent years, concerns have been raised regarding uncontrolled collection and exploitation of genetic resources from the deep seabed. The issues that governments, scientists and representatives of the civil society have highlighted as requiring particular attention include: the lack of knowledge about deep sea ecosystems, which are still largely unexplored; the need to identify the impacts that marine scientific research and other activities, including fishing practices, have on these ecosystems; the need to ensure the sharing of benefits arising from utilizing deep seabed genetic resources; and whether the recovery of deep seabed genetic resources and subsequent development of commercial products is, or should be, subject to an international legal regime, and if so, to which regime and how.

The international community has taken steps towards addressing these issues, some of which were brought to the attention of States by the UN Secretary-General as early as 1995. Parties to the Convention on Biological Diversity have agreed, at their seventh meeting in 2004, to carry out information-gathering activities regarding the status and trends of, and threats to, genetic resources beyond national jurisdiction, as well as activities and processes under Parties' jurisdiction or control, which may have significant adverse impact on deep seabed ecosystems. At its 59th session in 2004, the United Nations General Assembly established an *Ad Hoc* Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction. This Working Group is likely to have to consider such activities as the search for, and commercial development of, deep seabed genetic resources, including whether there is a need for a unified regime to address them.

Regulating activities relating to deep seabed genetic resources requires taking into account a broad range of considerations, including environmental, scientific, economic, ethical, legal and political aspects. On the environmental front, there is a need to balance the sustainable use of these resources with conservation needs. On the scientific side, questions include the role of scientists, either publicly or privately funded, since they often represent the first point of access to deep seabed resources, identify the potential of these resources for biotechnology, and contribute to, and benefit from, the development of commercial products derived from them. From an economic point of view, which is linked to the ethical aspect, deep seabed genetic resources are a potential source of significant profit for the private companies and scientific institutions involved in their development and application. This raises questions about whether and how exclusive private rights can be obtained over genetic resources recovered from the seabed beyond national jurisdiction, whether sharing the benefits derived from their utilization is required, and if so, how. Legal and political issues include: the status of deep seabed genetic resources as open-access or as common heritage of humankind; the development of a sui generis system of intellectual property rights; and States' obligations with regard to activities carried out under their jurisdiction or control in international areas.

This report, elaborated on the basis of publicly available information, aims to provide the necessary information to help address possible scientific, legal and policy gaps related to deep seabed bioprospecting. The report, which focuses on activities carried out with respect to genetic resources found in seabed areas beyond national jurisdiction, begins with a description of the main features of deep seabed ecosystems, followed by a review of bioprospecting activities in the deep seabed, put in the context of similar activities elsewhere. A review of relevant international instruments and activities is then provided, and a brief overview given of measures adopted at the national level. Some possible approaches to address deep seabed bioprospecting are proposed in conclusion.

2 Characteristic features of deep seabed ecosystems

On the basis of available scientific literature, this section briefly depicts the types of environments and ecosystems in which deep seabed genetic resources are found, in order to help understand some of the scientific and policy issues associated with bioprospecting of these resources.

The world's oceans can be divided into various oceanic realms, according to the difficulty and necessary technology to explore them.² The realm of human reach encompasses near-shore waters, coastal and margin zones, which correspond, respectively, to the intertidal zone, the continental shelves and continental slopes. The realm of central waters, far from the coastline, corresponds to the abyssal plains at the bottom of the oceans. The ice realm corresponds to those areas that are covered with ice most of the year, i.e. Antarctica and the Arctic. The realm of hidden boundaries is made up of the seabed area and its subsoil, in particular the continental shelf and contiguous continental slopes, as well as part of the abyssal plains. The realm of active geology is constituted by areas of active volcanic activity, mainly the mid-ocean ridges, as well as by the remains of past geological activity, such as seamounts. The last realm is the 'crosscutting' realm of microorganisms. See Figure 1.

The realm of active geology and part of the realm of hidden boundaries are the foci of this report. The realm of active geology corresponds to about two percent of the total area covered by the world's oceans. This realm hosts seamounts,³ which are no longer geologically active but are very active biologically in most cases, and hydrothermal vents, which are both geologically and biologically active. Hydrothermal vents are associated with mid-ocean ridges in which extreme environmental conditions, in terms of temperature, pressure and toxicity, prevail. The processes occurring at hydrothermal vents are powered by chemical energy rather than sunlight. Because of the peculiar characteristics in which life develops in these ecosystems, hydrothermal vent organisms represent a subject of interest from both a scientific and a commercial point of view. Seamounts, which are highly important ecological deep seabed systems, are also the subject of bioprospecting. Reaching and exploring the abovementioned deep sea ecosystems requires sophisticated, expensive technology, which is at the reach of only a few countries.4

The realm of hidden boundaries is made of unstable continental sediments of the oceans' slopes and by the sediments of the abyssal plain.⁵ This realm hosts ecosystems known as cold seeps, characterized by microorganisms feeding upon groundwater, methane or oil seeping out of rocks. Although the ecological and biological characteristics of cold seeps are different from those of hydrothermal vents, they constitute a matter of similar scientific and commercial interest since their inhabitant species are also adapted to thriving in extreme conditions of depth and toxicity. Continental slopes⁶ are part of the continental margin, the outer edge of which is the limit of States' continental shelves under the United Nations Convention on the Law of the Sea (UNCLOS). The abyssal plain is part of the Area, defined under UNCLOS as the seabed and ocean floor and subsoil thereof, beyond the limits of national

jurisdiction.⁷ Organisms which depend on methane hydrates as a source of energy, as well as organisms found in brine pools – features similar to lakes at the bottom of the ocean, which result from the higher salinity of water bodies above certain areas of the ocean floor where significant amounts of salt deposits are buried – are also of potential interest to marine scientists and bioprospectors as a result of their unique physiological characteristics.

It is noteworthy that there is no international legal definition of the term "deep seabed." While the seabed can fall either within or beyond the limits of national jurisdiction as delineated by UNCLOS, the term deep seabed is generally used to identify the Area. ⁸This report uses the terms deep seabed and the Area interchangeably.

The following sections provide a detailed description of the main ecological and biological features of deep seabed ecosystems.

2.1 Various deep seabed ecosystems

2.1.1. Hydrothermal vents

Hydrothermal vents are found along mid-ocean ridges, where magma from the deep parts of the Earth emerges. A vent is typically formed as seawater penetrates the crust, is heated by the magma, and goes back into the ocean through a hot vent, bringing with it mineral substances.

While it was thought that hydrothermal vents were more frequent at locations where the rate of ridge spreading was higher, this correlation has proven incorrect. Vents have been found in areas of mid-ocean ridges characterized by ridge spreading rates that span from very moderate to very significant. The combination of high or focused magmatic activity with effective intrusion of seawater into the seafloor due to tectonic faulting is such that it determines the origin of vents.⁹ Thus, vents can be expected much more frequently than originally thought. For example, the Southwest Indian ridge, which hosts vent ecosystems, spreads at the very slow rate of 11 mm/year. This contradicts the model of a linear relationship between ridge spreading rate and vent activity, i.e. the faster ocean ridges spread, the more intense hydrothermal activity is.¹⁰

The term "black smokers," commonly used to designate hydrothermal vents, indicates intense and dense fluid emissions from the ocean floor. These emissions are the result of magmatic activity and are characterized by very high temperatures (300°C and more). They support a dense microbial community, but rarer macrofaunal assemblages, than cooler vents. Moreover, hydrothermal vents located up to a few tens of kilometers away from ocean ridges have been discovered. These vent systems are defined as "off-axis" and are characterized by much cooler emissions (40-75°C) and much more alkaline conditions than black smokers. One of these off-axis vent systems, the Lost City Found, located at 30° N 15 km away from the eastern intersection between the Mid-Atlantic Ridge and the Atlantis fracture zone, features carbonate pinnacles, some of which are as high as 60 meters. There is good evidence that off-axis vents are much more frequent than

previously thought, and that they may even be frequent along the Mid-Atlantic, Indian Ocean and Arctic Ridges. " The discovery of off-axis vent systems has important policy implications, because it demonstrates that large portions of the oceanic crust support hydrothermal activity and associated life.

Hydrothermal vents can also be found within seamounts where the type of volcanic activity and interaction between the ocean water and the ocean floor allow their formation.

Hydrothermal vents are qualified as either chronic or transient plumes, ¹² depending on the intensity and duration of the venting phenomenon. All vents are characterized by extremely high pressure due to the depth at which they are located, by extremely high temperatures and pH values, and by extreme salinity and toxicity due to the minerals that escape from the Earth crust.

Microorganisms, which are at the basis of the vents' trophic chains, and correspondingly at the basis of the functioning of the whole vent ecosystem, depend on these mineral substances. Vent microorganisms do not utilize the light as a source of energy in the process of forming organic substances (also known as "primary production"). As a result, they are referred to as "chemolytotrophic" organisms as opposed to photosynthetic. Hydrothermal vent communities show differences in structure, depending on surrounding physical and geological oceanographic processes, such as gradients in the toxicity of vent fluids. ¹³ For example, one tubeworm vent species seems to have developed an adaptive physiology for its survival, responding to the scarce availability of sulfide and thus being able to colonize areas with very limited vent flow.¹⁴

There is evidence that not only prokaryote species but also eukaryotes¹⁵ living in vent ecosystems are tolerant to extreme conditions. For example, observations conducted in the M-Vent site (9° 50.6' N, 104° 17' W) in the Axial Summit Caldera on the East Pacific Rise¹⁶ have allowed to measure the tolerance of a deep seabed worm (*Alvinella pompejana*) to temperatures as high as 81° C and to a one hour-lasting gradient of up to 60° C along the body of the worm. This species was the most thermotolerant and eurythermal (temperature gradient) eukaryote known when these research results were published in 1998.¹⁷

The main characteristic of hydrothermal species is their tolerance to extreme conditions and their very peculiar physiology. These organisms mostly belong to the domain Archaea – an evolutionary branch that is separate from those of Bacteria and Eukarya. Archaea's adaptation mechanisms to extreme toxicity, pressure, temperature and pH values make them particularly attractive to industry and the pharmaceutical sector.



Figure 1. Ocean realms and zones. The realms are diagrammed in the cross section on the basis of the difficulty to explore them. The near-shore zone, the nearest to people and the coastal zone, the area of fishermen's activity, constitute the realm of human edges. Unstable continental margins and the sediment of the abyssal plain constitute the hidden boundaries of the oceanic bowl. Small drifters, such as plankton, and swimmers, like fish, inhabit the upper light zone of the central waters. A different type of creatures inhabits the dark waters below 200 meters from the surface. The realm of active geology includes ghost volcanoes, called seamounts, which rise from the abyssal plain, and hot vents, located in the plain. The ice realm surrounds the poles. The microscopic realm cuts across all realms. Inset A illustrates in detail the near shore zone. Inset B compares the respective coverage of the oceans and ice. OBIS is the Ocean Biogeographic Information System – the information component of the Census of Marine Life (see Box 1). Source and courtesy of: Baseline Report of the Census of Marine Life.

Hydrothermal vents also contribute to the cooling of the planet as a whole, to its thermal balance, and to the chemical balance of the oceans and the atmosphere.¹⁸ In addition to performing an important geophysical role, vent ecosystems are areas where life develops and from which it spreads. There is clear evidence that hydrothermal plumes are associated with upper zooplankton communities, which are supported by both ascending and descending organic matters. It is thought that hydrothermal vents contribute to ascending organic matters.¹⁹ Zooplankton communities located close to hydrothermal vents are trophically complex and behave opportunistically.²⁰ An example is the medusa Stygiomedusa gigantea, which lives within 10 km from vent areas.²¹ Hydrothermal vent ecosystems participate in the global carbon cycle since the organic substance originated at hydrothermal vents support the transfer of energy through resident species and probably also through upper water column species.

2.1.2. Cold seeps and other similar deep sea ecosystems

Cold seeps are deep soft-bottom areas where water, oil or gases seep out of the sediments. These are extreme areas due to high pressure and toxicity levels. However, in contrast with hydrothermal vents, temperatures have the same moderate values as those of the surrounding waters. Hypersaline or "brine" pools are a legacy of ancient subfloor deposits that progressively dissolve into the upper water column. These environments can host both prokaryotic and eukaryotic species, some of which are capable of living and reproducing at salt concentrations close to saturation, previously thought to be incompatible with life.²² Mud volcanoes are geological structures characterized by mud and fluid seeping out of the seafloor, rich in observed fauna and the size of some of the species they host.²³

Geomorphologic variations may influence the composition of the communities inhabiting cold seeps, brine pools and mud volcanoes, but one common factor to methane seeps is that they are soft-seabed ecosystems, which support two types of interlinked chemosynthetic metabolism: sulfideoxidizing organisms; and methanotrophs.²⁴

Methane is present in deep sea sediments as a consequence of geochemical or microbial production. This methane is anaerobically oxidized into bicarbonate by a combination of organisms belonging to the Archaea group and sulphatereducing bacteria, and thus does not escape into the ocean.²⁵ This process contributes to the global carbon cycle and the regulation of greenhouse gases.²⁶

Solid crystallines made of methane surrounded by water molecules, called "methane hydrates," are in certain instances associated with cold seeps.²⁷ These crystallines have a strong potential as a source of energy and, if utilized, would constitute a positive greenhouse gas.²⁸ Because methane is a powerful greenhouse gas, there is evidence that gas hydrates constitute a methane buffer and therefore a buffer to the greenhouse effect. At the same time, deep seabed methane systems are also considered to provide a thriving ground for surrounding biological communities.²⁹ Despite important differences among hot and cold deep seabed ecosystems, they are all characterized by extreme conditions. Certain taxonomic groups (taxa) have adopted similar life patterns in deep seabed environments presenting different but equally extreme characteristics. An example is the polychaete (marine worm) belonging to the genus *Meganerilla*, which inhabits deep anoxygenic bacterial mats in the Santa Barbara Basin, and is in symbiosis with external bacteria (ectosymbiosis). The same type of symbiotic arrangement occurs in the case of *Alvinella pompejana*, a hydrothermal vent polychaete species.³⁰ However, despite evolutionary links between the multicelled animals inhabiting the different anoxic habitats of the deep seabed, there are very few shared species.

2.1.3. Seamounts

Seamounts, which are millions of years old, are the remains of past geological activity. They do not normally present active geological features, although some vent systems can be found within seamounts. Seamounts are characterized by active water circulation processes, which result in great richness of species belonging to the functional group of suspension feeders;³¹ taxa typical of seamounts are deep sea corals, sponges, crinoids, hydroids and ophiuroids.³² Seamounts also provide a habitat to several species of fish of commercial interest, such as orange roughy, and are visited by swordfish, tuna, sharks, turtles and whales.³³

One study conducted in six seamounts along the Norfolk Ridge and four seamounts belonging to the Lord Howe Rise, both located between New Zealand and Australia, demonstrated that an increased sampling effort revealed an increase in species richness. This indicates that the number of seamount species yet-to-be discovered is much larger than that already discovered (see Figure 2). This finding also applies to other deep seabed habitats, namely the continental slopes and abyssal plains, which have only been poorly sampled so far, due to their large size (they cover most of the ocean's bottom).



Figure 2. Distribution of large seamounts.²⁴ This map displays approximately 14,000 particularly well-defined (conical), seamounts. Including a wider range of seamount shape and size could increase their number to 100,000. Source and courtesy of: Convention on Biological Diversity.

The same study also showed, on the basis of data obtained from sampling along 14 seamounts located in the South of Tasmania that for seamounts separated by a distance of more than 1,000 km, there were differences in species composition when those seamounts were situated at different longitudes. There was even a complete substitution of species in the case of seamounts located at different latitudes.³⁵

Several other studies have shown that seamounts are characterized by very high rates of endemism.³⁶ For example endemism reaches 31% for the Lord Howe Island seamounts, 35% for seamounts off Tasmania, 36% for seamounts on the Norfolk Ridge, and 44% for fish and 52% for invertebrates on the Nasca and Sala-y-Gomez seamount chain off Chile.³⁷

Some species inhabiting seamounts possess conservative larval dispersal strategies. This has biogeographic implications.³⁸ Some authors consider seamounts as ecological exceptions in the deep sea, in comparison with soft-bottom ecosystems, the communities of which may show strong affinities even at great geographic distances.³⁹

2.1.4. Similarities and differences between deep seabed ecosystems

Species inhabiting deep seabed ecosystems may have very different biological characteristics: some are transient migrants; some may be carried from one area to another as a consequence of water circulation; some have a free living-larval stage; and some microorganisms originate in the sub-seabed biosphere. Moreover, some organisms can move by themselves or with the help of outside forces. Vent organisms include free-living microorganisms around up-welling vent fluids or rocks and chimneys, microorganisms living within vent water plumes, and symbiotic microorganisms associated with vent macrofauna. Depending on their biology, those microorganisms may be considered as sedentary or not.⁴⁰ This has implications with regard to their treatment under UNCLOS, as will be shown in section 5 of this report.

One study has shown that microbial community composition within two hydrothermal sites at separate locations (one, the Snake Pit site, in the Mid-Atlantic Ridge at 23° 22' N, 44° 57' W, and the other at 9° 22' N, 104° W) was highly similar, as 92% of the genes encoding small subunit ribosomal DNA were the same in sequence.⁴¹ Different vent biogeographic provinces have been identified.⁴² Atlantic vents are dominated by shrimps and clams, while Pacific vents mainly host giant tube worms and clams. Some vent species are restricted to small geographic regions. It is likely that microorganisms from vents may have a wider distribution.⁴³

Some vent species are characterized by high dispersal strategies, possibly because of the ephemeral nature of hot vents. For example, it has been shown that the larvae of the giant tubeworm *Riftia pachyptila* have an average lifespan of 38 days, which equates to a maximum distance of 100 km in the specific hydrodynamic conditions of the ridge site where the study was conducted (9° 50' N in the East Pacific Rise).⁴⁴ Shrimp larvae of the family Bresiliidae have been reported to have attained the dispersal value of more than 100 km.⁴⁵

Dispersal of larvae of hydrothermal vent organisms is facilitated by megaplumes – transient, separated volumes of warm water resulting from submarine volcanic activity and rising up to 1,000 meters above the ocean floor.⁴⁶ In the case of seamounts, one study identified active circulation processes as the factor responsible for the retention of hydroid larvae along a limited vertical gradient of a few hundred meters and a much more extended horizontal gradient (up to 40 km away from the seamount).⁴⁷

It has been hypothesized that the patterns of behavior of cold seep communities are close to those of seamount communities, when endemism is concerned.⁴⁸

Despite important differences, especially in terms of species' metabolism and dispersal strategies, hot and cold deep seabed ecosystems also show some similarities. For example, a giant white clam, found in large population quantities in the Sagami Bay of Japan at the depth of 1,100 meters, and dependent on sulphide-rich cold water seeps, appeared to belong to the same genus of clams – *Calyptogena* – as that found in hydrothermal vents in the eastern Pacific. The two species share the same dependence on sulphide-oxidizing microorganisms, which are symbiotically hosted within the clams.⁴⁹

A team of Japanese scientists demonstrated that the spawning of the Sagami Bay giant white clam was induced by minimal changes in water temperature (between 0.1 and o.2°C), thus indicating that deep seabed organisms respond dynamically to surrounding environmental variations.⁵⁰ Surrounding environmental conditions can also affect species' growth rates. In environmentally dynamic ecosystems, species grow quickly, and their dispersal strategies are well developed. In the case of hydrothermal vent species, scientific studies have demonstrated that changes in hydrothermal flux temperatures were likely to affect vent communities.⁵¹ A study monitoring the evolution of a new hydrothermal vent following an eruption has indicated that recruitment of new species at the site took place within a year, and that within the second year, one-third of the vent species found in the region had populated the site.52

In less dynamic environments, species tend to grow slowly. Extreme cases recorded so far are those of cold water reefs of up to 8,000 years old⁵³ and a species of tubeworm (*Lamellibranchia sp.*) living on oil seeps at depths of more than 500 meters along the continental margin of Louisiana. Conservative estimates of the tubeworm's growth rate indicate a lifespan comprised between 170 and 250 years.⁵⁴

Further studies would be needed regarding the role of slow-growing deep seabed species, such as *Lamellibranchia sp.*, in providing habitats and energy to other species, including transient ones, in areas that are normally deprived of shelters and sources of nutrition.⁵⁵ Similarly, it has been hypothesized, on the basis of evidence from comparative rRNA analysis of mytilids living on decomposing wood and whale bones, that wood and whale bones have acted as vectors for the colonization of vent systems by these organisms.⁵⁶ The unusual physiological characteristics of organisms inhabiting hydrothermal vents, cold seeps and other deep seabed ecosystems, resulting from these ecosystems' extreme (although different) conditions, make them particularly interesting to scientists and bioprospectors alike.

Similarities and differences of deep seabed ecosystems may have implications for their management.

2.2 Deep seabed ecosystems and the origin of life

Some scientists advance the idea that the beginning of life at hydrothermal vents corresponded with the development of life on Earth, thus supporting the theory that life developed at submarine hotsprings.⁵⁷ Other scientists favor the 'hyperthermophile Eden' hypothesis, which assumes that life developed in both hydrothermal and nonhydrothermal environments.⁵⁸ In both cases, hydrothermal systems seem to have played a key role in the development of life on Earth, and the differentiation of a common ancestor into Bacteria and Archaea. Nowadays, species can be differentiated on the basis of their ribosomal RNA (rRNA). This technique has revealed that the phylogenetic tree of Archaea has emerged as a different domain of life than those of Bacteria and Eukarya, thus proving the importance of hydrothermal vents for phylogeny and evolution.⁵⁹

Geological evidence has shown that life has been present on Earth for at least 3.5 Gyr (billion years), with demonstrated records of photosynthesis activity dating as long as some 3.8 Gyr ago.⁶⁰ By way of comparison, sulphatereducing microorganisms – organisms that produce sulphide by oxidizing hydrogen or organic matter with sulphates – are typical of hydrothermal vent ecosystems and as ancient as 3.47 Gyr.⁶¹ Evidence has also been brought of hydrothermal vent microbial activity dating 3,235 million of years.⁶²

Deep water is also thought to have provided an area for diversification of eukaryote organisms, in that it provided them a shelter from ultraviolet radiation, which causes damage to DNA. In modern deep sea microbial mats systems, such as those found in the Santa Barbara Basin (34°15'N, 120°02'W, maximum depth: 600 meters), symbiotic relationships between prokaryotes and eukaryotes have allowed the latter to overcome the anoxygenic conditions of the milieu and to diversify.⁶³ These symbioses are important in light of the increase of oxygen-depleted habitats due to human activities (also called 'dead zones'), and may play a crucial role in guaranteeing certain processes in the oceans, such as nutrient cycling.⁶⁴ Deep seabed organisms can show "endosymbiosis" such as intracellular symbiotic sulphide-oxidizing bacteria within Lamellibranchia satsuma and *Calyptogena laubier*i,⁶⁵ or "ectosymbiosis" such as the filamentous bacteria along the body of Alvinella pompejana.

There is thus evidence that both oxygenic and anoxygenic photosynthetic life, as well as non-photosynthetic life, have existed around hydrothermal vents for more than 3

Gyr. Molecular biology techniques have also provided data showing that chemosynthetic life at hydrothermal sites preceded photosynthetic life.⁶⁶

The role of hydrothermal vents with regard to the origin of life may also have implications for their management, because of their scientific and emblematic importance.

2.3 Information on researched sites

A number of databases containing information on deep seabed resources and expeditions exist. The InterRidge website, for example, hosts several relevant databases, including the Hydrothermal Vent Database, the Mid-Ocean Ridge Backarc Basin (MOR & BAB) Cruise Database, and the Hydrothermal Vent Faunal Database. The latter, which contains almost 500 species, is currently being merged with the ChEss database, a project of the Census of Marine Life.⁶⁷

The Hydrothermal Vent Database was originally created in 1994, and published on the InterRidge website in 1999.68 This database, which counted 212 sites as of 1 December 2004, includes ascertained and suspected hydrothermal vent sites, that is, sites where the presence of geological activity indicating vent formation was observed but no hydrothermal vent was located. This database also contributes to the International Seabed Authority (ISA) Central Data Repository (CDR), developed in 2000 by the ISA Secretariat to collect and centralize all public and private data and information on marine mineral resources. In addition to information on ferromanganese crusts and polymetallic nodules, the CDR comprises data originally assembled by the Geological Survey of Canada on the worldwide distribution of seafloor polymetallic sulphides sites (327 sites).

The ISA CDR contains specific data on the geochemical composition of samples of seafloor polymetallic sulphides and metainformation such as latitude and longitude, depth, jurisdiction, site description (geology and biology), types of hydrothermal activity, description of mineral deposits, tectonic setting, and bibliographic references. Data are organized according to different geographic zones of midocean ridges (North Pacific, North West Pacific, Central Pacific, South West Pacific, Chile Rise, Antarctica, South Atlantic, Mediterranean, etc.), and a distinction is made between active and fossil vents. However, information on the biology of recorded hydrothermal vents is very limited.⁶⁹

The InterRidge MOR & BAB Cruise Database contains 432 records corresponding to the period 1992-2003. This database provides a proxy for identifying the sites that are most subject to scientific research. An analysis of the information contained in this database showed that the most visited sites were the Juan de Fuca Ridge in the Northeast Pacific (72 cruises) and the Mid-Atlantic Ridge located between 20°N and 40°N (61 cruises). These are followed by the Northern East-Pacific Ridge (42 cruises) and the Mid-Atlantic Ridge comprised between 0°N and 20°N (24 cruises), as well as the Manus & Woodlark Basins in the Pacific Ocean (21 cruises). The only site extensively studied in the Indian Ocean is the Southwest Indian Ridge (17 cruises). In the Arctic, the most researched site is the Kolbeinsey Ridge (6 cruises), while the Pacific-Antarctic Ridge area was visited 6 times. Overall, the sites in the Pacific Ocean lead with a number of 218 cruises, followed by Atlantic Ocean sites (129 cruises), Indian Ocean sites (40 cruises) and the Arctic Ocean (16 cruises).⁷⁰

According to the InterRidge databases, in the case of the above-mentioned most researched sites, out of the 21 sites located in the Juan de Fuca Ridge, 12 fall under Canadian jurisdiction while nine are located in the Area. Sites comprised between 20°N and 40°N in the Mid-Atlantic Ridge are located in the Area, except for the Menez Gwen and Lucky Strike sites, which fall under Portugal's jurisdiction. The sites of the Kolbeinsey Ridge (Northern Atlantic) all fall within Iceland's jurisdiction. Ascertaining the jurisdiction of sites comprised between o°N and 20°N in the Mid-Atlantic Ridge was difficult. Regarding the 50 vent sites recorded in the Northern East-Pacific Ridge, the jurisdictions of Canada (the 12 sites mentioned above), the US (six sites) and Mexico (seven sites) have been identified. 11 sites fall outside national jurisdiction and, for some vents, it is unclear whether these fall within or beyond national jurisdiction. The 12 sites recorded in the Indian Ridge fall either in the Area or it is unclear whether they are located within or beyond national jurisdiction. Out of the 12 sites listed for the South-East Pacific, Chile is thought to have jurisdiction over two to four sites, while the others seem to be located in the Area. Of the 35 sites in the South-West Pacific, nine fall under Papua New Guinea's jurisdiction (including six sites in the Manus & Woodlark Basins), one under the Solomon Islands' jurisdiction, five under Fiji's

jurisdiction, and two under New Zealand's jurisdiction. The other sites are located in the Area or it is unclear whether they are located within or beyond national jurisdiction.

The table below provides an overview of the jurisdiction over the 212 hydrothermal vent sites recorded in the InterRidge Hydrothermal Vent Database. As a preliminary conclusion, and taking into account remaining uncertainties, it seems that an even number of sites fall either within (61 ascertained sites) or beyond (55 ascertained sites) national jurisdiction. It is important to note that no information is provided on the InterRidge site regarding the criteria used to identify the jurisdiction under which the sites fall. It is assumed that this information is based on the information provided by research teams.

Records in the database can be sorted according to, *inter alia*, the scientific objectives of cruises. A search based on biology-related keywords (e.g. biology, physiology, ecology, etc.) demonstrated an increase in time in the number of cruises aimed at fulfilling biology-related scientific objectives. This is of particular relevance to bioprospecting.

In addition to the InterRidge and the ISA databases, an equally authoritative source of information regarding the location of hydrothermal and cold seep sites of interest to science and bioprospectors are peer-reviewed scientific articles including details of sites' location and samples. Such articles are found in journals such as Deep-Sea Research I and II.

Country under the jurisdiction of which vents are located (number of vents)	Total of 61 sites divided as follows: Canada (12), USA (12), Papua New Guinea (8), Fiji (5), Italy (5), Japan (4), Mexico (4), Chile (2), Greece (2), New Zealand (2), Portugal (2), Norway (1), Russia (1), Solomon Islands (1)	
No national jurisdiction	55 (plus 2 uncertainly so)	
No specified jurisdiction	28	
Uncertain jurisdiction	Chile (2), Japan (2), USA (2)	
Sites qualified with a question mark (?)	33	
Uncertain meaning of the information	12	
contained in the database	12	
Likely errors in the database	11	

3 Review of bioprospecting activities in the deep seabed

This section describes the main type, intensity, and impacts of both scientific research and commercial activities related to deep seabed ecosystems and genetic resources. Some key working definitions are provided in introduction, followed by an overview of the applications made of deep seabed genetic resources, as well as the technology required for deep seabed research and bioprospecting.

3.1 The object and nature of bioprospecting

In the absence of an internationally-agreed definition of bioprospecting, an attempt is made in this section to identify what types of activities constitute bioprospecting. Definitions of genetic resources are also considered.

3.1.1. Marine bioprospecting and marine scientific research

A common distinction is made between scientific research undertaken for non-commercial purposes, also called "pure scientific research," and commercially-oriented research, also called "applied scientific research." Bioprospecting in the marine environment could be considered as a form of applied marine scientific research. With regard to deep seabed activities, which are usually undertaken thanks to partnerships between public research institutions, such as universities, and private companies (see section 3.2.1.), it is difficult to differentiate between pure marine scientific research and applied research. In order to ensure that the costs of research expeditions are met, links are increasingly established between pure marine scientific research activities and onshore commercial bioprospecting activities,⁷¹ whereby organisms collected following noncommercial marine scientific research are passed on to industry.72

There are currently no internationally-agreed definition of the terms "marine scientific research" and "bioprospecting." However, defining what these terms cover is crucial in order to determine the legal regime applicable to activities related to deep seabed genetic resources.

Bioprospecting is neither used nor defined in the Convention on Biological Diversity (CBD) or UNCLOS, and the expression seems to cover a broad range of activities. The CBD does not make the distinction between pure and applied research, and only requires Parties to promote and encourage research that contributes to the conservation and the sustainable use of biological diversity in general.⁷³ However, a note prepared by the CBD Secretariat defined bioprospecting as "the exploration of biodiversity for commercially valuable genetic and biochemical resources" and further as "the process of gathering information from the biosphere on the molecular composition of genetic resources for the development of new commercial products."⁷⁴

Elements of definitions of bioprospecting are provided in several domestic laws, ranging from restrictive definitions limited to the search for resources, to broader definitions encompassing collection and application. Under New Zealand's Biodiversity Strategy, bioprospecting is "the search among biological organisms for commercially valuable compounds, substances or genetic material."75 Within the context of the European Community, bioprospecting "entails the search for economically valuable genetic and biochemical resources from nature."⁷⁶ The South African 2004 Biodiversity Act defines bioprospecting as "any research on, or development or application of, indigenous biological resources for commercial or industrial exploitation, and includes the systematic search, collection or gathering of such resources or making extractions from such resources for purposes of such research, development or application (...)."77 The 2001 Philippines' Wildlife Resources Conservation and Protection Act defines bioprospecting as the "research, collection and utilization of biological and genetic resources for purposes of applying the knowledge derived therefrom solely for commercial purposes."78 Fiji's draft Sustainable Development Bill refers to bioprospecting as "any activity undertaken to harvest or exploit biological resources for commercial purposes... [including] investigative research and sampling."

While definitions still diverge as to whether bioprospecting covers the subsequent stages of the search and sampling of resources, including further application and development,⁷⁹ this brief survey shows that there is an emerging common understanding that the term "bioprospecting" involves research for commercial purposes. Possible elements of a definition of bioprospecting include:

- systematic search, collection, gathering or sampling of biological resources for purposes of commercial or industrial exploitation;
- screening, isolation, characterization of commercially useful compounds;
- testing and trials; and
- further application and development of the isolated compounds for commercial purposes, including large-scale collection, development of mass culture techniques, and conduct of trials for approval for commercial sale.

As with the term "bioprospecting", there is no internationally-agreed definition of "marine scientific research." While UNCLOS provides for a regime for marine scientific research (MSR), it does not define what MSR is. With regard to the right of coastal States to withhold consent to MSR projects proposed by other States or international organizations in their Exclusive Economic Zone (EEZ) or on their continental shelf, UNCLOS draws a distinction between MSR intended to increase scientific knowledge for the benefit of all humankind, and MSR "of direct significance for the exploration and exploitation of natural resources."80 The distinction between those two types of research, which equate to pure scientific research for the former and applied research for the latter, is not made with regard to MSR undertaken beyond national jurisdiction.

The difficulty of distinguishing, in practice, between pure scientific research and applied research, prompted the drafters of UNCLOS to include a specific provision requesting States "to promote through competent international organizations the establishment of general criteria and guidelines to assist States in ascertaining the nature and implications of marine scientific research."⁸¹ To date, such criteria and guidelines have not been developed.

The study prepared by the Secretariat of the CBD and the United Nations Division for Ocean Affairs and the Law of the Sea (UNDOALOS) on the relationship between the CBD and UNCLOS with regard to deep seabed genetic resources noted 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 humankind's knowledge of the environment, and is not undertaken with the intent of economic gain."⁸²

This definition implies that MSR, in the context of UNCLOS, for research undertaken in areas beyond national jurisdiction, would equate to pure marine scientific research, and differ therefore from bioprospecting. In this respect, a parallel can be drawn between bioprospecting and prospecting, as defined within the context of UNCLOS. The International Seabed Authority's Regulations on Prospecting and Exploration for Polymetallic Nodules define prospecting as the search for deposits of polymetallic nodules in the Area, including estimation of the composition, size and distributions of polymetallic nodule deposits and their economic values, without any exclusive rights.⁸³ Prospecting differs from MSR undertaken to increase scientific knowledge of the oceans in that it is undertaken with the specific aim of estimating the economic value of a resource prior to its future commercial exploitation. Data and information resulting from prospecting may be retained as confidential, in accordance with the regulations.⁸⁴ However, like MSR, prospecting does not confer any rights over the resources.85

It is noteworthy that the UN Secretary-General, in his 57th report to the UN General Assembly stressed potential problems resulting from the fact that UNCLOS "does not adequately distinguish between the terms 'marine scientific research,' 'prospecting' and 'exploration,' nor does it make a distinction between 'pure' and 'applied' scientific research."⁸⁶

Academic researchers play a key role at the forefront of biodiversity and biotechnology sciences. The use of the word "bioprospecting" to describe their activities is reductive, because the discovery of drugs with potentially important medical applications often represents a side effect of scientists' continuous search for new knowledge.

Since marine scientific research and bioprospecting can have the same object, i.e. sampling of biological organisms, the distinction between those two types of activities resides mainly in their intent and purpose. In theory, the distinction is clear. However, as has been noted above, the difference in practice remains difficult to establish, particularly regarding research carried out in the deep seabed. Identifying a coherent comprehensive legal regime for activities related to deep seabed genetic resources is relatively difficult as a result of these practical impediments.

3.1.2. Genetic resources, genetic material and microorganisms

Article 2 of the CBD defines genetic resources as genetic material of actual or potential value. Genetic material is defined as any material of plant, animal, microbial or other origin containing functional units of heredity. It follows that marine genetic resources are marine plants, animals and microorganisms, and parts thereof containing functional units of heredity that are of actual or potential value. This definition applies to deep seabed organisms. It is noteworthy that photosynthetic organisms are not found in deep seabed ecosystems as a result of the absence of solar light.

While the Oxford University Press Dictionary of Biology defines microorganisms as organisms that "can be observed only with the aid of a microscope [and] include bacteria, viruses, protoctists (including certain algae), and fungi,"87 there is currently no common definition of microorganisms. Scientific definitions tend to converge towards a description of microorganisms as organisms that are not visible to the human eye, and that include individual living cells of the domains of Bacteria and Archaea, as well as non-visible eukaryotes such as microscopic nematodes (although from an ecological point of view these are defined as part of the 'meiofauna'). What really distinguishes taxonomic groups of organisms are therefore genetic analogies or differences based on ribosomal RNA techniques, while size only determines whether living organisms fall within macro or and micro organisms.⁸⁸ Oldham notes problems raised by the lack of definition of microorganisms within specific intellectual property rights instruments, including the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO), and the International Patent Classification system. In practice, a wide range of categories of material have been accepted as microorganisms, including biological and genetic material derived from macroorganisms, such as tissue cultures and plasmids, as well as viruses, undifferentiated human, animal or plant cells, and protozoa.⁸⁹ The understanding of microorganism under intellectual property rights (IPRs) instruments seems therefore broader than the scientific definitions.

This report adopts a broad definition of genetic resources and microorganisms as encompassing the definition provided by the CBD as well as the practice of IPRs instruments.

3.2 Analysis of the type and level of activities involving genetic resources from the deep seabed

3.2.1. Review of relevant research programmes

The exploration of deep seabed areas started at the end of the nineteenth century with the British research oceanographic vessel Challenger (1872-1876). However, it was not until 1977 that hydrothermal vents were discovered with the help of the submersible Alvin during a survey of the Galapagos Rift in the Eastern Pacific Ocean at depths of more than 1,000 meters.

Today, a host of exploration activities are undertaken to study the ecology, biology and physiology of deep seabed ecosystems and species. Different types of research activities allow the subsequent commercial exploitation of genetic material from the deep seabed.

The majority of activities are scattered, small-scale, independent research activities and programmes, ongoing in many universities and research institutions in the world.⁹⁰ While most of these activities are of an exploratory nature and are not directly commercially oriented, they represent the backbone of any commercial application of deep seabed genetic resources since they generate the necessary scientific information for bioprospecting. Some of these research activities are a joint effort between the scientific communities of two or more States, such as the 2001 Arctic Mid-Ocean Ridge Expedition (AMORE), conducted by US and German scientists.⁹¹

More ambitious programmes, which require a strong international scientific cooperation as well as joint ventures between public and private institutions, are also ongoing, such as The New Challenger Global Ocean Expedition, organized by Deep Ocean Expeditions, the P.P. Shirshov Institute of Oceanology, the Russian Academy of Sciences, and Diversa Corporation.⁹² One of these research programmes, the Census of Marine Life (CoML), which has a strong focus on deep sea species, is described in detail in Box 1 below.

Box 1: The Census of Marine Life

CoML's mission is to assess and explain the diversity, distribution and abundance of marine life. It is a timebound project, at least in its first phase, which will be completed in 2010. CoML addresses four main questions:

- What lived in the oceans? (History of Marine Populations project – HMAP)
- What does live in the oceans? (Ocean Realm Field Projects, which deals with technologies and protocols)
- What will live in the oceans? (Future of Marine Populations project FMAP)93
- How to access and visualize data on living marine resources? (Ocean Biogeographic Information System – OBIS)

According to the Census, at 3,000 meters of depth, the probability of a new record being a new species is about 50:50 in the deep sea. Life is therefore not lacking, but suitable sampling tools are missing. Consequently, less than 0.1% of abyssal plains have been sampled. Out of 15,000 estimated isolated seamounts, only 250 have been sampled thus far.⁹⁴

CoML activities are organized according to boundaries. Those most relevant to the issues dealt with in this report are the: Continental Margins activities; Abyssal Plain activities (coordinated by the French Research Institute for the Exploitation of the Sea – Ifremer – in France), including on the Diversity of Abyssal Marine Life (CeDAMar);⁹⁵ Ice Oceans activities, including on the Arctic Ocean Biodiversity (ArcOD, coordinated by the US and Russia); Census of Antarctic Marine Life (coordinated by the Scientific Committee for Antarctic Research (SCAR) of the International Council for Science); Active Geology activities, including on Chemosynthetic Ecosystems (ChEss, coordinated by the UK); Census of Seamounts (coordinated by New Zealand's National Institute of Water and Atmospheric Research); and the Central and Deep Oceanic activities, including on the Mid-Atlantic Ridge Ecosystems (MAR-ECO, coordinated by Norway).⁹⁶

The Census relies on national and regional CoML committees to promote the Census and decide on priorities. Such committees are currently being established in Australia, Canada, Europe, Japan, South America and the US.

Public research organizations in some countries devote significant time and energy to deep sea research. If remer is a French public research institute, the mission of which is to: promote the development of technological and commercial applications related to the identification and sustainable exploitation of marine resources; undertake observations, forecast and protection of the marine environment; and explore possibilities for the economic development of maritime activities. Between 1993 and 2001, a programme on ocean ridges, the Dorsales programme, was co-funded and implemented by Ifremer and the French National Scientific Research Center (CNRS). Currently, Ifremer's main programmes related to the exploration and exploitation of the ocean floor include: a programme on cold seeps on the Mediterranean continental margins called Nautinil (as part of the European Science Foundation-sponsored EUROMARGINS programme⁹⁷); a programme on evaluating the impacts of oil-related activities and research on chemosynthetic ecosystems on the Gabon-Angola margin called Biozaire; the Ocean Ridges programme, which focuses both on developing deep ocean-related technology and on the biodiversity of deep water ecosystems; and studies and activities associated with the establishment of ocean floor observatories. More particularly, Ifremer implements a programme on biotechnological transfer from deep water species, which focuses on the oncological, cardiovascular and tissue regeneration applications of deep sea bacterial exopolysaccharides and on new anti-tumor strategies. This programme is conducted in cooperation with the University of Western Brittany, the Regional University Hospital Center in Brest, INSERM (the French National Institute of Health and Medical Research), CNRS and the Faculty of Odontology of the University of Paris V.98

The US National Oceanic and Atmospheric Administration (NOAA) runs a Vents Programme, which provides a framework for research activities on the impacts and consequences of submarine volcanoes and hydrothermal venting on the global ocean. This is an integrated research programme, which focuses on research activities in relation to the distribution and evolution of hydrothermal plumes, their geological, physical, chemical and geophysical characteristics, as well as their continued monitoring at various sites (five in the Northwestern Pacific, one in the Western Pacific, one in the East Pacific, and one in the North Atlantic). ⁹⁹ The NOAA Vents Programme, although an ambitious one, seems to only indirectly contribute to the collection of information important to bioprospecting of deep seabed genetic resources.

Another type of research activity is that of applied programmes that promote the systematic collection and culture of, and research on, deep sea organisms. This type of activity entails describing the genetic and physiological features of deep sea organisms and assessing their potential for biomedical, industrial, environmental and other types of applications. Such research is being carried out, among others, by the Extremobiosphere Research Center of the Japan Agency for Marine-Earth Science and Technology (JAMSTEC). JAMSTEC's activities are further described in section 3.4 of this report.

Marine genomics has recently attracted the interest of the J. Craig Venter Institute, a non-profit research organization based in the US.¹⁰⁰ In the spring of 2003, staff at the Institute, in collaboration with scientists of the Bermuda Biological Station for Research, embarked in a pilot expedition in the Sargasso Sea – the Sorcerer II Expedition. The expedition, undertaken in an area considered as poor biologically, found more than 1,800 species of marine bacteria, 150 of which had not been described, and more than a million "new" genes, previously unsequenced, in about 200 liters of sampled sea water. In February 2004, the Institute announced the launch of its Marine Microbe Genome Project, which aims to sequence the genome of more than 100 of the key marine microbes stored in culture collections around the world, and provide a baseline against which to interpret the structure and functions of marine microbial genes, including the new genes discovered during the Sorcerer II Expedition. For this project, the Institute received a grant of US\$8.9 million from the Gordon and Betty Moore Foundation. All the results of this project will be made public through the National Center for Biotechnology Information (NCBI).¹⁰¹ Although the Institute's activities have focused on water column species, some of the techniques used may be relevant to future studies on deep seabed genetic resources.

Another type of research is situated at the interface of research and development (R&D). R&D activities are usually specifically designed at bridging the gap between discovery and commercialization, hence responding to the needs of private companies. In most instances, partnerships between public and private research institutions and commercial companies are required to undertake bioprospecting of deep seabed genetic resources. A specific example of how programmes of this type are designed is the Marine Bioproducts Engineering Center (MarBEC) research programme, outlined in Box 2.

Box 2: The Marine Bioproducts Engineering Center Research Programme

MarBEC is a US National Science Foundation (NSF) Engineering Research Center established through a timebound NSF grant (November 1998- March 2004), which resulted from a partnership between the University of Hawaii at Manoa and the University of California, Berkeley, US.

The Center was established on the basis of the realization that many microorganisms found in various marine environments can, through biotechnology, provide new products and processes for use in many sectors, including the chemical, health, energy, food, and environmental sectors as well as national security.

MarBEC is structured in such a way as to bridge research activities with development of products and processes. Working with a range of marine microorganisms, including extremophiles, the Center's activities span from discovery and screening of new organisms to the design of cultivation and purification systems, towards the production of marine bioproducts such as polyunsaturated fatty acids, antibiotics, antivirals and enzymes.

MarBEC has developed techniques for deep sea sampling while maintaining deep sea temperatures and pressures *ex situ*. Genetic engineering techniques are used to transfer metabolic pathways of marine microorganisms into common industrial organisms (such as *E. coli*). Production systems, including bioreactors for extremophiles, were developed. A biological bank was set up. Engineering and life science students were trained as the Center's contribution to forming the next generation of engineering and scientific leaders and practitioners in marine biotechnology.

A specific programme – the MarBEC Industry Sponsor Program – was set up to interact with industrial sponsors, with the aim of building a group of industry participants in the Center's activities, following the termination of the financial support by the NSF.

The Center has developed an industrial strategy made of the following main strategic axes: recruiting member companies from the pharmaceutical, chemical, food and similar industries; identifying the needs of those companies; developing patents; conducting directed and industry-sponsored research; and positioning MarBEC as a global leader in the exploration, development, and production of novel compounds and marine natural products. The NSF financial allocation to MarBEC for its fifth and last year (November 2002- October 2003) amounted to US\$ 949,231.¹⁰²

MarBEC's Industry sponsors are Cyanotech Corporation, Diversa and BiophoriX. Hawaii Biotech, Coast Seafoods, Ceatech USA and Ocean Nutrition Canada LTD are affiliate sponsors.

Expeditions aimed at raising awareness of deep sea areas are also implemented, such as the American Museum of Natural History Black Smokers Expedition. These expeditions have an impact on deep seabed ecosystems. For example, the second Black Smokers expedition in 1998 led to the collection of four chimneys of several tons each from the Endeavor segment of the Juan de Fuca Ridge, at the depth of 2,300 meters.¹⁰³ Educational missions are also undertaken, such as the REVEL expedition. This project, sponsored by the US NSF and the University of Washington, was conceived as a teacher development programme, and allowed scientists and teachers to jointly conduct observations in the Juan de Fuca Ridge.¹⁰⁴

According to the InterRidge database, since 1992, deep seabed expeditions have been led by scientists from the US (196 cruises), followed by France and Japan (67 cruises each), Germany (34 cruises), Canada (27 cruises), Russia (13 cruises) and Portugal (11 cruises). This information from the InterRidge database may underestimate the scale of international collaboration, since researchers from certain countries participate in other countries' research expeditions.

Overall, it has proven difficult to determine the level of participation of the private sector in publicly-driven expeditions, as well as the type of arrangements that may have been agreed upon between private and public partners with regard to access to sampled resources and sharing of benefits following eventual commercialization. This difficulty stemmed from limited public availability of information, as well as lack of response to requests for information from the main actors.¹⁰⁵ Because this report shows the importance of public-private ventures in deep seabed research, it is necessary to further study the role and modalities of public-private partnerships for deep seabed research so as to better assess the type of international regime required, if any.

3.2.2. Review of various uses of deep seabed genetic resources

From discovery and recovery of an organism from its original habitat to practical application of the organism, several steps take place. For example, in the case of pharmaceutical applications, the cycle of development can be summarized in the following phases:

- research phase: this phase encompasses screening for lead compounds, patent application, and the pre-clinical development phase (selecting candidates on the basis of pharmacology and toxicity);
- clinical trials phase: these are performed during three different clinical phases and consist in testing candidates for toxicity, efficacy and pharmacology in in vivo models;
- administrative procedures: this phase includes registration and marketing authorization, as well as licensing of the patent;
- production and launching of the product.

The cycle lasts about 15 years, with the research and clinical phases lasting up to 13 years and the administrative phase between two to three years. The last phase, called "pharmacovigilance," lasts about five years. Some of these phases, especially the research phase, can be shortened by using various methods. For example, in vaccine production, "reverse vaccinology" is proposed as an approach to significantly reduce the time of production. The approach, which is based on computerized analyses of genome sequences and the development of test vaccines on the basis of the results of those analyses, is also thought to allow the discovery of vaccines otherwise impossible to realize through conventional techniques and to reduce the health risks associated with the toxicity of vaccine discovery.¹⁰⁶

This sections aims to provide a preliminary assessment of the type and level of current or potential uses for deep seabed genetic resources. The examples outlined in this section were gathered from a variety of sources, namely: information contained in national patent databases as well as international patent metadatabases; information available in the public domain (Internet and published material, both peer-reviewed and gray literature, as well as information brochures); and information obtained through e-mail or phone interviews with scientists or managers at research institutions and commercial companies.

At the outset, it is worth noting that assessing the type and level of activities using genetic resources from the deep seabed proves relatively difficult for several reasons. First, public information, including patents, do not necessarily point out at the practical applications (although, in several cases, they do indicate their potential applications). Second, with the current configuration of the patent classification system, it is difficult, if not impossible, to readily map trends for microorganisms arising form bioprospecting in the deep seabed or even on land if the organisms do not fall into known categories of the system.¹⁰⁷ Last, information regarding the origin of the samples used is not always disclosed, even in patents' descriptions.

3.2.2.1. The role of patents with regard to deep seabed genetic resources

Patents, which are a method to assert IPRs over an invention, confer upon their holders more or less extensive rights for a certain period of time, in exchange of publication of information thereon. IPRs are usually used as a way to stimulate research and innovation through rewards.

There are usually three criteria for patenting: the invention must be new (or novel); the invention must involve an inventive step, i.e. be non-obvious; and the invention must be capable of industrial application, i.e. be useful or of utility. Patents may be granted to public or private research institutions, private companies, as well as to individuals. Whether the object of the patent is a source material itself or an invention derived therefrom, third parties need the consent of the holder of the intellectual property to access or use the invention. It is noteworthy that while a patent may have been claimed for non-commercial purposes, a subsequent license to use the invention may be granted to companies that intend to apply the invention for commercial purposes. Besides the type of uses that can be made from the invention licensed, this raises questions about the sharing of benefits ensuing from the commercial application of the invention, with the patent holder. Licenses can specifically exclude certain types of uses, as well as include provisions regarding sharing of benefits.

There are two scenarios with regard to patenting of genetic resources:

- direct patenting of a source material, whereby the patent claims genetic resources or organisms obtained from a separate source as an invention, on the basis of their novel physical, chemical or biological properties; and
- patenting of inventions derived from the source material, whereby a patent claims an invention derived from or using genetic resources or organisms.¹⁰⁸

A distinction can also be drawn between productoriented and process-oriented patents. Product-based patents relate to the isolation of compounds from deep seabed samples and to the creation (through molecular engineering techniques) of new organisms of potential use in pharmaceuticals and many other fields, such as food processing. Process-based patents relate to the isolation or creation (also through molecular engineering techniques) of compounds and derivates (usually proteins having an enzymatic function) that improve the pace of industrial processes and/or the quality of ensuing products. It is noteworthy that both types of patents can result in *per se* claims over the source organisms.

The following section provides examples of the type of patents granted with regard to genetic resources recovered from the deep seabed.

3.2.2.2. Review of patents related to deep seabed genetic resources

A brief search of selected Patent Office Databases has revealed that several deep seabed organisms have been used for commercial application. Most inventions concern the genomic features of deep seabed species, the isolation of active compounds, and sequencing methods. Others relate to the isolation of proteins that present enzymatic activity of potential for industrial applications. Several inventions concern the cell components and biological compounds themselves, which offer interesting properties for use in biomedical applications.

The company Sederma, located in France, has used enzymes isolated from deep sea bacteria¹⁰⁹ to develop commercial skin protection products providing higher resistance to UV and heat exposure. These inventions have been the object of patents.¹¹⁰ The enzymes used for these products, isolated from the extremophile *Thermus thermophilus*, are effective in counteracting free radicals that form as a result of UV action, especially at high temperatures, thus preventing the skin from damage. Sederma was granted the authorization to commercially exploit some of the samples collected during expeditions by the CNRS. Enzymes derived from *T. thermophilus* are also used by the California-based company California Tan for developing and commercializing the same type of products.¹¹¹

T. thermophilus and other species of thermophiles are also the subject of research by the company Roche. Roche's patents relate to improvements in the amplification of nucleic acids, and include a number of inventions based on thermophiles such as a DNA sequence using a *Thermus* aquaticus DNA polymerase (patent US5075216), a *Thermus* thermophilus polymerase (patent US5407800), a mutated thermostable polymerase from *Thermotoga maritima* (patent US5420029), a mutated thermostable polymerase from *Thermus sp.* (patent US545170), a thermostable polymerase from *Pyrodictium sp.* (patent US5491086), and a thermostable polymerase from *Thermosipho africanus* (patent US 5968799).¹¹² These products are used in conventional molecular biology such as sequencing.

The California-based company Diversa Corporation has been granted a significant number of patents related to discoveries involving genetic resources from deep seabed organisms.¹¹³ Products have been commercialized largely thanks to partnerships between Diversa and market companies such as BASF, The Dow Chemical Company, Givaudan Flavors Corporation, Invitrogen Corporation, Syngenta AG and others.¹¹⁴ As of November 2004, Diversa has commercialized several products developed on the basis of deep sea organisms,¹¹⁵ including: the Pyrolase[™] 160 enzyme, derived from a hydrothermal organism and used in industry to reduce viscosity;¹¹⁶ and the thermostable ThermalAce[™] DNA Polymerase, derived from a non-declared Archaea species, and used in DNA sequencing.¹¹⁷

The company New England BioLabs Inc., headquartered in Beverly, Massachusetts, US, has an extensive list of commercialized products derived from deep seabed organisms. Examples include: the Deep VentR® DNA Polymerase, obtained from a bacterium carrying polymerase genes, *Pyrococcus sp.* – a hydrothermal vent species found at 2010 meters of depth and growing at temperatures of up to 104°C;¹¹⁸ and the Therminator^a DNA Polymerase, obtained from a genetically-engineered form of the DNA polymerase of *Thermococcus sp.*¹¹⁹

The company Aquaartis, based in France, has developed BactoScreen[™] – a library of extracts of some 1,000 marine bacteria isolated from marine organisms and sediments. Most likely, several of these microorganisms belong to deep seabed environments.¹²⁰

The US NOAA reports that several marine compounds are under clinical investigation as possible anti-cancer products, including metabolites obtained from deep seabed organisms, such as lasonolides, obtained from the deep sea sponge belonging to the genus *Forcepia*, commonly found in deep sea habitats in the Gulf of Mexico. Reference is also made to the discovery of discodermolide, a potent antitumor agent, isolated from a deep sea sponge by the Harbor Branch Oceanographic Institution, Inc. (HBOI), a not-forprofit oceanographic research and education organization based in Florida, US, which has been conducting expeditions aimed at sampling organisms of potential interest to identify compounds of biomedical importance. Discodermolide was subsequently licensed to Novartis.¹²¹

Many other examples of applications of genetic material derived from deep seabed organisms can be found in the public domain, such as:

• the *Thermus aquaticus* DNA polymerase Taq Red, commercialized by the company HyTest Ltd., based

in Turku, Finland. HyTest manufactures and markets cardiac markers, hormones, toxins, human proteins, and infectious and autoimmune disease reagents.¹²² Taq Red is used as an enzyme for molecular biology;

 the thermostable *Tth* DNA Polymerase^a commercialized by the company Promega, headquartered in Madison, Wisconsin, US.¹²³ This product is also used as an enzyme for molecular biology.

There are many patents involving genetic resources from the deep seabed. However, for many of these patents, it is difficult to demonstrate whether or not practical applications have been developed. Following are some examples of patents for which commercial applications have not been identified yet:

- Diversa is among the applicants of patent WO03093434,¹²⁴ concerning the genome of the hyperthermophilic *Nanoarchaeum equitans*, its proteins (including enzymes), identified genes encoding these proteins, and also the isolated *Nanoarchaeum* equitans;
- patent US2003235902¹²⁵ concerns the production of thioredoxin from the hyperthermophilic *Aeropyrum pernix* and *Pyrococcus horikoshii*, growing at temperatures between 90 and 100°C. Thioredoxin has an interest for the pharmaceutical industry, including as an agent detoxifying snake venom protein and preventing skin inflammation caused by UV radiation. This protein is relevant to the food industry as a compound that eliminates food allergens, and to the cosmetic industry for development of products used as protection against adverse effects of UV radiation;¹²⁶
- patent US2003129734¹²⁷ relates to the coppertolerant yeast *Cryptococcus sp.*, isolated from deep sea sediments;
- patent US5989587¹²⁸ concerns the production of novel ether lipids from the Archaea Methanospirillum hungatei, Methanococcus jannaschii, Methanococcus voltae, Methanosarcina mazei, Methanobrevibacter smithii and Halobacterium cutirubrum. These liposomes (lipid vesicles) prove to be very stable, making them good candidates for many liposome applications, including as components of biological membrane systems for the study of processes such as transmembrane transport, immunological adjuvant, carriers of drugs, skin care compounds, and insecticides;
- patent application US20020106660¹²⁹ relates to the structure of the 30S ribosome unit of *Thermus thermophilus*, on the basis of which 30S inhibitors can be developed, and potentially used as antibiotics;
- at least 21 patents meet the search criteria 'Archaea' under the metadatabase of the European Patent Office.³⁰ These span from methods for detecting and identifying DNA in a sample (patent US2004176584) to novel extreme halotolerant and halophilic (patents TW579390 and WO0130934)

as well as thermostable enzymes (patents US2004002075, US6391604, WO9833895), the formation of stable lipids from Archaea's lipid extracts (WO9308202), and the genome of particular species, such as patents related to the genome of the hyperthermophile *Methanopyrus kandleri*;

• the patent database of HBOI¹³¹ lists more than 120 patents related to compounds obtained from marine species, several of which are from the deep seabed. These include anti-tumor and antiviral compounds, anti-inflammatory and anti-allergy agents, and anticoagulant agents. Patents also cover inventions related to methods for determining the composition of those compounds as well as their possible uses. The database does not specify whether or not the isolated compounds have been commercialized. Funding for this research has been provided by the US government agencies, including NOAA and the National Cancer Institute (NCI). Partnerships were established with universities, as well as with biotechnology and pharmaceutical industries.

3.3 Information on recorded or potential impacts of research activities carried out in the deep seabed

As shown in section 3.2 of this report, distinguishing between pure marine scientific research and applied marine scientific research is difficult in practice. Deep seabed activities driven by commercial objectives would not be possible without strategic partnerships with academic institutions, the interest of which lays generally in furthering our knowledge of deep seabed ecosystems.¹³² For the purposes of this section, pure marine scientific research and bioprospecting activities are considered jointly.

Research in the deep seabed has both positive and negative impacts. Among the positive impacts, marine research contributes to expanding our knowledge of the deep sea. Thus, in Resolution A/RE5/59/24 (Oceans and the law of the sea), the UN General Assembly called "upon States, individually, or in collaboration with each other or with relevant international organizations and bodies, to improve understanding and knowledge of the deep sea, including, in particular, the extent and vulnerability of deep sea biodiversity and ecosystems, by increasing their marine scientific research activities in accordance with the Convention [i.e. UNCLOS]."¹³³

Without marine scientific research, industry and academia would not be in a position to continue exploring the value of deep seabed genetic resources for health and industrial applications. Marine scientific research is the most immediate means to increase our knowledge about the structure, functioning and role of deep seabed ecosystems, as well as their value and that of deep seabed genetic resources to human well-being. Marine scientific research is also the most immediate means to build an informed basis upon which to make management decisions, including conservation measures.

Marine scientific research will also assist in revealing the unknown, as well as determining what cannot yet be known, as far as life in the deep seabed is concerned.¹³⁴ The Baseline Report of the Census of Marine Life estimates that six thousand species have yet to be discovered in the oceanic realm of active geology.¹³⁵ This figure may be much larger, as patterns in discoveries are not clear.¹³⁶ These discoveries will have implications for scientific knowledge, including with regard to theories on the origin of life and evolution, and for regulating conservation of, access to, and the sharing of the benefits deriving from the utilization of deep seabed genetic resources.

At the same time, marine scientific research represents a source of potential and actual adverse impacts on deep seabed ecosystems. Marine scientific research may entail physical disturbance or disruption, e.g. the removal of parts of the vent physical infrastructure and/or of the associated fauna. Research vessels and scientific equipment installed to carry out long-term measurements may also negatively impact on the deep seabed physical environment. As has been shown, alteration of environmental conditions is likely to impact on the organisms living in those areas. Alterations can occur for example, in the context of *in situ* experiments aimed at clarifying the reproductive biology of some organisms, bringing changes in water temperature. Introducing light and noise in an environment that is naturally deprived of the former, and in which characteristic patterns of noise are very different from those induced by human activities, is also likely to cause alterations.¹³⁷ Moreover, marine scientific research may entail pollution in the form of debris or biological contamination due to disposal of biological material in areas different from the sampling area.138

The frequency of research expeditions is also a source of negative impact. Among the few hundred hydrothermal vents discovered so far, only a few are visited once a year, and others once every few years.¹³⁹ It is likely that some deep seabed sites may become the subject of systematic observations under various monitoring programmes.¹⁴⁰ The reference document for the draft implementation plan of the Global Earth Observing System of Systems (GEOSS) calls for repeated observations in the deep seabed in the years to come.¹⁴¹

An international programme on Monitoring the Mid-Atlantic Ridge (MOMAR), sponsored by the European Commission, will conduct systematic abiotic and biodiversity observations over a five to ten-year period using equipment and performing sampling that may have a bigger impact than sporadic measurements and observations.¹⁴² The North-East Pacific Time-series Undersea Networked Experiments (NEPTUNE) plans to implement a permanent system of deep seabed multidisciplinary observations on the entire Juan de Fuca plate, using 3,000 km of fiber-optic cable, while the European Sea Floor Observatory Network (ESONET) will undertake repeated real-time observations in the seabed on the Atlantic and Mediterranean coasts. Japan will set up an Advanced Real-time Earth Monitoring Network in the Area (ARENA) along the Japan Trench.¹⁴³ Some monitoring programmes are already fully operational, such as the New Millennium Observatory (NEMO), which focuses on the impacts of volcanic activity on hydrothermal vents.¹⁴⁴

Scientific activities can interfere with each other and are sometimes incompatible. Concerned about the impacts of their increasing activities on deep seabed ecosystems, scientists have cooperatively agreed to address these impacts, including through coordination of site visits to minimize conflicting uses and simultaneous expeditions, as well as through the development of codes of conduct. Such codes of conduct are outlined in section 5 of this report. In order to conduct scientific research in the most possible undisturbed conditions, the InterRidge website hosts requests by scientists conducting deep seabed research and observations to consider a given site as a scientific reserve.¹⁴⁵ In 1998, five requests were put forward by scientists operating in the East Pacific Rise for: Biotransect (9°49.6'N - 9°50.4'N, 104°17.4'W), East Wall (9°50.54'N, 104°17.52'W), M vent and X5 (9°50.7'N, 104°17.52'W), Riftia Fields (9°50'N, 104°W) and Worm (or Tevnia) Hole (9°48.95'N, 104°17.31'W).¹⁴⁶ In the mid-Atlantic Ridge, requests concerned Eiffel Tower (37°17.356'N and 32°16.486'W - 1695 meters), «PP24» (37°17.646'N and 32°16.888'W) and Rainbow, markers PP28 (36°06.690'N, 33°11.290'W), 35 and PP37. These last requests were put forward between 1998 and 1999.147

Overharvesting of marine resources for bioprospecting purposes poses a conservation and sustainable use problem, as explained in more details in section 4.2 of this report. Other threats are to be highlighted, including mining activities and climate change. According to some, climate change represents the widest and most significant threat to the largest number of species in the deep sea. Fossil records show that past episodes of global warming have led to widespread dysaerobia in deep sea ecosystems, wiping out much of the fauna. Recent studies have shown that even relatively small changes in the quality of phytoplankton at the surface can change the abundance of species at the seabed, 4,000m below.¹⁴⁸

In order to assess the status of various deep sea ecosystems and improve management of risks to such ecosystems, States have agreed, within the CBD and the UN General Assembly, to engage in information-gathering activities (see section 5).

There seems to be a common understanding that marine scientific research can be run and fulfill its objectives in a way that minimizes potential disruption to deep sea ecosystems, while remaining one of the freedoms of the High Seas as set out under UNCLOS, as will be detailed in section 5 of this report.

3.4 Technological constraints and opportunities for deep seabed bioprospecting

Important technological considerations have to be taken into account when discussing bioprospecting of deep seabed genetic resources. These are due to the difficulties in accessing environments that are extreme in terms of depth, pressure, and temperature, as well as in preserving collected samples *ex situ* in order to identify culture and further study them.¹⁴⁹

Reaching deep seabed extreme environments and maintaining sampled organisms intact and alive, as well as culturing them, requires sophisticated and expensive technologies. Typically, the technology associated with research on deep seabed genetic resources involves: manned or unmanned submersible vehicles (the latter are normally referred to as Remote Operation Vehicles or ROV);¹⁵⁰ in situ sampling tools; technology related to culture methods, including pressurized aquaria to maintain sampled organisms at original pressure conditions; molecular biology technology and techniques; and the technology associated with the different steps of the commercialization process of derivates of deep seabed genetic resources. With the exception of basic molecular biology techniques, most of the technology necessary for accessing the deep seabed and studying and isolating organisms from the deep seabed is owned by research institutions, both public and private.¹⁵¹ To date, only very few countries have access to these technologies.

On the other hand, emerging techniques such as that of DNA Barcoding may soon be available on a large scale and help study deep seabed ecosystems and organisms.¹⁵² As sequence-based techniques for determining microbial community composition have limitations, a combination of rapid assessment and conventional techniques, including culturing the sampled microorganisms, will probably have to be applied when studying the properties and potential applications of deep seabed genetic material.¹⁵³

A limited number of institutions worldwide own or operate vehicles that are able to reach areas deeper than 1,000 meters below the oceans' surface, and can therefore be actively involved in deep seabed research. A larger number of institutions operate vehicles that are capable of reaching shallower depths.¹⁵⁴ In either case, developing and operating deep sea technology is a highly consuming exercise, financially as well as time-wise.

Many institutions undertaking deep sea research and owning and/or operating deep sea vehicles and associated technologies are publicly owned. Partnering with private companies interested in possible commercial applications/ uses of deep sea genetic resources is common in order to ensure that the costs of deep sea expeditions are adequately covered.

Box 3 contains a brief description of the technology owned and operated by an institution active in deep seabed research: JAMSTEC.³⁵⁵

Box 3: The Japan Agency for Marine-Earth Science and Technology

JAMSTEC is an independent administrative institution undertaking research and development activities in the field of marine environmental sciences, with particular attention to interactions between geological features and biological communities on the deep sea floor. The objectives are to: understand changes in the global environment; provide knowledge on natural disasters so as to protect people; provide knowledge and information that contribute to social and economic development; and deepen and broaden human knowledge about the ocean and the Earth to enrich the intellectual property of humankind.

JAMSTEC Headquarters host the Extremobiosphere Research Center (XBR). The Center's mission is to search for new organisms and investigate ecosystems so as to: explore and understand their characteristic functions; carry out research on the functions and ecology of organisms through experiments and simulations; and contribute to social and economic development through industrial applications. One of the stated objectives of the work of JAMSTEC-XBR is "to establish new fields of biotechnology by discovering unique microbes and enzymes, analyzing their genomes, and identifying industrial applications for the knowledge obtained through such study." XBR has several programmes relevant to research on deep seabed genetic resources, such as the Extremophiles Research Program, which specializes in the establishment of partnerships with private companies with a view to developing commercial applications based on the findings of research activities undertaken by XBR.

JAMSTEC owns and operates several vehicles to undertake deep seabed research. These include: the manned Deep Submergence Research Vehicle (DSRV) SHINKAI 6500, which can reach depths of 6,500 meters;¹⁵⁷ the unmanned vehicle DOLPHIN-3K and the ROV "Hyper Dolphin" System going at maximum depths of 3,300 and 3,000 meters respectively, and used for sampling and taking images with specialized TV cameras;158 the ROV KAIKO 7000, which can reach a maximum depth of 7,000 meters, and is used for sampling and imaging;¹⁵⁹ and the Autonomous Underwater Vessel (AUV) URASHIMA for autonomous deep sea cruising at depths of 3,500 meters, and which allows to detect deep seabed geological and biological activity and generate topographical data when coupled with direct imaging and sonar techniques.¹⁶⁰ A drilling ship, the CHIKYU, which will allow drilling several thousands of meters below the ocean floor to study the origin of the Earth and life, is under construction.161

Particularly innovative is a device called "Deep Bath" (Deep-Sea Baro/Termophiles Collecting and Cultivating System), developed by JAMSTEC and operated since the early 1990s, which allows maintaining samples at *in situ* conditions of pressure and temperature. Such conditions are a precondition for the survival of piezophiles – organisms that can only survive at very high pressure. Deep Bath is composed of four subsystems: a sediment sampler; a dilution device; an isolation device; and a culture vessel. While only 5ml of samples of sediment can be collected at a time, a mass cultivation of microorganisms of 1000ml can be obtained through dilution.

To date, JAMSTEC has been able to isolate 180 microbial species from the Mariana Trench, the deepest point on Earth at 10,898 meters, located off the Mariana Islands in the

Pacific Ocean. The aim was to have more than 3,500 strains of deep sea microorganisms preserved in liquid nitrogen by the end of 2004. JAMSTEC's website hosts a metadatabase of the genomes of several deep sea microorganisms that have been sequenced by JAMSTEC and other scientific institutions in the world.¹⁶²

According to interviews conducted with both a senior manager and a senior scientist at JAMSTEC in November 2004, only a few countries possess the technology to conduct deep seabed expeditions at depths greater than 1,000 meters. These are: France, Japan, Russia, and the US.¹⁶³ These countries all have DSRVs capable of reaching depths of 6,000 meters. While China is in the process of building adequate technology for this type of research, the US is developing a vehicle that could reach greater depths.

Some private companies also own deep sea research vehicles, but their capability of operating is limited to much shallower environments (< 1,000 meters). In the case of JAMSTEC, only a small percentage of its research budget is contributed from the private sector.

Other research institutions, including Ifremer in France and the Woods Hole Oceanographic Institution in the US, use technology similar to that of JAMSTEC.¹⁶⁴

Considering the technological issues outlined in this section as well as the potential value of deep seabed genetic resources to humanity, organizing technology transfer seems particularly relevant. While such transfer may result in increased research in the deep seabed, thereby putting at risk these ecosystems, the transfer of so-called "clean technologies" may allow sustainable research practices and at the same time respond to the need to expand our knowledge of the marine realm. It is anticipated that options for making those technologies available to developing countries will be found under "opportunity programmes," i.e. programmes combining activities such as oil drilling or commercial fishing with scientific research. Requirements for technology transfer of marine science technology are provided for in a number of international instruments outlined in section 5 of this report.

3.5 Consequences for management resulting from the features of, and threats to, deep seabed ecosystems, as well as from technological aspects

The slow growth rate, limited longevity, late sexual maturity and restricted distribution of certain species inhabiting deep seabed ecosystems make them potentially vulnerable to changes in the surrounding environment.¹⁶⁵ As indicated above, slight changes in those environmental conditions might significantly influence key biological processes of those species, such as reproduction. Hence, conservation and sustainable use measures for deep seabed ecosystems have to take into account the biology of species and the ecological characteristics of the ecosystems of which they are part, for example in terms of resilience.¹⁶⁶ Seamount ecosystems host deep sea fish of commercial interest. The use of some deep sea fishing techniques, such as bottom trawling, has caused the destruction of many seamount ecosystems and of associated communities of sponges and other sessile invertebrate organisms. Unsustainable fishing activity at seamounts has also caused the depletion or collapse of long-lived, slow-growing deep sea fish stocks that are very vulnerable to overfishing.¹⁶⁷ Associated ecosystems such as cold-water coral reefs have also been significantly impacted by these activities. A study on the patterns of species richness in marine areas beyond national jurisdiction concludes that the high degree of endemism at seamounts, combined with the high degree of threats, suggests that there is a need to focus conservation efforts on these ecosystems. The study highlights specific seamount areas in the tropical Indo-Pacific, Pacific, Indian and Atlantic Oceans as priority areas for conservation.¹⁶⁸

Vent and other deep seabed ecosystems are the subject of increasingly significant marine scientific research and bioprospecting. The precarious nature of hydrothermal vents and cold seeps – a vent may appear and then disappear in a decade or two, and the sediments on which cold seeps are located are intrinsically physically unstable - should not act as an impediment to conservation and sustainable use measures for these ecosystems and their associated resources. While the question may be asked of the relevance of conserving systems that are transient or unstable, the necessity of such conservation is clear. First, these ecosystems will better inform us about life in the deep seabed in general, a subject still very poorly known as "at best the technology to explore these dark, deep waters is brand new, and at worst it is still inadequate."¹⁶⁹ Second, only a very limited amount of vents and cold seeps have been found and explored, since vents typically cover only a few tens of square meters, which makes them difficult to detect.¹⁷⁰ The knowledge gathered from already and yetto-be discovered deep seabed ecosystems and species will generate important information on how these systems are structured and function in general, on their value to humankind, and on the way in which they should be managed. Moreover, vent biogeographic provinces may provide important information and become essential elements of possible systems of ecologically representative marine protected areas (MPAs) in areas beyond the limits of national jurisdiction, as called for recently under various international fora, including the CBD.

With regard to adverse impacts of marine scientific research on deep seabed ecosystems, new sophisticated technologies have been developed to study deep seabed ecosystems. Examples are devices to sample vent fluids at temperature and pressure values as high as 420°C and 600 bar and to maintain samples at original pressure values *ex situ*, which may reduce the intensity of sampling.¹⁷¹ Rapid assessment methods, including using taxon richness as a surrogate for species richness, can also be used to assess deep seabed communities, which would facilitate their study and management.¹⁷² This would suggest that new knowledge and technology should be made use of in order to reconcile the needs of pure and applied science with the conservation of deep seabed ecosystems.

4 Overview of global biotechnology and bioprospecting trends

Bioprospecting for genetic resources from the deep seabed has to be considered within the broader context of the biotechnology sector, the development of new products based on the use of natural resources, and the consolidation of genomics as a basis for both biotechnology and bioprospecting. This section provides a brief overview of global trends in these areas, as well as of bioprospecting for marine resources and other extremophiles such as those from Antarctica.

4.1 General industry trends

Industry sectors involved in bioprospecting include biotechnology, waste, agriculture, and the pharmaceutical and cosmetics industry. To varying degrees, all these sectors are increasingly using biotechnology to develop new products.

According to Ernst & Young's Global Biotechnology Report 2004, the global biotechnology sector, which went through a phase of significant recession between 2001 and 2002, has fully recovered. The report notes that the biotechnology industry worldwide, led by the US, rebounded in 2003 and 2004, making the global biotechnology industry a leader in the creation of a new health economy in which biotechnology, pharmaceutical, and medical device companies are converging with health care providers. The number of publicly-traded biotechnology companies declined slightly in 2003 to 611 from 619 in 2002, but these companies earned 17% more in revenues and hired more workers, boosting employment by 9%, while reducing R&D spending by 16% and improving their net loss by 65%.¹⁷³ New investments, including from governments, are directed towards the biotechnology sector.

Worldwide, biotechnology supported almost 200,000 employees and generated revenues of up to US\$ 46.6 billion in 2003, increasing by 9% and 17% respectively, compared to the 2002 figures. Between 1998 and 2003, revenues from the biotechnology industry have increased by 115% in the US, 246% in Canada and 754% in Europe. In the same period, the number of people employed by the biotechnology sector has increased by 38% in the US, 176% in Canada and 184% in Europe. The global distribution of revenues is as follows: 77% for the US, 16% for Europe, 4% for Canada, and 3% for Asia and the Pacific. These numbers show a decline of Europe's share from 21% in 1998, and an increase of the US share from 72% in 1998.¹⁷⁴

According to Ernst & Young, on the basis of the number of public and private biotechnology companies located in those countries, the top 12 biotechnology countries are: the US, Canada, Germany, the United Kingdom, France, Australia, Sweden, Israel, Switzerland, China and Hong Kong, India and Denmark.¹⁷⁵

Regional trends suggest that biotechnology in the Asia-Pacific region is a tool for improving the provision and nutritional value of food from agriculture as much as it is for developing health applications.¹⁷⁶ Japan has developed a strong supporting policy with regard to biotechnology, marking a shift from the conventional pharmaceutical sector, through public investments and the recognition of intellectual property.¹⁷⁷ China is also intensifying its protection of intellectual property; its pharmaceutical sector, which is the world's second largest chemical pharmaceutical producer, continues expanding at a rate of 15-17% per year.¹⁷⁸ In 2003, Singapore directed US\$ 1 billion to the development of its biotechnology sector.

In North America, a major shift from research into novel organisms and compounds to development of products based on known metabolites has occurred, due to the fact that the hit rate of new products based on biodiversity has been low.¹⁷⁹ In the US, the approval of new drugs increased by 25% in 2003, with some 300 biotechnology products based on natural compounds currently undergoing Phase III trials.¹⁸⁰ In Canada, financing for biotechnology in 2003 increased by 15% as compared to 2002.

The European biotechnology sector has shown contradictory signs in 2003. While financial investments do not seem to be a limiting factor, the number of marketable products is low, and the sector remains fragmented with very little concentration between companies. The public health sector and commercialization of new drugs are strictly regulated within most European countries. In 2003, both public and private biotechnology companies have experienced losses in revenues, number of companies and employees, and have reduced their R&D expenses. In terms of number of companies per country, Germany leads the European biotechnology sector (350 companies, 11 of which are public), followed by the UK (334 companies, 43 of which are public) and France (246 companies, six of which are public). Within all European countries, private biotechnology companies outnumber public ones.¹⁸¹

In Latin America, 432 biotechnology companies have been counted in 14 countries, the most active of which are Argentina, Brazil, Chile, Colombia, Cuba and Mexico. The region sees an increasing number of partnerships between biotechnology companies and national and regional professional societies such as the Latin American Federation of Biotechnology Companies and Associations (FELAEB).¹⁸²

With regard to sectoral trends, the role of biotechnology in the health care industry is increasing, and more and more partnerships are being created between biotechnology and pharmaceutical companies. From 22 in 1993, companies using biotechnology for the health sector ("biologics") now number 190, 13 of which are "blockbusters" that sell over US\$ 1 billion each annually.

Biotechnology is emerging as a sector that increases cooperation between pharmaceutical companies and other biotechnology companies, academic researchers, non-profit institutions, medical centers and foundations.¹⁸³ For example, the US-based company Targeted Genetics has entered into a collaboration with the International AIDS Vaccine Initiative, which aims at producing a vaccine at an accessible cost for developing countries and which can also be commercialized in developed countries. The nature of partnerships between biotechnology and pharmaceutical companies is changing: instead of simply out-licensing their products, biotechnology companies increasingly demand a partner role in most phases of the commercialization phase, including the sharing of royalties.¹⁸⁴

With the advent of recent technologies in genome mapping, genomics – the study of genes and their functions – has significantly developed as a research area, with 1182 projects on genome mapping being listed on the Genomes Online Database as of 14 September 2004 (representing a 47% increase over a one-year period, from 2003 to 2004).¹⁸⁵ Among these projects, 522 are about prokaryotic species, including Archaea (most of the deep seabed microorganisms belong to the class Archaea). Genomics, proteomics and biotechnology are associated with a shift in the balance of relationship within "the triple helix" of innovation, composed of government, universities and industry, towards universities. The majority of registered worldwide genome mapping projects appears to be conducted by universities or non-profit organizations. Oldham notes that this shift in the structure of innovation towards publicly-funded research may provide important ways forward in developing an international regime on access to genetic resources and benefit-sharing. The dominance of publicly-funded R&D in these areas would provide opportunities to develop alternative incentives directed towards internationally-agreed goals and alternative models for access and benefit-sharing that minimize the externalities of the patent system and maximize the benefits for global welfare.¹⁸⁶

The development of genomics has been favored by the advent of biological informatics or "bioinformatics," which can be loosely defined as the application of information technologies to biodiversity studies and their applications. Bioinformatics plays a key role in the identification of candidate compounds for pharmaceutical and many other purposes in that it allows the rapid screening and selection of potential compounds for further testing.¹⁸⁷ For example, in the US, the biotechnology company Incyte has been selling non-exclusive access to its genome sequence databases and the use of its bioinformatics software for the analysis of this data. The company also negotiated royalties regarding drugs developed on the basis of this data.¹⁸⁸ Since the technology and software associated with bioinformatics is increasingly being made available, including through 'open source' software, bioinformatics is likely to change the way biotechnology research is conducted in the future, with trends suggesting that there is a decreasing dependence on physical transfers of biological material in favor of electronic transfers. Bioinformatics is also likely to reduce R&D costs. Oldham notes that one of the opportunities is to link access and benefit-sharing arrangements with transfers of bioinformatics technology and knowledge.¹⁸⁹ The role of bioinformatics with regard to deep seabed genetic resources, the genomics of which has only started, should not be overlooked in these respects.

Quantifying the contribution that natural genetic resources make to the biotechnology market is difficult. Figures are often difficult to obtain due to the competitive nature of product development. Moreover, the contribution made by natural biochemical processes is frequently only one of many aspects leading to the final product. However, a study of small-molecule new chemicals introduced globally as drugs between 1981 and 2002 showed that 61% can be traced to, or were inspired by, natural products. This figure rose to 80% in the year 2002-2003.¹⁹⁰ Compounds from natural products are considered more agreeable to consumers and two-thirds of the anti-cancer drugs, for example, are derived from both terrestrial and marine natural products.¹⁹¹ This may lead to greater examination of novel genetic resources and biochemical processes as part of the product development phase of various sectors.

According to the Millennium Ecosystem Assessment (MA), biodiversity continues to be an important source of material for pharmaceuticals. Products and industries that depend on microbial diversity include enzymes for industrial applications such as waste treatment, chemical engineering, wood and pulp processing, biological mining and production of fuel from biomass. Macroscopic species have led to products such as antibiotics and other clinical drugs, surgical drugs, pest repellants, fibers and materials based on biomimetics, industrial adhesive and pigments, and antifouling paints. Industries, some of which are new, encompass bioremediation and ecological restoration, biomonitoring, agriculture and biological control, health, care/cosmetics and nanotechnology. Both the trend in bioprospecting and the ensuing commercial benefits in these industries are predicted to increase.¹⁹² Among the findings of the MA, it is noteworthy that bioprospecting partnerships are most effective when supported by a range of international and national laws, as well as self-regulation measures including codes of ethics.

Novel products and industries do not necessarily come from biodiversity-rich areas. The history of the discovery of new products from biodiversity shows that new products have been derived from both tropical and non-tropical species. There is currently no reliable way to assess the potential of species or ecosystems to provide such novel products, but the pace of discovery of new species as well as of products that are potentially useful to pharmacology is higher for marine and microbial than for terrestrial organisms.¹⁹³

A way of quantifying the contribution of biodiversity to novel products and processes is to analyze the number and nature of patents deposited that relate to inventions based on, or making use of, natural material. The European Patent Office Database, esp@cenet, contains information from 73 national patent offices, as well as regional patent organizations and the WIPO Patent Cooperation Treaty. As of 2004, there were an estimated 45 million documents within esp@cenet, 36.1 million of which were patent descriptions. A search of esp@cenet showed that patents pertaining to microorganisms and enzymes – the focus of this report – dominate over other patents. ¹⁹⁴

The relation between intellectual property, including patents, and biodiversity or natural resources, has been the subject of several studies and intense debates within intellectual property-related fora, such as the World Intellectual Property Organization, and environmentrelated fora, mainly the CBD. This relation is further addressed in section 5 of this report, but a question that has often arisen is whether genome-related patent claims represent true innovations or are simply presumed inventions.¹⁹⁵ Moreover, as noted by Oldham, the nature of genetic homologies between organisms signifies that intellectual property claims related to the biological or genetic components of one organism may lead to intellectual property claims in relation to the biological or genetic components of other organisms.¹⁹⁶ Another concern relates to the potential commodification of life ensuing from patenting of natural products.¹⁹⁷

The trends presented above suggest that biotechnology is a flourishing industry worldwide, and that it will most probably continue to grow in scope, activities and applications. Within this trend, biodiversity will continue providing an important basis for the development of new products and processes. It is also noticeable that small biotechnology companies have replaced large pharmaceutical companies as the drivers of innovation in drug discovery based on natural products. Large companies are no longer interested in screening natural product samples as a result of the longer time span to characterize and develop them than for synthetic molecules.¹⁹⁸

In such a dynamic context, deep seabed genetic resources, which are among those that are increasingly undergoing bioprospecting activities, are likely to become an important socioeconomic issue.

4.2 Bioprospecting for marine resources

The world's oceans appear to host 32 out of the discovered 34 phyla on Earth, and a diversity of species per area unit as high as 1000 species per square meter in the Indo-Pacific Ocean.¹⁹⁹ Because of their extraordinary diversity and properties, marine organisms hold promises for drug development.

Significantly, the ratio of potentially useful natural compounds to compounds screened is higher in marinesourced materials than with terrestrial organisms.²⁰⁰ There is, therefore, a higher probability of commercial success. Potential applications for marine organisms include: pharmaceuticals; enzymes; cryoprotectants; cosmaceuticals; agrichemicals; bioremediators; nutraceuticals; and fine chemicals. All the major pharmaceutical firms, including Merck, Lilly, Pfizer, Hoffman-Laroche and Bristol-Myers Squibb, have marine biology departments. Estimates put worldwide sales of marine biotechnology-related products at US\$ 100 billion for the year 2000.²⁰¹ Profits from a compound derived from a sea sponge to treat herpes were estimated to be worth US\$ 50 million to US\$ 100 million annually, and estimates of the value of anti-cancer agents from marine organisms are up to US\$ 1 billion a year.202

Marine drugs can be used as antioxidant, anti-fungal, anti-HIV, antibiotic, anti-cancer, anti- tuberculosis and antimalarial. Applications for the treatment of Alzheimer's disease, cystic fibrosis and impotence are also considered.²⁰³ Several marine compounds are currently at various phases of development, including anti-cancer agents and immunosuppressants. Considerable hope is placed in drugs based on marine organisms in light of the shortcomings of current anti-cancer drugs, which have either been limited to the treatment of specific cancers or to which patients have often become resistant.²⁰⁴ The hormone calcitonin, extracted from salmon, has been found effective in preventing osteoporosis. Protamine sulfate, also derived from salmon, provides an antidote to the anticoagulant heparin. Research has also shown that cryptophycins produced by cyanobacteria also have anti-cancer potential, as well as being effective against viral diseases such as HIV.²⁰⁵ Other useful compounds include anti-inflammatory compounds such as manoalide and topsentin, and the cosmaceutical anti-irritant pseudopterosin. The anti-tumor compounds bryostatin-1, ecteinascidin 743, dolastatin-10, halichondrin and spongistatin, have been obtained from organisms such as sponges and ascidians.²⁰⁶ Sponges are particularly targeted as potential sources of pharmaceutical products. Over 30 years, one of the most effective treatments for leukemia has been based on derivatives of a sponge.²⁰⁷ A compound, IPL576092 based on the sponge steroid contignasterol, completed US Phase I trials as an asthma drug in 2000.²⁰⁸ Cytotoxins from deep water sponges found on the Chatham Rise, 400 km off New Zealand, are also under investigation.²⁰⁹ Other work in progress includes research on: the Conus venoms; cytotoxic organic extracts; Eleutherobia sp., derivatives of which could treat breast and ovarian cancer and are at the preclinical development phase; Sarcodictyon roseum, derivatives of which are at the preclinical development phase; and Cacospongia mycofijiensis at the preclinical development phase.²¹⁰ It is estimated that many more compounds, in the order of low hundreds, could be developed from the marine compounds that have already been isolated.²¹¹

However, marine research is expensive as a result of the high cost associated with the necessary technology for sampling and laboratory investigation, among others. The odds of success are slim; only one to two percent of preclinical candidates actually become commercially produced.²¹² The following figures illustrate the quantity of lead material yielded from original material: 450 kg of acorn worms yielded 1 mg of cephalostatin; 1,600 kg of sea hares yielded 10 mg of dolastatin; and 2,400 kg of sponge yielded less than 1 mg of spongistatin.²¹³ It has been estimated that one kilogram of shallow-water marine invertebrate collected, prepared for sampling, identified and transported, costs approximately US\$ 1,000 per sample. From the one-kilogram sample, only approximately 20 to 50 grams of liquid and 4 to 15 grams of organic material will be extracted, costing approximately US\$ 200 per sample. Subsequent testing may cost as much as US\$ 300 per sample. If all associated costs, such as laboratory staff and equipment, are included, the total cost rises to tens of thousands of dollars per sample. These figures need to be assessed against the limited odds of success.

In spite of these odds, sampling from shallow water is economically more viable than from the deep sea, from which specimens are even more difficult to retrieve and investigate. The US NCI was one of the first organizations to begin systematic large-scale collection of marine invertebrates and, in the mid-1980s, formal collection programmes were initiated to protect access to the original material. NCI's deep sea programme was later suspended due to the high costs involved. The HBOI has successfully synthesized a molecule, discodermolide, from a previously undescribed deep sea sponge. Another compound, halichondrin B, has also been isolated from a sponge species by a New Zealand joint venture. In the latter case, one metric ton of sponge was harvested, which yielded 300 mg of pure halichondrin B. This process cost approximately US\$ 500,000.²¹⁴ The example of an institution actively working in the field of marine bioprospecting, the Australian Institute of Marine Science (AIMS), is outlined in Box 4.

The above figures highlight the importance of sustainable harvesting, as well as, whenever feasible depending on the biological characteristics of the targeted microorganisms, the need to use various alternatives, such as chemical synthesis, aquaculture, and cell and tissue culture. In the case of fish proteins, for example, it was noted that the proteins could be replicated from genetically modified organisms, and did not require the direct harvesting of fish. Similarly, most bacteria and sponges can be cultured.²¹⁵

Box 4: Marine Biotechnology at the Australian Institute of Marine Science

AIMS activities in the field of marine biotechnology are oriented towards the development of pharmaceutical and healthcare products, agrichemicals for crop protection, and novel bioremediation agents for environmental protection.

The Bioactive Molecule team at AIMS collects samples from Australia's waters to discover compounds which may be developed by industrial partners into clinically-useful drugs or other beneficial products. To date, AIMS researchers have discovered novel marine-derived antioxidants that may have commercial application in cosmetics and food processing. Several lead compounds are being evaluated in medicine for use in the prevention of neurological disorders, such as Alzheimer's and Parkinson's disease. Several anti-cancer agents from marine sponges are currently in the first stage of pharmaceutical development.

AIMS possesses one of the world's largest publicly owned collections of biotic extracts for bioactive chemical discovery, including material from around 20,000 marine macroscopic and microscopic organisms from around Australia. The collection, which holds a relatively small quantity of a large number of organisms, is designed specifically for bioprospecting, primarily for screening purposes.²¹⁶

The former Marine Bioproducts Project at AIMS, now discontinued, also sought to investigate mariculture, culture of microorganisms, molecular approaches and chemical synthesis as alternatives to wild bioharvesting. Since only an estimated one percent of microbial diversity can be cultured using standard techniques, a large proportion of the microbiology effort at AIMS is spent on the development of novel culture and fermentation procedures.²¹⁷ Prior to 1994, AIMS sampled organisms on the basis of scientific research permits, which restricted use of the resources. The permits did not include any benefit-sharing provisions. The caution and concern of management authorities regarding lack of sharing of the potential benefits resulting from the exploitation of sampled organisms, created an environment whereby conditions on access were made more stringent. This seems to have limited AIMS' biotechnology R&D activities, and affected the Institute's capacity to attract commercial R&D funding. More generally, uncertainty over access to marine biota can be a major impediment to potential benefits.

In the absence of a clear regulatory framework, AIMS started entering into agreements on both access and benefit-sharing with industry and governments. In 2000, AIMS signed a Deed of Agreement with the Queensland Government to share the benefits of any scientific and commercial exploitation arising from biodiscovery research undertaken by AIMS on biota sampled from Queensland's seabed. Under the Agreement, the benefits to be shared include non-monetary outcomes (e.g. capacity building and sharing of scientific knowledge), as well as potential commercial profit (15% of the profits to be transferred to the State). Royalties are only a small part of the arrangement, which includes other benefits, some of which are more certain and available in a shorter time frame, including documentation of biodiversity to aid better management, opportunity for intellectual property development in new discoveries, innovative biotechnology industry, and a new sustainable resourcebased industry. While access to the resources must still be sought from resource management agencies since the Agreement only deals with benefit-sharing, permit conditions are limited to environmental concerns. The Queensland Agreement has been thought to provide an improved legal framework, which is more favorable to attract R&D investment from industry.²¹⁸

4.3 Bioprospecting for extremophiles: the case of Antarctica²¹⁹

The application of extremophiles in industrial processes ranges from their use in liposomes for drug delivery and cosmetics, waste treatment, molecular biology, to the food industry. A eukaryotic homologue of the myc oncogene product from halophilic Archaea, for example, is being used to screen cancer patients' sera.²²⁰ Enzymes isolated or adapted from extremophiles are also used in clinical chemistry, pulp industries, food processing, cleaning, dyeing technologies, or refining and bioremediation.²²¹

Scientists and bioprospectors are interested in Antarctica for two reasons. First, the lack of knowledge surrounding Antarctic biota provides an opportunity to discover novel organisms of potential use to biotechnology. Second, Antarctica's environmental extremes, such as cold temperatures and extreme aridity and salinity, present conditions in which biota have evolved unique characteristics for survival. Thus, bioprospecting opportunities include, *inter alia*, the discovery of novel bioactives in species found in cold and dry lithic habitats, novel pigments found in hypersaline lakes, and anti-freezes in sea-lakes. $^{\scriptscriptstyle 222}$

Amongst the many examples of commercially-useful compounds discovered, is a glycoprotein which functions as the 'anti-freeze' that circulates in some Antarctic fish, preventing them from freezing in their sub-zero environments.²²³ The application of this glycoprotein in a range of processes is being considered, including to: increase the freeze tolerance of commercial plants; improve farm-fish production in cold climates; extend the shelflife of frozen food; improve surgery involving the freezing of tissues; and enhance the preservation of tissues to be transplanted.²²⁴

Patents applied for or granted so far based on bioprospecting of Antarctic biota are manifold. A patent database search, which is not deemed exhaustive but indicative of existing patents, has revealed that companies applying for patents include: Bayer AG (Germany), Henkel KGAA (Germany), SmithKline Beecham, Astra, Novonordisk (Denmark), Du Pont (US), Chisso Corporation (Japan), Loders Croklaan (The Netherlands), Haarmann & Reimer GmbH (Germany), Unilever (UK), Lysi HF (Iceland), DSM NV (The Netherlands), Jujo Paper Co Ltd (Japan), Mitsubishi Gas Chemical Company Inc (Japan), Higashimaru Shoyu Company Ltd (Japan), Tokuyama Corporation (Japan), Lion Corporation (Japan), and Nippon Soda Company Ltd (Japan).

Of the 18 companies that have applied for patents based on resources from Antarctica, most applicants are Japanesebased companies, followed by German ones. The patents examined indicate a recent decrease in patents granted. Thus, between 2002 and 2003, six patents were issued, whereas 10 patents were granted between 1996 and 1997. Prior to this, fewer patents were granted, with one being issued between 1990 and 1991. Most patents filed are process- rather than product-based, with many relating to the yeast *Candida antarctica*.

Examples of process-based patents relate to:

- the preparation of esters in the presence of Candida antarctica lipase A, or a variant thereof. The esters are useful as ingredients in fat blends such as margarine (WOO153511);
- the enzymatic synthesis of polyesters in the presence of a lipase derived from, amongst others, *Candida antarctica*. The polyesters are useful in formulating products such as skin cream and cosmetics as they normally function as thickeners or softeners in such formulations (US5962624);
- the preparation of an optically-active ester using an enzyme originating from *Candida antarctica*. The ester can be used for preparing pharmaceuticals such as benzothiazepines and benzazepines (US5407828);
- the hydrolosis (the chemical breakdown of molecules and addition to them of water molecules) of water-insoluble ester in the presence of a lipase derived from a strain of *Candida antarctica*. The ester hydrolosis can be applied to hydrolosis of resin ester. This is useful as

some types of pulp made from wood have high resin content, and the resin can create disturbances in the process of pulp manufacture and may have negative effects on the properties of the final pulp product (WO9218638);

- the use of a glycoprotein produced by *Pseudoalteromonas antarctica* in the preparation of pharmaceutical, veterinary and cosmetic compositions for topical or mucosal application aimed at the treatment and re-epithelialisation of wounds (WO02102406);
- the use of an extract from the green alga *Prasiola crispa spp. antarctica* for cosmetic skin treatment, care or protection, including as sun protector and after-sun cream (WO0238121).

Product-based patents relate to:

- the development of frozen confectionary products, such as ice cream, comprising one or more antifreeze proteins derived from plants, including from the Antarctic-based Nothofagus antarctica, Deschampsia antarctica and Umbilicaria antarctica. The anti-freeze proteins inhibit ice recrystallization and thus provide a good texture to frozen confectionary product (GB19970014412);
- a glycoprotein obtained by culture of the bacterial species *Pseudoalteromonas antarctica* CECT4664, which is useful for coating liposomes in order to improve their stability in relation to external factors such as surfactants (WO9842731);
- the production of a particular stimulating agent containing the extract of an alga belonging to the genus Durvillea, including *Durvillea antarctica*. The stimulating agent prevents the development of skin wrinkles (JP9176036).

5 International instruments and ongoing activities relevant to deep seabed bioprospecting

There is currently no specific international regime addressing bioprospecting in the deep seabed. However, a number of international instruments are relevant. This section focuses on relevant provisions of, and activities under, UNCLOS, the UN General Assembly, the CBD, as well as instruments addressing IPRs. Other relevant instruments and activities are also briefly considered.

5.1 United Nations Convention on the Law of the Sea

UNCLOS, which was adopted in 1982 and entered into force on 16 November 1994, aims to establish "a legal order for the seas and oceans which will facilitate international communication, and will promote the peaceful uses of the seas and oceans, the equitable and efficient utilization of their resources, the conservation of their living resources, and the study, protection and preservation of the marine environment."

UNCLOS also aims to develop the principles embodied in UN General Assembly Resolution 2749 (XXV) of 17 December 1970. This Resolution declared that the area of the seabed and ocean floor and the subsoil thereof, beyond the limits of national jurisdiction, as well as its resources, are the common heritage of humankind, and that their exploration and exploitation shall be carried out for the benefit of humankind as a whole, irrespective of the geographical location of States.²²⁵

In order to achieve its objectives, UNCLOS sets out the rights and obligations of Parties on the basis of maritime zones, delineated according to distance from the coastline on the basis of set baselines. States have sovereignty over their internal waters, territorial seas and archipelagic waters, and sovereign rights over the resources in their EEZ and continental shelf. Cooperation between States is required to manage the High Seas as well as the seabed and ocean floor and subsoil thereof beyond the limits of States' continental shelves. This is referred to as "the Area" under UNCLOS, ²²⁶ which are areas beyond national jurisdiction. UNCLOS defines the extent of the rights and obligations of States within the various maritime areas.²²⁷

It is worth noting that the specific delineation of the Area is still uncertain as a result of the possibility for States to establish the outer limits of their continental shelf beyond the 200 nautical miles limit, as provided for under Article 76 of UNCLOS. Claims to an extended continental shelf are to be submitted to the Commission on the Limits of the Continental Shelf within 10 years of entry into force of UNCLOS for Parties wishing to make such claims.²²⁸ Because this creates uncertainty regarding the specific boundaries of areas within and beyond national jurisdiction, it is unclear whether activities carried out in some areas of the seabed are to be governed by national law or international regulations.²²⁹

5.1.1. Genetic resources under the UN Convention on the Law of the Sea

UNCLOS does not use the term "genetic resources."

However, considering the object and purpose²³⁰ of UNCLOS as set out in its Preamble and outlined above, it is assumed that such resources, which are living resources, are covered by the provisions of UNCLOS related to living resources. UNCLOS provisions are based on the specific characteristics of the resources and activities known at the time of its negotiation, the language of which may need to be adapted to genetic material and related activities. The theory of the evolutionary interpretation of treaties supports this observation.

Within national jurisdiction, on the basis of Article 77(4), the regime applicable - i.e. that of the EEZ or that of the continental shelf - to genetic resources found on the seabed depends on whether these fall within the definition of sedentary species or not. UNCLOS defines sedentary species as 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.²³¹ It is noteworthy to recall that microorganisms found in hydrothermal vents and cold seeps are considered sedentary or not depending on their biology (see section 2). Most species currently of interest to bioprospectors are those considered as sedentary because these have evolved chemical compounds to deter predators, parasites and competitors, which may be of particular value for pharmaceutical research.232

Thus, following the definition of sedentary species, deep seabed genetic resources found within the 200 nautical miles limit of national jurisdiction and considered as sedentary fall under the regime of the continental shelf pursuant to Article 77(1) and (4) of UNCLOS, while nonsedentary resources are covered by the regime of the EEZ. Non-sedentary species and their genetic resources found on, or above, the continental shelf beyond the 200 nautical mile limit, fall under the regime of the High Seas.

It is noteworthy that, by operation of Article 76(3), the deep ocean floor and its oceanic ridges and the subsoil thereof are excluded from the continental shelf regime. It is assumed that resources associated with these features, whether living or not, are also excluded from the continental shelf regime. While non-living resources associated with these features clearly fall under Part XI of UNCLOS and the regime of the Area (which is described below), it is unclear whether the living resources, more particularly genetic resources, of oceanic ridges and the seabed in general would fall under the regime of the Area or that of the High Seas. So far, discussions related to deep seabed genetic resources have focused on the question of their status, which is deemed either analogous to that of living resources under Part VII of UNCLOS, i.e. openaccess, or common heritage of humankind. While it is beyond the scope of this report to provide an answer to this question, which may only be clarified by the Parties to UNCLOS themselves, the following sections set out the consequences attached to the regime of the High Seas and that of the Area.

5.1.2. Bioprospecting in the High Seas: the regime of living resources under Part VII

In the High Seas, which are all parts of the seas beyond the limits of the EEZ, States enjoy the freedom of the High Seas, which includes navigation, laying of submarine cables and pipelines, construction of artificial islands and other installations, fishing and scientific research.²³³ These freedoms are to be exercised subject to treaty obligations and measures for the conservation of resources, as well as with due regard for the interests of other States in their exercise of the freedom of the High Seas, and with due regard for their rights with respect to activities in the Area. The freedoms enumerated under Article 87 are not exhaustive and could presumably include activities such as collection and sampling of genetic resources and organisms. Under the regime of the High Seas, hydrothermal vent species would therefore be openly available for all to access and sample, subject to measures for the conservation of living resources and the protection of the marine environment.

Activities carried out on the High Seas, which would include bioprospecting, are subject to flag State jurisdiction, i.e. the laws and regulations of the State under whose flag the vessel is operating. Clearly establishing the "genuine link" between vessels and States is essential in this respect. In adopting regulation for activities carried out on the High Seas, flag States are bound by the provisions of a number of international agreements, including those on ship safety and pollution control. Moreover, under UNCLOS, complemented by a number of global and regional agreements, States are to cooperate in the conservation and management of High Seas living resources, including through determining allowable catches.²³⁴ While determining allowable catches may be inappropriate with regard to genetic material, setting sample quotas may be an option. Establishing High Seas MPAs on the basis of Article 119 on the conservation of High Seas living resources has been proposed as a possible conservation measure.²³⁵While MPAs were identified as one of the tools for the conservation of biodiversity beyond national jurisdiction by the Conference of the Parties to the CBD in Decision VII/5, and by the General Assembly in Resolution 59/24, their establishment is still discussed among States. MPAs in the High Seas could encompass varied levels of protection and regulation, and may involve regulating activities taking place therein, including through setting conditions for access and/or regulation of methods for undertaking samplings. However, unless States cooperate or harmonize their conservation measures, the approach will remain fragmented and may entail very different levels of regulation.

5.1.3. Bioprospecting in the Area: Part XI and the role of the International Seabed Authority

The Area is subject to a special regime set out under Part XI of UNCLOS, as modified by the 1994 Agreement on the Implementation of Part XI of UNCLOS. 236

The Area and its resources are the common heritage of humankind, the exploration and exploitation of which shall be carried out for the benefit of humankind as a whole, irrespective of the geographical location of States.²³⁷ States cannot claim or exercise sovereignty over the Area nor its

resources, nor appropriate any part of the Area. No State or natural or juridical person may claim, acquire or exercise rights with respect to the minerals recovered from the Area except in accordance with the provisions of UNCLOS.²³⁸

The regime of the Area only applies to "activities of exploration for, and exploitation of, the resources of the Area," which are defined as "solid, liquid or gaseous mineral resources *in situ* in the Area²³⁹ at or beneath the seabed, including polymetallic nodules."²⁴⁰ It is noteworthy that because biological and mineral resources are intrinsically linked in deep-sea ecosystems, sampling of biological resources may occur in the course of expeditions aimed at exploring the Area for mineral deposits. While there is no specific measure addressing exploration for, and exploitation of, biological resources in the Area under Part XI, several features of the regime set forth under Part XI may be extended to, or be the basis for developing a specific regime related to bioprospecting in the Area.

Activities in the Area are organized and controlled by the ISA.²⁴¹ The Authority is composed of a decision-making Assembly, the Executive Council, a Secretariat, and the Enterprise, which is the organ charged with carrying out activities in the Area as well as transporting, processing and marketing minerals recovered from the Area.²⁴² The Authority's responsibilities include:

- organizing, carrying out and controlling exploration and exploitation activities in the Area;²⁴³
- providing for the equitable sharing of financial and other economic benefits derived from activities in the Area;²⁴⁴
- carrying out and promoting MSR in the Area, as well as coordinating and disseminating the results of such research and analysis when available;²⁴⁵
- taking measures to acquire technology and scientific knowledge relating to activities in the Area as well as promoting transfer of such technology and scientific knowledge;²⁴⁶
- adopting measures for the protection of the marine environment against the harmful effects of activities carried out in the Area, including for the protection and conservation of the natural resources of the Area and the prevention of damage to marine flora and fauna;²⁴⁷ and
- establishing a system of inspection of activities undertaken in the Area to ensure compliance with UNCLOS and ISA rules and regulations.²⁴⁸

Part XI requires prospective miners to submit a plan of work for approval to the Council,²⁴⁹ which shall indicate two sites proposed for exploration²⁵⁰ and/or exploitation, and be accompanied by an assessment of the potential environmental impacts of the proposed activities.²⁵¹ Upon approval of the work plan, the Authority's Enterprise has the right to decide which of the two sites it wishes to mine.²⁵² This so-called 'parallel system,' which ensures a reserved area for the Enterprise, is designed at ensuring an equitable sharing of the Area's mineral resources.

ISA's role regarding biodiversity in the Area was on the agenda of the Legal and Technical Commission at the

ISA's ninth (28 July – 8 August 2003) and tenth (24 May - 4 June 2004) sessions.²⁵³ Members of the Legal and Technical Commission (LTC) emphasized the need to work within the ISA's mandate under UNCLOS and the 1994 Part XI Agreement. A seminar was proposed to consider seabed and deep ocean biodiversity to enable drawing up regulations for the protection and preservation of the marine environment during prospecting and exploration for mineral resources.²⁵⁴ At the ISA's tenth session in 2004, the LTC considered a study on the legal implications of the management of seabed living resources in the international seabed area within the framework of UNCLOS. The study stressed the need for the ISA to cooperate with other competent bodies to establish a regime for the management and protection of the living resources of the Area, within the law of the sea framework. Some members recommended addressing the legal gap existing in the current regime with regard to bioprospecting. ISA's Secretary-General stressed the need to encourage scientists to enter into good practices regarding their research in deep-sea areas.²⁵⁵

Outside the context of the ISA itself, it has been proposed to expand ISA's mandate to include activities related to genetic resources of the Area.²⁵⁶ While this would require amending UNCLOS and entail a time-consuming and complex process, the advantage of such an option would be to build on an existing institutional framework and regulations addressing benefit-sharing, sustainable use as well as conservation needs.

To fulfill its mandate regarding the protection of the deep seabed marine environment, ISA has adopted regulations and undertaken cooperative scientific projects, which address the harmful effects of mining activities on the Area's biodiversity.²⁵⁷ In September 2004, a workshop was held on the establishment of environmental baselines at deep seafloor cobalt-rich crusts and deep seabed polymetallic sulphide mine sites in the Area. The workshop aimed to evaluate the likely effects of exploration and exploitation of these resources on the marine environment.²⁵⁸

5.1.4. The Regulations of the International Seabed Authority

The regulations developed by the ISA to address the impact of mining on the Area's marine environment could be used as a model to develop regulations addressing the impacts of bioprospecting activities in the Area.

At its sixth session in 2000, the ISA adopted Regulations on Prospecting and Exploration for Polymetallic Nodules in the Area.²⁵⁹ The Regulations state that they "shall not in any way affect the freedom of scientific research (...) or the right to conduct marine scientific research in the Area" or the exercise by States of the freedom of the High Seas.²⁶⁰

Under Regulation 2, prospecting is not to be undertaken if substantial evidence indicates a risk of serious harm to the marine environment.²⁶¹ Regulation 2 also states that prospecting does not confer rights on the prospector with respect to resources, but that the prospector may "recover a reasonable quantity of minerals, being the quantity necessary for testing and not for commercial use."²⁶²

In contrast, entering into contracts to explore for polymetallic nodules confers the exclusive right to explore an area specified in a plan of work for a period of 15 years.²⁶³ This right is balanced by the contractor's responsibility regarding damage arising out of wrongful acts in the conduct of its operations, in particular damage to the marine environment.²⁶⁴

Each contractor is required to, inter alia, take necessary measures to prevent, reduce and control pollution and other hazards to the marine environment arising from his activities in the Area, as well as monitor the likely effects of these activities.²⁶⁵ Regulation 31(2) requires applying a precautionary approach. Of particular interest is the requirement for a contractor applying for exploitation rights to set aside "impact reference zones" and "preservation reference zones." Impact reference zones are areas to be used for assessing the effect of each contractor's activities on the Area's marine environment and which are representative of the environmental characteristics of the Area. Preservation reference zones are "areas in which no mining shall occur to ensure representative and stable biota of the seabed in order to assess any changes in the flora and fauna of the marine environment."266

Confidentiality of data and information gathered in the course of commercially-oriented activities is also to be considered. In this respect, with the exception of a few cases, data and information obtained from prospection, exploration or exploitation, designated by the contractor in consultation with the ISA's Secretary-General as confidential, shall be treated as such. Whether such data and information should remain confidential is reviewed periodically, and requires establishing that there would be a substantial risk of serious and unfair economic prejudice resulting from their release.²⁶⁷

It is noteworthy that under Regulation 40, if a prospector or contractor finds resources in the Area other than polymetallic nodules, the prospecting and exploration for, and exploitation of, such resources shall be subject to the rules, regulations and procedures of the ISA relating to such resources in accordance with UNCLOS and the 1994 Agreement. Such rules would only apply to mineral resources, leaving open the question of biological material collected during activities aimed at exploring and exploiting polymetallic nodules.

At the ISA's tenth session in 2004, the LTC developed "Draft regulations on prospecting and exploration for polymetallic sulphides and cobalt-rich ferromanganese crusts in the Area."²⁶⁸ The Council will review these draft regulations at the ISA's eleventh session in 2005. The draft is modeled on the basis of the Regulations for Polymetallic Nodules, and adopts essentially the same rules and principles, with some additions.

Of particular relevance are additional provisions relating to addressing threats to, and harmful effects on, the marine environment. Under Regulation 5, each prospector shall take necessary measures to prevent, reduce and control pollution and other hazards to the marine environment arising from prospecting. Cooperation with the Authority is also required to establish and implement monitoring and evaluation programmes regarding the potential impacts of exploration and exploitation activities. Regulation 7 states that data and information relating exclusively to environmental monitoring programmes shall not be considered confidential.

Moreover, applicants for exploration shall either: contribute a reserved area; offer an equity interest to the Enterprise, enter into a joint-venture arrangement with the Enterprise; or enter into a production-sharing contract with the Enterprise.²⁶⁹ These provisions aim to ensure sharing of benefits arising out of the utilization of the Area's resources.

Regarding confidentiality, under Regulation 38(2), data and information necessary for the formulation by the ISA of rules, regulations and procedures concerning protection of the marine environment and safety, other than equipment design data, shall not be deemed proprietary.

Thus ISA's Regulations integrate various concerns with respect to exploration of the Area's resources that address some of the aspects embedded in the concept of common heritage of humankind principle, including conservation, sustainable use, and sharing of benefits in the form of non-monetary benefits, such as public availability and dissemination of data.

5.1.5. Part XIII: Marine scientific research

As shown in section 3.1.2 of this report, there is a fine line between marine scientific research and bioprospecting. It is therefore necessary to consider the provisions of Part XIII of UNCLOS related to MSR. It should be noted, at the outset, that UNCLOS provisions regarding MSR are not confined to mineral resources.

Article 241 states that MSR activities shall not constitute the legal basis for any claim to any part of the marine environment or its resources. In theory, MSR is therefore different from other investigative marine activities including a commercial component, such as prospecting and exploration, which may entail confidentiality or proprietary rights. Under UNCLOS, MSR is primarily aimed at furthering humankind's knowledge of the marine environment, its resources and various phenomena, and shall not be used to search for natural resources for commercial purposes.²⁷⁰ As noted in section 3.1.2. of this report, with regard to coastal States' right to withhold consent to MSR, a distinction is made between research carried out for "peaceful purposes and in order to increase scientific knowledge of the marine environment for the benefit of all humankind" and research "having a direct significance for the exploration and exploitation of natural resources." While UNCLOS does not explicitly elaborate on the distinction, nor use it in any other context than that of coastal States' rights, one could assume that the latter refers to prospecting and that the difference of regime lies in the treatment of research results, as well as authorization procedures to carry out these activities.

Under Article 238, all States and competent international organizations have the right to conduct MSR, including in the Area and the High Seas²⁷¹ subject to the rights and duties of other States. MSR is to be conducted for peaceful purposes exclusively, shall not interfere unjustifiably with other legitimate uses of the sea, and shall be conducted in compliance with all relevant regulations, including those for the protection and preservation of the marine environment.²⁷² The latter provisions are particularly important considering the threats that marine scientific research pose to marine fauna and flora.

Within their territorial sea, their EEZ and continental shelf, coastal States have the right to regulate, authorize and conduct MSR.²⁷³ MSR undertaken under the consent regime set out in Article 246, must comply with certain conditions, including: the provision of information on the nature and objectives of the project; the right for the coastal State to participate in the project and have access to all data and samples derived from the project as well as to assessment and interpretation of such data and results; and making available internationally the research results.²⁷⁴

MSR activities within the Area are to be carried out for the benefit of humankind as a whole.²⁷⁵ The ISA has the mandate to promote and encourage the conduct of MSR in the Area and to coordinate and disseminate the results of such research and analysis. It may also engage in MSR itself.²⁷⁶ When conducting MSR in the Area, States are required to, *inter alia*, promote international cooperation, develop programmes for the benefit of developing States and technologically less-developed States to strengthen their research capabilities among others, and to effectively disseminate the results of their research and analysis.²⁷⁷ The sharing of the results of MSR undertaken in the Area is therefore ensured in the form of non-monetary benefits.

Because MSR is to benefit humankind as a whole, Part XIII contains elaborate rules regarding publication and dissemination of information and knowledge gathered from MSR. Such provisions are particularly important with regard to deep sea organisms, considering their potential applications and the difficulties in accessing them. However, such publication and dissemination of data may not be appropriate when the information is acquired in the course of commercially-oriented activities such as bioprospecting.

The publication and dissemination of information and knowledge gathered from MSR is addressed under Article 244, which states that information on proposed programmes, their objectives and resulting knowledge are to be made available. States and competent international organizations are required to promote data and information flow and the transfer of knowledge actively, in particular to developing States. Under Article 242, States shall provide other States, as appropriate, "with a reasonable opportunity to obtain from [them], or with [their] co-operation, information necessary to prevent and control damage to (...) the marine environment." Finally, Article 250 notes that communications on MSR projects are to be made through appropriate official channels, unless otherwise agreed.

Considering the non-commercial purpose of MSR

under UNCLOS and the very fine line between activities undertaken in the deep seabed, one could assume that if the results of MSR be used at any stage for commercial gains, the regime for MSR would cease to apply. In such a case, the research would then be deemed to have been a commercially-oriented activity.²⁷⁸ It can also be assumed that if the results of marine scientific research are not made available as per Article 244, the activity does not qualify as MSR, and should be subject to another regime. Considering the consequences in terms of dissemination of information among others, it is therefore crucial to identify suitable definitions for MSR and bioprospecting, and determine the relationship between them. Moreover, it has been suggested that intellectual property claims over resources collected in the course of MSR may run counter to UNCLOS Article 241, in that they would constitute a "claim to any part of the marine environment or its resources."279 Another issue to consider is whether, and if so how, the patenting process affects the public availability of the results of MSR.

5.1.6. Part XIV: Development and transfer of marine technology

The provisions of UNCLOS addressing development and transfer of marine technology under Part XIV are of particular relevance to deep seabed activities, which require sophisticated and expensive technological equipment and skills. These provisions, which act as a means for benefitsharing, are all the more relevant in a context where resources of such an extreme and still largely inaccessible environment are exploited for economic benefits.

Under Article 266, States shall cooperate in accordance with their capabilities to actively promote the development and transfer of marine science and marine technology on fair and reasonable terms and conditions. They are to "promote the development of marine scientific and technological capacity of States which may need and request technical assistance in this field, particularly developing States (...) with regard to the exploration, exploitation, conservation and management of marine resources, the protection and preservation of the marine environment, marine scientific research and other activities in the marine environment." States are to foster favorable economic and legal conditions for technology transfer on an equitable basis. Notwithstanding these provisions, Article 267 binds States to have due regard to all legitimate interests, including the rights and duties of holders, suppliers and recipients of marine technology. It is conceivable that the protection of confidential data regarding such technology may fall under legitimate interests and rights of holder and suppliers of the technology.

In order to achieve the objectives of Part XIV, a number of measures are outlined, including the establishment of programmes of technical cooperation for the effective transfer of marine technology, promotion of the exchange of scientists and technological and other experts, and promotion of favorable conditions for concluding agreements and contracts under equitable and reasonable conditions.²⁸⁰

With regard to activities undertaken in the Area, and in

line with the principle of common heritage of humankind, the transfer of skills and marine technology to developing States, their nationals and the Enterprise shall be facilitated.²⁸¹ Article 274, which outlines the responsibilities of the ISA in this regard, provides that the ISA shall ensure, among others, that: technical documentation is made available to all States, in particular developing States; and adequate provision is made to facilitate technical assistance and the acquisition of necessary equipment and technical know-how in the field of marine technology for States which may need and request it, in particular developing States.

Under the 1994 Part XI Agreement, seabed mining technology shall be acquired on "fair and reasonable commercial terms and conditions, on the open market or through joint-venture arrangements" and "consistent with the effective protection of intellectual property rights." States are also required to promote international technical and scientific cooperation with regard to activities in the Area.²⁸²

Similar provisions for the transfer of technologies are to be found in the CBD as outlined in section 5.3 of this report.

5.1.7. Part XII: Protection and preservation of the marine environment

Part XII of UNCLOS sets out general obligations on the protection and preservation of the marine environment. These may have consequences on the ability to undertake bioprospecting activities in the deep seabed.

Under Article 192, States have the general obligation to protect and preserve the marine environment. Article 194 elaborates on this general obligation by requiring States to, *inter alia*, take measures to ensure that activities under their jurisdiction or control are conducted in such a way as not to cause damage by pollution to other States and their environment. UNCLOS defines pollution of the marine environment as "the introduction by man, directly or indirectly, of substances or energy into the marine environment, including estuaries, which results or is likely to result in such deleterious effects as harm to living resources and marine life, hazards to human health, hindrance to marine activities, including fishing and other legitimate uses of the sea, impairment of quality for use of sea water and reduction of amenities."²⁸³

Measures include those designed to minimize pollution from installations and devices used in exploration or exploitation of the natural resources of the seabed and subsoil.²⁸⁴ These measures include those necessary to protect and preserve rare or fragile ecosystems as well as the habitat of depleted, threatened or endangered species and other forms of marine life. These measures shall not interfere unjustifiably with activities carried out by other States in the exercise of their rights and pursuance of their duties under UNCLOS.²⁸⁵

With regard to seabed activities, Article 208 requires coastal States to adopt laws and regulations to prevent, reduce and control pollution of the marine environment arising from,
or in connection with, seabed activities subject to their jurisdiction, as well as establish global and regional rules, standards and recommended practices and procedures through competent international organizations. This could provide a basis for adopting common/international regulations aimed at harmonizing rules related to bioprospecting activities taking place in the seabed under national jurisdiction, when these activities are thought, or proven to create pollution.

Article 209 specifically addresses pollution from activities in the Area. Pursuant to the definition of "activities in the Area," measures adopted under Article 209 would only relate to activities for exploration for, and exploitation of, the resources of the Area, i.e. non-living resources. Regulating bioprospecting on this basis is therefore excluded.

5.2 The UN General Assembly and the UN Informal Consultative Process on Oceans and the Law of the Sea

5.2.1. UN General Assembly resolutions and reports of the Secretary-General

The regime embedded in UNCLOS governing activities in the Area stems from UN General Assembly Resolution 2749 (XXV) of 17 December 1970. Recognizing that the regime governing the High Seas did not provide substantive rules for the exploration and exploitation of the resources of the seabed and ocean floor and the subsoil thereof beyond national jurisdiction,²⁸⁶ Resolution 2749 required the establishment of an international regime applying to the area "to, inter alia, provide for the orderly and safe development and rational management of the area and its resources and for expanding opportunities in the use thereof, and ensure the equitable sharing by states in the benefits derived therefrom, taking into particular consideration the interests and needs of developing countries."287 The Resolution sets out the consequences attached to the concept of common heritage of humankind, now embedded in Part XI of UNCLOS.

It is noteworthy that following the adoption of Resolution 2749, the UN General Assembly adopted Resolution 2750 (XXV) addressing the reservation exclusively for peaceful purposes of the Area and use of its resources in the interests of humankind. It requested the Secretary-General to cooperate with the UN Conference on Environment and Development and other competent organizations of the UN system to identify issues related to the production of certain minerals from the Area and examine the impacts on the economic well-being of developing countries.²⁸⁸ This shows that addressing the issue of exploitation of non-living resources of the Area was proving delicate in a context of limited relevant information, as is now the case regarding the exploitation of the Area's living resources. A similar study could be undertaken within the UN system to assess various aspects of bioprospecting, including its ethical, economic, scientific and environmental aspects. The present report could be used as a contribution to such a study.

In spite of the UN Secretary-General's repeated expressions of concern regarding the issue of exploitation of deep seabed genetic resources,²⁸⁹ the UN General Assembly did not adopt any resolution of relevance to the issue until 2002, when it requested the UN Informal Consultative Process on the Law of the Sea (UNICPOLOS or ICP) to address the protection of vulnerable marine ecosystems at its fourth meeting.²⁹⁰ Relevant measures recommended by the UN General Assembly after this date will be considered in conjunction with the ICP's recommendations, below.

In his annual report to the 57th session of the UN General Assembly in 2002, the UN Secretary-General noted the need to clarify aspects of the regime for MSR, including the lack of distinction between pure and applied research, and how to address newly discovered marine genetic resources. Possible conflicting uses of the deep seabed were also highlighted between pure MSR, mineral prospecting, and bioprospecting as well as with the conservation and management of the deep ocean environment.²⁹¹

The issue of conflicting uses was underscored again in the UN Secretary-General's annual report to the 58th session of the UN General Assembly in 2003.²⁹² Marine scientific research was identified as a specific threat to hydrothermal vents,²⁹³ and the need to address the legal lacuna with respect to commercially-oriented activities relating to marine genetic resources in the Area was noted.²⁹⁴

In his report to the 59th session of the UN General Assembly in 2004, the Secretary-General noted that "although the conservation and management of the biodiversity of the seabed beyond national jurisdiction is not directly addressed in UNCLOS (...) [t]he provisions for the protection of the marine environment, for the conservation of marine living resources and other forms of marine life, as well as for the protection of rare and fragile ecosystems provide a basis for the conservation and sustainable use of the biodiversity of the deep seabed. Other relevant provisions include the rules for the exploration and exploitation of mineral resources on the seabed beyond the limits of national jurisdiction, including those elaborated by the International Seabed Authority, and for marine scientific research."295 The report also noted that because the biological resources of the deep seabed are intermingled with its mineral resources, their conservation and management is inevitably related to the regulation of deep seabed mining. It was further noted that no specific legally binding regulations have been adopted regarding the protection of seabed biodiversity from marine scientific research.296

With regard to bioprospecting in particular, the report recognized the link between marine scientific research activities, especially those related to biological and geological sampling, and onshore commercial activities. The importance of distinguishing between pure academic research and research carried out for commercial purposes, which may involve confidentiality or proprietary rights, was reiterated. Because of its exploitative purpose and profitmaking goals, it was suggested that bioprospecting may be compared to prospecting for mineral resources, which is an investigative activity undertaken for the discovery and estimation of the economic value of a resource, prior to its future commercial exploitation.²⁹⁷ The report recommended clarifying the legal lacuna regarding commercially-oriented activities targeting the Area's biodiversity.²⁹⁸

5.2.2. Further activities of the General Assembly, including the UN Informal Consultative Process on the Law of the Sea

With Resolution 54/33 of 24 November 1999, the UN General Assembly established an open-ended informal consultative process to undertake annual reviews of developments in oceans affairs. It was decided that the Consultative Process would consider the Secretary-General's annual reports on oceans and the law of the sea, and suggest particular issues for consideration by the General Assembly, with an emphasis on identifying areas where intergovernmental and inter-agency coordination and cooperation should be enhanced.²⁹⁹ To date, the ICP has held five meetings.

At its third meeting in 2002, the ICP proposed that the General Assembly invite various organizations, including the Food and Agriculture Organization (FAO), the Intergovernmental Oceanographic Commission (IOC), the ISA, the Secretariat of the CBD, UNDOALOS and the United Nations Environment Programme (UNEP), to consider urgently how to integrate and improve, on a scientific basis, the management of risks to the fauna and flora of seamounts and certain other underwater features under threat within the framework of UNCLOS.³⁰⁰

The ICP recommended that the General Assembly reiterate the importance of the ongoing elaboration by the ISA of recommendations to ensure the effective protection of the marine environment from harmful effects that may arise from activities in the Area. It was further proposed that the General Assembly invite various organizations, including those mentioned above, to consider what action, consistent with UNCLOS, should be suggested to address priority problems in the marine environment, in particular any that may be highlighted by future global marine assessments.³⁰¹

The ICP also identified some issues that could benefit from future work by the General Assembly that are of relevance to deep seabed bioprospecting, including: marine protected areas; potential and new uses of the oceans; development and transfer of marine technology; impact of activities in the international seabed area as a source of contamination of the marine environment; competing uses of the continental shelf; and the protection of biodiversity of the seabed.³⁰² The UN General Assembly adopted these recommendations in Resolution 57/141, and requested the ICP to consider the protection of vulnerable marine ecosystems as one of its areas of focus at its next meeting.³⁰³

At its fourth meeting in June 2003, the ICP discussed the protection of vulnerable marine ecosystems, including seamounts, hydrothermal vents, deep-sea trenches, deep-sea coral reefs, cold seeps and pockmarks. During the debate, seabed activities, including exploration and exploitation of non-living resources, marine scientific research and bioprospecting, were identified as having potential adverse impacts on those ecosystems.³⁰⁴ Among the tools proposed to protect those ecosystems, delegations noted, *inter alia*, marine protected areas, the ecosystem approach and the precautionary principle.³⁰⁵

The ICP proposed that the General Assembly reiterate its call for urgent consideration of ways to integrate and improve, on a scientific basis, the management of risks to marine biodiversity of seamounts, cold water coral reefs and certain other underwater features, and note relevant scientific and technical work under the CBD. It was also proposed to invite relevant international bodies at all levels to: consider urgently how to better address, on a scientific and precautionary basis, the threats and risks to vulnerable and threatened marine ecosystems and biodiversity beyond national jurisdiction; examine how existing treaties and other relevant instruments can be used in this process, consistent with UNCLOS in particular; and explore a range of potential approaches and tools for protection and management.³⁰⁶

The ICP further proposed that the General Assembly reaffirm the efforts of States to develop and facilitate the use of diverse approaches and tools for conserving and managing vulnerable marine ecosystems, including the establishment of marine protected areas, consistent with international law and based on the best scientific information available, and the development of representative networks of such MPAs by 2012.³⁰⁷

The 58th session of the UN General Assembly adopted these recommendations,³⁰⁸ further requesting the Secretary-General to submit an addendum to his annual report to the fifty-ninth session of the General Assembly, describing the threats and risks to vulnerable marine ecosystems and biodiversity in areas beyond national jurisdiction as well as details on any conservation and management measures in place at the global, regional, subregional or national levels regarding these issues. It also recommended that the fifth meeting of the ICP discuss new sustainable uses of the oceans, including the conservation and management of the biodiversity of the seabed in areas beyond national jurisdiction.³⁰⁹

At its fifth meeting in June 2004, the ICP heard a presentation on the types of uses of deep seabed biological resources and bioprospecting undertaken in the deep seabed. In the ensuing discussions, delegates expressed conflicting views regarding the legal status and the regime for bioprospecting in the deep seabed beyond national jurisdiction.³¹⁰

Delegates in favor of policies regulating bioprospecting in the Area, argued that, on the basis of the symbiotic relationship of deep seabed biodiversity with its environment, all deep seabed resources beyond national jurisdiction, including biological resources, are the common heritage of humankind and should be dealt with under the regime established for the Area under Part XI of UNCLOS. Complementarities were noted between UNCLOS and the CBD regarding the fair and equitable distribution of benefits arising from utilizing the resources. Some delegations said commercially-oriented activities regarding biodiversity in the Area should be subject to these legal frameworks, and access to the biodiversity and genetic resources of the Area should be subject to the regime of MSR. It was noted that the results of such research should be subject to benefit-sharing on a non-discriminatory basis. The role of IPRs was also noted, with some delegations expressing concerns over the fact that improper use of IPRs may deprive countries that do not possess yet the necessary technology of the benefits derived from deep seabed bioprospecting.

Delegates who expressed reservations about policies addressing bioprospecting pointed out that UNCLOS only contains general principles for the conduct of MSR and does not provide for restrictions to the freedom to conduct MSR and undertake bioprospecting activities on the High Seas. They noted that UNCLOS excludes marine living resources from the regime of the Area and the common heritage of humankind principle. Some delegations were opposed to regulating MSR on the High Seas, and pointed out that UNCLOS did not provide a definition of MSR nor did it mention bioprospecting. It was also noted that the distinction between pure and applied MSR had never been accepted universally, since there was no perceivable difference in activities or methods.

Some delegations expressed the view that there is a legal lacuna in respect of deep seabed biodiversity. Delegates discussed the appropriate forum to address deep seabed bioprospecting, including the ICP and the ISA. Other delegations recommended undertaking further work, particularly on the nature of the resources and their potential use, before considering any legal regime.³¹¹

There was agreement that bioprospecting should be further discussed at the ICP's sixth meeting. It was recommended that the General Assembly welcome Decision VII/5 of the seventh meeting of the Conference of the Parties (COP) to the CBD on the use of deep seabed genetic resources, as well as Decision VII/28, which requires exploring options for cooperation to promote the establishment of MPAs beyond national jurisdiction, consistent with international law, including UNCLOS, and based on scientific information.312 The meeting further proposed that the General Assembly encourage the ISA's work regarding the regulations for prospecting and exploration for polymetallic sulphides and cobalt-rich crusts in the Area and procedures to ensure the effective protection of the Area's marine environment and natural resources. It was also suggested to encourage States to improve their understanding and knowledge of the deep sea in areas beyond national jurisdiction by increasing their MSR activities in accordance with UNCLOS.³¹³ The ICP also identified genetic resources as an issue that may benefit from further work by the General Assembly.314

During the debate on oceans and the law of the sea of the 59th session of the General Assembly, some States stressed that bioprospecting required regulation in such a way as to ensure the sustainable use of biological resources, including the equitable sharing of benefits with humankind as a whole. One delegation expressed concerns regarding the debate over whether all resources found in the seabed were for the benefit of humankind or whether they fell outside the provisions of UNCLOS, noting that there was no need to draw any such distinction.³¹⁵ The role of UN-Oceans, a new inter-agency mechanism for coordination and cooperation on issues relating to oceans and coastal issues, regarding marine biodiversity beyond national jurisdiction was also recognized.³¹⁶

The General Assembly adopted most of the recommendations from ICP-5, and further reaffirmed the need for States and competent international organizations to urgently consider ways to integrate and improve, on a scientific basis and in accordance with UNCLOS and related agreements and instruments, the management of risks to the marine biodiversity of seamounts, cold water corals, hydrothermal vents and certain other underwater features. States and international organizations were called upon to urgently take action to address, in accordance with international law, destructive practices that have adverse impacts on marine biodiversity and ecosystems, including seamounts, hydrothermal vents and cold water corals. The General Assembly also reaffirmed the need for States to continue their efforts to develop and facilitate the use of diverse approaches and tools for conserving and managing vulnerable marine ecosystems, including the possible establishment of MPAs and networks of such areas, consistent with international law and based on the best scientific information available, as well as the development of representative networks of any such areas by 2012.317

Significantly, the General Assembly decided to establish an *Ad hoc* Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biodiversity beyond areas of national jurisdiction, through: surveying relevant past and present activities of the UN and other relevant international organizations; examining the scientific, technical, economic, legal, environmental, socioeconomic and other aspects of these issues; identifying key issues and questions where more detailed background studies are needed; and indicating possible options and approaches to promote international cooperation and coordination. The Working Group is expected to convene in 2006, following the release of the Secretary-General's report to the 6oth session of the General Assembly, which should address these issues.³¹⁸

Additionally, the General Assembly recognized the urgent need to initiate a start-up phase, the "Assessment of Assessments," as a preparatory stage towards the establishment of a regular process for global reporting and assessment of the state of the marine environment, including socioeconomic aspects, as called for under the Johannesburg Plan of Implementation, and General Assembly Resolutions 57/141 and 58/240.³¹⁹ Presumably, this assessment would include an assessment of the state of deep seabed biodiversity.

These activities are likely to help assess the impacts of bioprospecting in the deep seabed and understand the extent to which an international legal framework is required. As has been evidenced by discussions on the topic within the ICP, agreement on need and modalities of a regulatory framework is far from being reached.

5.3 The Convention on Biological Diversity

The CBD was adopted in June 1992, and entered into force on 29 December 1993. The CBD aims at the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and transfer of relevant technologies.³²⁰ It adopts a holistic, ecosystembased approach to the conservation and sustainable use of biological diversity, and recognizes States' sovereignty over their natural resources.321 Measures for the conservation and sustainable use of biodiversity are contained in Articles 6 to 14, which address respectively: general measures for conservation and sustainable use; identification and monitoring; *in situ* conservation; *ex situ* conservation; sustainable use of components of biological diversity; incentive measures; research and training; public education and awareness; and impact assessment. Access to genetic resources and benefit-sharing are addressed in Articles 15 to 21, which deal respectively with: access to genetic resources; access to and transfer of technology; exchange of information; technical and scientific co-operation; handling of biotechnology and distribution of benefits; financial resources; and the financial mechanism.

The CBD is a framework instrument setting out goals, key objectives and general principles which are to be implemented through national-level measures on the basis, *inter alia*, of guidance provided by the COP. It is noteworthy that, although the CBD addresses the use of genetic resources, the term bioprospecting is neither used nor defined in the CBD or any COP decision.³²²

5.3.1. Deep seabed genetic resources under the Convention on Biological Diversity

Under Article 4, the jurisdictional scope of the CBD is limited to components of biodiversity found in areas within the limits of national jurisdiction. Per se, deep seabed genetic resources beyond national jurisdiction are therefore excluded from the CBD's scope. However, the CBD applies to processes and activities, regardless of where their effects occur, carried out under the jurisdiction or control of States within or beyond areas subject to national jurisdiction.³²³ It follows that activities undertaken in the High Seas or the Area, including navigation, scientific research, bioprospecting, exploration, exploitation, dumping and tourism, fall within the scope of the CBD if they are carried out under the control or jurisdiction of a CBD Party. In these areas, flag State Parties are required to cooperate directly, or through competent international organizations for the conservation and sustainable use of biodiversity. It is assumed that these processes and activities should only be regulated to the extent that they have, or are likely to have, a significant adverse impact on the conservation and sustainable use of biodiversity.³²⁴ This raises the question of the level of impact required for it to be considered as significant, a level that is all the more difficult to establish with regard to deep seabed environments, for which gaps in knowledge still need to be filled.

To date, some States have adopted regulations related to marine scientific research carried out within waters subject to their jurisdiction, but no measures specifically addressing bioprospecting undertaken by their nationals outside the limits of national jurisdiction have been adopted.

Under Article 22, the CBD does not affect the rights and obligations of Parties deriving from existing international agreements, except where the exercise of those rights and obligations would cause a serious damage or threat to biodiversity. More specifically, with respect to the marine environment, Parties are required to implement the CBD consistently with the rights and obligations of States under the law of the sea.³²⁵

Since the exploitation of deep seabed genetic resources implies a succession of value-adding activities, from exploration through laboratory analysis to the eventual commercialization, several articles of the CBD could provide a basis for States to regulate bioprospecting activities related to deep seabed genetic resources, including Articles:

- 8(d) on the protection of ecosystems and species in situ;
- 9(d) on the regulation and management of collection of resources;
- 7(c) on the identification and monitoring of processes and activities which have or are likely to have a significant adverse impact;
- 8(I) on the management and regulation of processes and activities having a significant adverse impact; and
- 14(a) and (c) on environmental impacts assessments and exchange of information regarding activities having a significant adverse impact.

These provisions provide a basis for measures such as technical standards for equipment, maximum amounts of material that can be collected, planning expeditions, monitoring of activities and processes impacting on deep seabed ecosystems, and the conduct of environmental impact assessments.

Articles 10(b) (regulation of uses to minimize impacts) and 8(i) (compatibility between present uses and conservation and sustainable use) can help ensure that uses that are made of genetic resources, following *in situ* collection, are sustainable, including through incentives such as the granting of exclusive rights over the resources.³²⁶

Following discussions at the first meeting of the Subsidiary Body on Scientific Technical and Technological Advice (SBSTTA),³²⁷ the COP adopted Decision II/10, which contains the so-called Jakarta Mandate on Marine and Coastal Biological Diversity providing a basis for a programme of work to implement the CBD in respect of marine and coastal biodiversity.³²⁸ The COP also requested the Secretariat of the CBD,

"in consultation with the UN Office for Oceans Affairs and the Law of the Sea, to undertake a study of the relationship between the CBD and the UN Convention on the Law of the Sea with regard to the conservation and sustainable use of genetic resources on the deep seabed, with a view to enabling the SBSTTA to address at future meetings, as appropriate, the scientific, technical and technological issues relating to bioprospecting of genetic resources on the deep seabed."³²⁹

It is worth noting that the programme of work on marine and coastal biodiversity, as adopted by the fourth meeting of the COP, included among its operational objectives the provision of information on marine and coastal genetic resources, including bioprospecting.³³⁰

The study, called for in Decision II/10, was presented at the 8th meeting of the SBSTTA in March 2003. It outlined relevant provisions of the CBD and UNCLOS, and concluded that "neither the United Nations Convention on the Law of the Sea nor the Convention on Biological Diversity provides a specific legal regime for commercially-oriented activities relating to marine genetic resources on the High Seas and in the Area," and stressed the need to develop a legal regime to regulate them.³³¹ A similarity between the objectives pursued by the international community both under UNCLOS and the CBD was noted, since both instruments aim at the conservation of marine biodiversity and attempt to ensure a sustainable use of its components. The study stressed that while the CBD further aims at a fair and equitable sharing of the benefits arising out of the use of genetic resources, UNCLOS aims at an equitable sharing of benefits arising out of mineral resources from the Area.332 The following options to address bioprospecting for deep seabed genetic resources were weighed: maintaining the status quo and leaving the exploitation of deep seabed genetic resources unregulated; applying the regime of the Area and its resources to deep seabed genetic resources, which would entail the application of the common heritage of humankind principle to deep seabed genetic resources as well as their management by an international body for the benefit of all; and amending the CBD to bring deep seabed genetic resources within its framework. The study further noted that while "individual Parties may impose certain strictures on their nationals regarding the exploitation of genetic resources in (...) areas [beyond national jurisdiction], (...) such interventions would not represent a coordinated approach to the issue and do not constitute an effective response to the vast array of issues that need to be dealt with."333

Discussions on the issue at SBSTTA-8 proved rather divisive. Some delegates from developing countries stressed that genetic resources beyond national jurisdiction fall outside the CBD mandate, and opposed expanding CBD's scope. Many delegates supported further studies on the issue. The need to address benefit-sharing was stressed, as were strengthening the relationship with the ISA, discussing the issue within the UN General Assembly, and exploring options for a code of conduct.³³⁴ In substance, delegates agreed on information-gathering activities regarding deep seabed genetic resources within and beyond national jurisdiction.³³⁵

Delegates also discussed the establishment of MPAs and agreed, *inter alia*, that "there is an urgent need to establish in areas beyond national jurisdiction further marine and

coastal protected areas consistent with international law, and based on scientific information, including in relation to areas of seamounts, hydrothermal vents, cold-water corals and open ocean." 336

On the basis of the SBSTTA recommendations, the seventh meeting of the COP (February 2004) further discussed the issue of deep seabed genetic resources and MPAs beyond national jurisdiction. Some delegates opposed addressing bioprospecting within the programme of work on marine and coastal biodiversity.³³⁷ Regarding MPAs, some delegates opposed creating MPAs in areas beyond national jurisdiction, while others stressed the need to act within the framework of UNCLOS when doing so.³³⁸

COP Decision VII/5 on marine and coastal biodiversity contains a specific section on deep seabed genetic resources beyond national jurisdiction, which calls for informationgathering activities including on: methods to identify, assess and monitor seabed genetic resources in areas beyond the limits of national jurisdiction; the status and trends of, and threats to, these resources; technical options for their protection; and activities and processes under Parties' jurisdiction or control which may have significant adverse impacts on deep seabed ecosystems and species beyond the limits of national jurisdiction. The UN General Assembly is also called upon to further coordinate work relating to the conservation and sustainable use of genetic resources of the deep seabed beyond the limits of national jurisdiction.³³⁹

Decision VII/5 also stresses the need for rapid action to address threats to marine biodiversity in areas beyond the limits of national jurisdiction, in particular areas with seamounts, hydrothermal vents, and cold-water corals, other vulnerable ecosystems and certain other underwater features, on the basis of the precautionary approach and the ecosystem approach. The General Assembly and other relevant international and regional organizations are also called upon, within their mandate, to urgently take the necessary short-term, medium-term and longterm measures to eliminate/avoid destructive practices, consistent with international law, on a scientific basis, including the application of precaution and consideration of interim prohibition of destructive practices adversely impacting marine biodiversity associated with these areas.340

With regard to MPAs beyond national jurisdiction, the COP recognized the urgent need for international cooperation and action including the establishment of further MPAs, consistent with international law and based on scientific information, for seamounts, hydrothermal vents, coldwater corals and other vulnerable ecosystems. The COP specifically recognized that the law of the sea provides the legal framework to regulate activities in those areas.³⁴¹ It was also stated that integrated networks of marine and coastal protected areas consist of: areas where threats are managed and extractive uses may be allowed; and areas where extractive uses are excluded and other significant human pressures are removed or minimized.³⁴²

On the basis of this Decision, the programme element on

marine and coastal living resources, within the revised programme of work on marine and coastal biodiversity, includes a specific operational objective on informationgathering activities regarding marine genetic resources in areas under and beyond national jurisdiction. The programme element on marine and costal protected areas includes a specific operational objective on MPAs beyond national jurisdiction.

5.3.2. Bioprospecting under the Convention on Biological Diversity

Besides provisions related to the conservation and sustainable use of biodiversity, the CBD sets forth measures addressing access to genetic resources, transfer of technologies, technical and scientific cooperation, funding and handling of biotechnology.³⁴³ According to the jurisdictional scope of the CBD, these provisions are limited to genetic resources falling within the limits of national jurisdiction. However, some of the measures could be adapted, within an appropriate institutional and regulatory framework, to access to, and use of, genetic resources found beyond the limits of national jurisdiction.

With respect to access to genetic resources, Article 15(1) provides that the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.³⁴⁴ It is further stated that each State shall facilitate access to genetic resources for environmentally-sound uses by other Parties, and that access shall be provided on mutually agreed terms.³⁴⁵ Parties shall moreover undertake scientific research related to resources provided by other Parties with these Parties' full participation, and take measures to share, in a fair and equitable way, the results of research and benefits arising from a commercial and other utilization of genetic resources with Parties providing the resources.³⁴⁶ The parallel between Article 15 and Part XIII of UNCLOS on MSR has been noted in this respect.³⁴⁷

Regarding access to, and transfer of, technology, which includes biotechnology,³⁴⁸ Parties are to provide and/or facilitate access to, and transfer of, technologies that are relevant to the conservation and sustainable use of biodiversity or make use of genetic resources.³⁴⁹ Such access and transfer to developing countries shall be provided under fair and most favorable terms and, in the case of technologies subject to patents and other IPRs, on terms which recognize and are consistent with the adequate and effective protection of IPRs.³⁵⁰ States are further required to adopt measures to ensure that the private sector facilitates access to, and joint development and transfer of, technology for the benefit of governmental institutions and the private sector of developing countries.³⁵¹ The CBD further recognizes that patents and other IPRs may have an influence on the implementation of the CBD, and requires Parties to co-operate to ensure that IPRs are supportive of its objectives.³⁵² The issue of technology transfer is particularly relevant in the context of deep sea activities, which require extremely sophisticated equipment, the development of which is particularly costly. As has been pointed out above, this has meant that so far, scientific research and exploitation of deep seabed genetic resources has remained

the privilege of a very few. The provisions of the CBD, in conjunction with relevant UNCLOS provisions, could be used, in an appropriate framework, as a basis to further developing countries' capacities in this respect.

Article 19, which addresses the handling of biotechnology and distribution of its benefits, provides that measures shall be adopted to provide for the effective participation in biotechnology research by countries providing the genetic resources, and that they be given priority access, on a fair and equitable basis, to results and benefits arising from biotechnologies based upon such genetic resources.³⁵³

On the basis of Articles 8(j), 10(c), 15, 16 and 19, Parties to the CBD have developed Guidelines aimed at regulating access to, and sharing of benefits arising out of the utilization of, genetic resources. Adopted by COP-6 in 2002,³⁵⁴ the Guidelines, known as the Bonn Guidelines on Access and Benefit-Sharing, provide guidance for policy makers and persons using and providing genetic resources.

The Guidelines apply to all genetic resources covered by the CBD, as well as to benefits arising from the commercial and other utilization of such resources, with the exception of human genetic resources. On the basis of the CBD's jurisdictional scope, it follows that the Guidelines are only applicable to marine genetic resources found in areas under national jurisdiction. However, the Guidelines provide a framework on the basis of which a regime for access to deep seabed genetic resources beyond the limits of national jurisdiction and sharing of benefits can be organized.

The Guidelines, which are voluntary,³⁵⁵ are to be applied in a manner that is mutually supportive of the work undertaken by other fora, including the FAO and the World Intellectual Property Organization (WIPO).³⁵⁶ It is specifically stated that nothing in the Guidelines, including the terms "provider", "user" and "stakeholder" should be interpreted to assign any rights over genetic resources beyond those provided in accordance with the CBD.³⁵⁷ While it is not clear what the rights referred to may be, one can think that this provision excludes proprietary rights other than IPRs.

Section II of the Guidelines lays out roles and responsibilities of National Focal Points, Competent National Authorities and Providers and Users with respect to access and benefit-sharing pursuant to Article 15 of the CBD. Section III addresses the participation of stakeholders when developing and implementing access and benefitsharing arrangements. Section IV identifies steps in the access and benefit-sharing process.

Accordingly, access to genetic resources is to be subject to prior informed consent (PIC) of the Party providing the resources, unless otherwise determined by that Party.³⁵⁸ Paragraph 27 details possible elements of a PIC system, including specification of use of the resources. The second step proposed to form part of the access and benefitsharing process is the adoption of mutually agreed terms (MATs) to ensure the fair and equitable sharing of research results and benefits arising from commercial and other utilization of genetic resources.³⁵⁹ Such MATs may include regulation of the use of the resources in order to take into account ethical concerns, the use of IPRs and joint ownership of IPRs.³⁶⁰ An indicative list of typical MATs is provided, which includes the type and quantity of genetic resources, the geographical area of activity, limitations on the possible use of the material, capacity building, transferability of genetic resources, and treatment of confidential information.³⁶¹ The Guidelines further state that the MATs can cover, *inter alia*, the types of benefits, i.e. monetary and non-monetary, timing, and the persons/ entities sharing the benefits. It is stated that these will vary depending on what is regarded as fair and equitable in light of the circumstances.³⁶²

The Bonn Guidelines also provide guidance on incentives, accountability in implementing access and benefit-sharing arrangements, national monitoring and reporting, means for verification of compliance, dispute settlement, and remedies.³⁶³ Finally, Appendix I outlines suggested elements for Material Transfer Agreements, and Appendix II addresses monetary and non-monetary benefits.

COP Decision VI/24 also recognizes the role of IPRs in the implementation of benefit-sharing arrangements, and encourages the disclosure of origin of the resources in applications for IPRs.³⁶⁴ The relationship between the provisions of the CBD and those of the TRIPS are also noted.³⁶⁵

Interestingly, at its most recent meeting in 2004, the COP noted that a number of relevant terms not defined in the CBD may need to be examined, and requested information regarding national definitions of such terms as "access to genetic resources," "benefit-sharing," "commercialization," "derivatives," "provider," "user," "stakeholder," and "ex situ collection."366 All these are particularly relevant in the case of activities related to deep seabed genetic resources found in areas beyond national jurisdiction, for which questions of ownership arise and which may be subject to several transformation stages as well as transfers from one industry to the other. Difficulties and associated costs of collecting those resources in situ also make ex situ collections particularly relevant. COP-7 also stressed the need to further examine other approaches to access to resources and benefit-sharing, such as interregional and bilateral arrangements as well as an international certificate of legal provenance/origin/source.³⁶⁷

Furthermore, on the basis of calls from the World Summit on Sustainable Development (WSSD) and the UN General Assembly,³⁶⁸ COP-7 mandated the CBD *Ad hoc* Open-ended Working Group on Access and Benefit-sharing (ABS Working Group) to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument/instruments to effectively implement relevant provisions of the CBD.³⁶⁹ Further recognizing the need for transparency in the international exchange of genetic resources, Decision VII/19 requests the ABS Working Group to identify issues related to the disclosure of origin of genetic resources and associated traditional knowledge in applications for IPRs, including those raised by a proposed international certificate of origin/source/legal provenance.³⁷⁰ These requests for further information on issues of relevance to access to, and benefit-sharing of, genetic resources show that the issue of bioprospecting is still contentious and needs further policy clarification. This is even more so in respect of seabed genetic resources in areas beyond national jurisdiction, the status of which remains uncertain and the potential economic value of which is considerable.

While the provisions of the CBD and the Bonn Guidelines may not be applicable to deep seabed genetic resources as a result of the CBD's bilateral approach to the issue of access and benefit-sharing, all the provisions outlined above can be used as a starting point to develop a regime for access to deep seabed genetic resources and sharing of the benefits arising out of their utilization. If a regime similar to that of the Area's mineral resources is contemplated, a body such as the ISA could be mandated to negotiate access and benefitsharing arrangements, keeping in mind the requirements stemming from the principle of common heritage of humankind. Delaying negotiations on benefit-sharing until a compound reaches patent protection and the commercial phase is launched has been proposed as a possible option, considering the odds of success. It has been suggested to replace benefit-sharing negotiations at the time of granting access by an agreement to negotiate should a compound originating from an organism collected under the access permit proceed to commercial research.³⁷¹ Such requirements as specification of use, disclosure of origin, and certificates of provenance could also be used to ensure that the benefits arising out of the commercialization or other use of deep seabed genetic resources benefit all.

The CBD-UNDOALOS study noted the particular relevance of benefit-sharing regarding deep seabed genetic resources, which are not easily accessible due to scientific and technological constraints but have great potential scientific and economic value. The need to ensure that rules related to IPRs take into account and abide by the principles regarding MSR in the Area was noted, especially in light of the close links between MSR and commercially-oriented activities.³⁷² In order to do so, it may be worth considering a sui generis system of IPRs for deep seabed genetic resources in areas beyond national jurisdiction. The CBD-UNDOALOS study concluded that benefit-sharing arising from the exploitation of resources beyond the limits of national jurisdiction can only be effected if such resources are brought under a regime similar to that governing the mineral resources of the Area under UNCLOS.373

5.4 Intellectual property rights instruments

As shown in section 3 of this report, patents have already been granted to inventions using deep seabed organisms. Because commercial applications of deep seabed organisms are likely to increase in the future, it is necessary to consider how international instruments related to intellectual property address genetic resources.

5.4.1 Intellectual property rights and genetic resources

Patenting life forms, including genetic resources, has ethical aspects which cannot be overlooked. Concerns have been expressed that patenting of a source material, e.g. genetic resources or organisms, may lead to compromising a growing proportion of biodiversity, discovered or yet-to-be found, from unconditional use over time. It is essential to ensure that the resources or organisms have been legitimately accessed and that benefits arising out of the utilization of the source genetic resources are shared between owners of the resources and users. This is especially true for deep seabed genetic resources, the status of which as open-access or common heritage of humankind is still disputed, but the potential commercial applications of which are numerous. Noting the emergence of a consensus regarding the better suitability of sui generis systems of IPR to biological material and traditional knowledge, Oldham concludes that some resources are too important, in terms of the present and future public benefit, to be subject to strong intellectual property protection.374

It appears that the extension of patentability to biological and genetic material has not been based on sufficient economic analysis and that the positive benefits expected from patent protection with regard to trade, foreign direct investment and technology transfer have not been evidenced.³⁷⁵ Nevertheless, granting IPRs over inventions derived from novel resources has some benefits. Patents can be part of the legal and commercial framework used to generate benefits from the use of genetic resources and agreements concerning patent ownership, while licensing exploitation can help define how access is granted and benefits are shared.

5.4.2. Activities of the World Intellectual Property Organization³⁷⁶

WIPO promotes the protection of intellectual property throughout the world through cooperation among its 180 Member States and in collaboration with other international organizations. WIPO implements this mandate by, *inter alia*, administering various multilateral treaties dealing with the legal and administrative aspects of intellectual property.

In 1998, WIPO established a programme on global intellectual property issues to explore, among others, the intellectual property aspects of biodiversity and biotechnology, and the protection of traditional knowledge. The WIPO General Assembly established, in 2001, an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). This Committee provides the main forum within WIPO for discussions on intellectual property aspects of access to genetic resources and benefit-sharing and the protection of traditional knowledge. It is worth noting that WIPO uses the term "genetic resources" as defined by Article 2 of the CBD as "genetic material of actual or potential value."

At its fourth session in 2002, the IGC agreed to develop a pilot database of contractual practices and clauses relating to intellectual property and access to genetic resources and benefit-sharing. A document prepared by the Secretariat for the IGC's fifth session in July 2003 provides an overview of intellectual property aspects of contracts relating to biological materials and associated traditional knowledge.³⁷⁷ The document notes that due to the central role of confidentiality in the patent system, its maintenance is crucial until appropriate protection is in place. This is frequently done by entering into stand alone confidentiality agreements, which generate legal certainty by stipulating that the party providing the material considers it to be confidential, supplied for an express purpose, not to be used for other purposes, and not to be disclosed to third parties.³⁷⁸ Other elements proposed for inclusion in such contractual arrangements include a description of the information covered by the agreement, the nature of the protection required, the scope of the permitted disclosure and use, ownership and management of further IPRs, and monitoring and reporting on the use of confidential information.379

Responding to an invitation from the sixth COP to the CBD (April 2002), WIPO prepared a technical study on patent disclosure requirements related to genetic resources and traditional knowledge,³⁸⁰ which was subsequently adopted by WIPO's General Assembly and presented at the seventh meeting of the CBD COP in February 2004. Disclosure of origin is particularly relevant to deep seabed genetic resources, the status of which as common heritage of humankind or resources open-access is still largely disputed. The study aims to analyze methods, consistent with international patent-related obligations, to disclose within patent applications, among other things, genetic resources used in the development of the invention, the country of origin of the resources and evidence of PIC as well as associated traditional knowledge, innovations and practices used in the development of the claimed inventions.

WIPO's study proposes various scenarios for disclosure, which revolve around the following requirements: disclosure of origin or source of genetic resources used in an invention (or in some way connected with the development of the invention); and disclosure of the legal context in which relevant genetic resources were accessed (this may include providing evidence that the access complied with a certain procedure or legal standard).³⁸¹ The study notes the need to clarify the link between input, i.e. the source genetic material, and invention and whether this link is sufficient to trigger any particular disclosure requirement. This raises the issue of whether the requirement would also apply when the invention for which the application is filed concerns synthesized substances that were isolated or derived from active compounds of an accessed genetic resource and, if so, what the definition of "derived" is. The study stresses the need for further work on the nature of disclosure requirements, noting that a requirement can concern disclosure per se, or be used as an effective mechanism to prevent securing a patent if certain preconditions are not met.³⁸² The study identifies several possible legal bases for disclosure requirements, some of which are particularly interesting considering the status of deep seabed genetic resources. Those are:

compliance with laws governing access to genetic resources;

- compliance with morality and ordre public considerations relating to genetic resources applied within the jurisdiction of the country where the patent is filed, as well as considerations based on concerns about genetic resources collected inconsistently with foreign laws or international law; and
- possible invocation of equitable principles to limit the enforceability of patent rights when required information is withheld or when access to, or use of, genetic resources is considered to violate equity.³⁸³

A distinctive disclosure mechanism of particular relevance to deep seabed genetic resources (because of the extreme difficulty to access the resources in situ) is the system of deposit of microorganisms or biological materials with a recognized culture collection. Such a mechanism can be part of the obligation to give a full description of the invention in order to enable a person skilled in the art to carry out or to repeat the invention. In some cases, it is impossible to describe the strain and its selection sufficiently to ensure that another person can obtain the same strain from soil himself because the organism may have been improved by mutation and further selection. In such a case, the microorganism itself might be considered to be an essential part of the disclosure. Moreover, if the microorganism is not generally available to the public, as is the case regarding deep seabed genetic resources, the written disclosure of the invention might be considered insufficient.384

In this regard, it is worth referring to the 1977 Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, which entered into force in August 1980.³⁸⁵ According to the Budapest Treaty, Contracting Parties recognize a deposit made in specified culture collections, or International Depositary Authorities (IDA), as adequate for the purposes of their patent procedure.³⁸⁶ The IDA must make its collection available to depositors on equal terms, accept and store deposited microorganisms for the period specified in the Treaty, and provide samples only to those entitled to them.³⁸⁷ The Treaty contains procedures governing the behavior of depositors and IDAs, the duration of storage of microorganisms and the mechanism for providing samples.³⁸⁸ Between 1980 and 2000, a total of 43,533 microorganisms were deposited with IDAs under the Budapest Treaty. While data on the origin and conditions of collection of such microorganisms has been limited to date, the establishment of online databases, including the online sequence listing of WIPO, may facilitate tracking such origin and conditions.³⁸⁹ The system established under the Budapest Treaty provides a practical example of how benefit-sharing could be organized with respect to genetic resources from the deep seabed, if such arrangements were to be considered.

5.4.3. The Agreement on Trade-Related Aspects of Intellectual Property Rights of the World Trade Organization

Under the TRIPS, WTO Member States have to raise their national standards on the protection of intellectual property to a uniform level, and provide protection for

subject matters not covered at the national level in most developing countries.

Under Article 27 of the TRIPS, "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application." Patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.³⁹⁰

Pursuant to Article 27(3), high taxonomic levels of plants or animals are excluded from patentability, but microorganisms and microbiological and non-biological processes can be subject to patents.³⁹¹ It follows that under the TRIPS, deep seabed genetic resources are patentable.

Under Article 28, a patent confers on its owner the exclusive rights to prevent third parties who do not have the owner's consent from:

- making, using, offering for sale, selling, or importing for these purposes the product that is the subjectmatter of the patent;
- using the process that is the subject-matter of the patent; and
- using, offering for sale, selling, or importing for these purposes the product obtained directly by the process, which is the subject-matter of a patent.

Patent owners have the right to assign, or transfer by succession, the patent and to conclude licensing contracts. Applicants for a patent have to disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art, and may be required to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.³⁹²

The 2001 Doha Declaration requires that in its review of Article 27(3), the TRIPS Council consider the relationship between the TRIPS Agreement and the CBD, among others. Work on these topics is to be guided by the objectives of the TRIPS Agreement set out in Article 7³⁹³ and its principles embedded in Article 8,³⁹⁴ and should take development issues into account.³⁹⁵

With respect to patentability of genetic material and biological resources, issues raised during TRIPS Council's discussions include: ways of applying TRIPS provisions on patenting biotechnological inventions, including the extent to which life forms should be patentable; ways to implement the TRIPS Agreement and the CBD together and whether the TRIPS Agreement should be amended to avoid potential conflicts; whether patents should disclose the source of the genetic material; and the type of approval necessary prior to using genetic material.³⁹⁶ Discussions are ongoing in the TRIPS Council regarding disclosure requirements.³⁹⁷

The TRIPS Agreement also contains provisions regarding technology transfer. Article 7 includes the transfer and

dissemination of technology as one of the basic objectives of the protection of IPRs.

5.5 Other relevant international instruments and activities

5.5.1. Regional marine environment-related instruments

In consistency with UNCLOS and the CBD, a number of regional instruments provide a basis for assessing the status of the marine environment and organizing cooperation to regulate potentially harmful activities, including in areas beyond national jurisdiction. In this respect, the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR), the Convention for the Protection of the Natural Resources and Environment of the South Pacific Region (Noumea Convention), the legal framework of the Mediterranean Action Plan (MAP), and the Antarctic Treaty System (ATS) are relevant.

5.5.1.1. Convention for the Protection of the Marine Environment of the North-East Atlantic

OSPAR, which entered into force on 25 March 1998, is the instrument providing for international cooperation for the protection of the marine environment of the North-East Atlantic.³⁹⁸ The Convention applies to the area situated not only within the internal waters, territorial seas and EEZ of its Contracting Parties,³⁹⁹ but also to a significant proportion of the High Seas and the underlying seabed and subsoil in the North East Atlantic and Arctic Oceans as delineated by the Convention.⁴⁰⁰ In fact, more than 50% of the OSPAR area is beyond national jurisdiction. There are at least four known hydrothermal vent fields in the OSPAR maritime area, including the Menez Gwen, Lucky Strike, Saldanha and Rainbow vent fields.

Annex V of OSPAR and the accompanying Sintra Ministerial Statement (22-23 July 1998), provide a strategy for the protection and conservation of the ecosystems and biodiversity of the area covered by OSPAR. The strategy includes the establishment of a network of MPAs, as well as an assessment of species and habitats requiring protection, as well as human activities that are likely to have an adverse effect on such species and habitats. The network of MPAs is likely to include hydrothermal vents and other deep seabed ecosystems found in the High Seas. Appendix 3 to Annex V sets out a non-exhaustive list of criteria to identify human activities covered by Annex V, including: the extent, intensity and duration of the activity; its actual and potential adverse effects on specific species, communities and habitats; actual and potential adverse effects on specific ecological processes; and irreversibility or durability of these effects.

The revised Strategy (June 2003, Bremen) includes provisions regarding the development of programmes and measures for the protection of species and habitats threatened or in decline, as well as to safeguard against the harm caused by human activities, which may have an adverse effect.⁴⁰¹ The Bremen Ministerial meeting also agreed that the assessment of the impact of specific activities and identification of the necessary programmes and measures should be completed by 2010. Among these activities, exploration for oil, gas and solid minerals was mentioned. Presumably, investigative activities undertaken in regard of biological resources could be assessed.

Several deep sea habitats within OSPAR waters, including sponge aggregations, seamounts and oceanic ridges with hydrothermal vents/fields, have been included on the OSPAR List of Threatened and/or Declining Species and Habitats.⁴⁰² Some hydrothermal vents, including Lucky Strike and the Menez Gwen fields, were proposed as possible candidates for the MPA network.⁴⁰³ Bioprospecting activities at hydrothermal vents in the North East Atlantic could therefore be regulated on the basis of OSPAR. However, it is likely that such activities could only be regulated in so far as they may have an adverse impact on their surroundings, like in the CBD context. Moreover, measures adopted in this context would only be applicable to nationals of OSPAR Contracting Parties. This is likely to raise difficulties considering that bioprospecting activities are often carried out in the context of multinational joint ventures and consortia, as noted above.

5.5.1.2. Noumea Convention

The Convention for the Protection of the Natural Resources and Environment of the South Pacific Region, which entered into force on 22 August 1990, aims to contribute to the care and responsible management of the special hydrological, geological and ecological characteristics of the South Pacific Region.⁴⁰⁴ The Convention Area excludes the internal waters or archipelagic waters of its Parties, but includes their EEZ and the areas of the High Seas which are enclosed from all sides by the Parties' EEZ.⁴⁰⁵ To date, several hydrothermal vents/fields have been identified in the South Pacific Region, including the Vienna Woods, PACMANUS, Su Su Knolls, Willaumez and Conical Seamount fields in the Manus Basin, and the Franklin Seamount in the Woodlark Basin.

While it is not explicitly stated that the Convention also applies to the seabed underlying these areas, some provisions address pollution from seabed activities. It is therefore reasonable to assume that activities such as bioprospecting would be covered when carried out at hydrothermal vents and around other deep seabed features.

Under Article 4, each Party shall ensure that activities within its jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of its national jurisdiction. Under Article 5, Parties are required to take all appropriate measures to prevent, reduce and control pollution of the Convention Area from any source, and to ensure sound environmental management and development of its natural resources. Seabed activities are specifically addressed under Articles 8 and 13, which require Parties to take appropriate measures to prevent, reduce and control pollution and environmental damage in the Convention Area, resulting directly or indirectly from exploration and exploitation of the seabed and its subsoil. The Noumea Convention also provides for the establishment of specially protected areas under Article 14 to protect and preserve rare or fragile ecosystems, depleted, threatened or endangered flora and fauna as well as their habitat, including through the establishment of protected areas and the prohibition or regulation of any activity likely to have adverse effects. Finally, Article 17 provides for scientific and technical cooperation, requiring Parties to cooperate in scientific research, environmental monitoring, and the exchange of data and other scientific and technical information. Research and monitoring programmes should also be developed.

5.5.1.3. The Mediterranean Action Plan

The legal framework that constitutes the Mediterranean Action Plan (MAP) includes maritime areas in the High Seas, beyond the national jurisdiction of the 22 Parties to the Barcelona Convention for the Protection of the Marine Environment and the Coastal Region of the Mediterranean (Barcelona Convention). The MAP draws on the Barcelona Convention and its six protocols, which address specific environmental issues.

Under the Convention, Parties are to apply the precautionary principle and the polluter-pays principle, as well as undertake environmental impact assessment for activities that are likely to have a significant adverse effect on the marine environment.⁴⁰⁶

Article 7 of the Convention specifically requires Parties to take all appropriate measures to prevent and eliminate pollution resulting from exploration and exploitation of the continental shelf and the seabed and its subsoil.

Under Article 10, Parties shall take measures to protect and preserve biological diversity and rare or fragile ecosystems, as well as species of wild fauna and flora which are rare, depleted, threatened or endangered and their habitats.

Parties shall endeavor to establish a pollution monitoring system,⁴⁰⁷ and undertake to cooperate in the adoption of rules and procedures on liability and compensation for damage resulting from pollution.⁴⁰⁸

Among the Protocols to the Barcelona Convention, it is worth noting the 1995 Protocol concerning Specially Protected Areas and Biological Diversity in the Mediterranean, which provides for the establishment of "specially protected areas of Mediterranean importance" beyond Parties' jurisdictional waters.⁴⁰⁹ The Protocol applies to the seabed and its subsoil.⁴¹⁰

Under the Protocol, Parties shall identify and compile inventories of the components of biodiversity, as well as monitor these components. Parties are also required to identify processes and categories of activities which have or are likely to have a significant adverse impact on the conservation and sustainable use of biodiversity and monitor their effects.^{4ⁿ} Article 17 provides for environmental impact assessments of projects or activities that could significantly affect protected areas and species and their habitats. The 1995 Protocol includes a list of possible protection measures, including: the regulation of the passage, stopping and anchoring of ships; the regulation or prohibition of any activity involving the exploration or modification of the soil or the exploitation of the subsoil of the land part, the seabed or its subsoil; the regulation of any scientific research activity; and the regulation or prohibition of taking of animals and harvesting of plants or their destruction, as well as trade in animals and plants or parts thereof, which originate in specially protected areas.⁴¹² Measures adopted on this basis could provide a basis to regulate bioprospecting.

Article 20 of the Protocol requires Parties to encourage and develop scientific and technical research.

5.5.1.4. The Antarctic Treaty System

Some hydrothermal vents have been identified in Antarctica waters, including at the Bransfield Strait.413 Relevant instruments of the Antarctic Treaty System (ATS) to regulate access and activities related to hydrothermal vents include the Antarctic Treaty, the 1980 Convention on the Conservation of Antarctic Marine Living Resources (CCAMLR), the 1991 Protocol on Environmental Protection to the Antarctic Treaty (Madrid Protocol), and the 1988 Convention on the Regulation of Antarctic Mineral Resources Activities (CRAMRA). It is noteworthy that most of the States involved in deep seabed research and bioprospecting are Parties to CCAMLR, including France, Australia, Japan, the US and New Zealand. Discussions on bioprospecting in Antarctica are ongoing within ATS institutions.414 Considering similarities in terms of uncertainty of legal status and potential for scientific research and exploitation of extremophiles, several provisions of the ATS can provide a model for developing a regime for deep seabed bioprospecting.

Antarctic Treaty

The Antarctic Treaty, which entered into force on 23 June 1961, provides for the freedom of scientific investigations and the promotion of international co-operation in Antarctica.⁴¹⁵ Under Article III(a) to (c), Contracting Parties agree to, *inter alia*, exchange information regarding plans for scientific programmes, and exchange and make freely available scientific observations and results. Parties are also required to give prior notice to other Parties of all expeditions to, and within, Antarctica, on the part of their ships or nationals, and all expeditions to Antarctica organized in, or proceeding from, their territory.⁴¹⁶

CCAMLR

CCAMLR, which entered into force on 7 April 1992, aims at the conservation of Antarctic marine living resources, including their "rational use."⁴¹⁷ The Convention applies to the area south of 60° South latitude and to the Antarctic marine living resources of the area between that latitude and the Antarctic Convergence, which form part of the Antarctic marine ecosystem.⁴¹⁸

Article II(2) defines Antarctic marine living resources as "the population of fin fish, molluscs, crustaceans and all other species of living organisms." Presumably, species of molluscs

and crustaceans associated with hydrothermal vents would fall within this definition, as would Bacteria and Archaea found at hydrothermal vents.

Harvesting of marine living resources and any associated activities must be conducted in accordance with a number of principles of conservation set out in Article II (3) of CCAMLR, including: the prevention of decrease in the size of harvested population to levels below those which ensure its stable recruitment; and the prevention of changes or minimization of the risk of changes in the marine ecosystem, which are not potentially reversible over two or three decades.

The Commission for the Conservation of Antarctic Marine Living Resources, established under Article VII, is mandated to, *inter alia*: facilitate research into Antarctic marine living resources; compile and disseminate data on those resources; and formulate, adopt and revise conservation measures on the basis of the best scientific evidence available.⁴¹⁹ Conservation measures of relevance to bioprospecting include: designation of quantities for harvested species; quantities that may be harvested in specific regions and sub-regions; designation of protected species; designation of opened and closed areas for the purposes of scientific study or conservation, including special areas for protection and scientific study; and regulation of the methods of harvesting.

A Scientific Committee is established to provide a forum for consultation and cooperation regarding the collection, study and exchange of information with respect to marine living resources covered by the Convention.⁴²⁰

Madrid Protocol

The Madrid Protocol, which entered into force on 14 January 1998, promotes the comprehensive protection of the Antarctic environment and dependent and associated ecosystems. It designates Antarctica as a natural reserve, devoted to peace and science.⁴²¹

Antarctica's value as an area for the conduct of scientific research, in particular research essential to understanding the global environment, is one of the fundamental considerations to take into account when planning and conducting activities in the Antarctic Treaty area. Priority over any other planned activity is accorded to scientific research, and any activity relating to mineral resources, other than scientific research, is prohibited.⁴²²

To achieve the Protocol's objective, a series of principles are set out which require, *inter alia*, planning and conducting activities in such a way as to limit adverse impacts, avoid significant changes in the marine environment and detrimental changes in the distribution, abundance or productivity of species or populations of species of fauna and flora, and avoid degradation of, or substantial risk to, areas of biological and scientific significance among others.⁴²³

The Protocol includes provisions on environmental impact assessment (EIA), outlined in Annex I. Under Article 8, activities subject to EIA are activities carried out pursuant to scientific research programmes, tourism and all other governmental activities. Decisions regarding whether an activity may proceed or not rest with the Antarctic Treaty Consultative Meetings following advice by the Committee on Environmental Protection, established under Article 11. Bioprospecting would therefore be subject to prior EIA to assess whether collection of genetic material would affect specific species or habitats among others.

The Protocol also provides for cooperation among Parties when planning and conducting activities in the Treaty Area, including with regard to the development of scientific and technical programmes, the choice of sites for prospective stations, and the undertaking of joint expeditions and sharing of information.⁴²⁴

In order to ensure compliance with the Protocol, a system of inspections by observers is set forth under Article 14. Considering the difficulties associated with monitoring activities in the deep seabed, a similar system could be contemplated with regard to bioprospecting in deep seabed areas falling outside the scope of the Antarctic Treaty System.

Annex V to the Protocol provides for the establishment and management of protected areas, including marine areas. Activities in those areas shall be prohibited, restricted or managed in accordance with management plans.⁴²⁵ The provisions set forth would likely require regulating access to and activities carried out in hydrothermal vents located in such areas.

It is noteworthy that the question of whether the Protocol applies to the deep seabed is unresolved to date. While CRAMRA explicitly excluded the application of the Convention to the deep seabed, the Protocol remains silent in this respect. Possible inconsistencies have been noted between the Protocol's provisions, including its ban on mining, and UNCLOS' provisions related to the Area, which authorize mining activities.⁴²⁶

CRAMRA

CRAMRA's measures on mineral activities in Antarctica, although not related to biological resources, could be considered in the context of a regime for bioprospecting. The Convention provides for a system of authorization by Sponsoring States for prospecting activities, and authorization by the Convention's bodies for exploration and exploitation.⁴²⁷

CRAMRA's provisions on data and information that have potential commercial value are particularly interesting as a possible model for regulating deep seabed bioprospecting. Article 16 provides that data and information shall be made freely available to the greatest extent feasible, whereas data and information of commercial value gained through prospecting may be retained by the operator in accordance with Article 37. Finally, Article 16(b) notes that regarding data and information deriving from exploration or development, the Commission shall 'adopt measures relating, as appropriate, to their release and to ensure the confidentiality of data and information of commercial value'. Under Article 37, Sponsoring States may, at any time, release part of or all data and information of commercial value generated by prospecting on conditions which they shall establish, for scientific or environmental purposes. Such data and information shall be made readily available when not, or no longer, of commercial value and, in any event, no later than 10 years after the year the data and information were collected, unless the data and information continue to have commercial value.

5.5.2. The World Summit on Sustainable Development

Several paragraphs of the Plan of Implementation adopted in 2002 at the WSSD are of relevance to the issue of bioprospecting in the deep seabed.

Paragraph 44 of the Plan of Implementation calls upon States to negotiate an international regime promoting and safeguarding the fair and equitable sharing of benefits arising out of the utilization of genetic resources, within the framework of the CBD and bearing in mind the Bonn Guidelines.⁴²⁸ Such a regime could have a broader scope than the Bonn Guidelines and address genetic resources found in areas beyond national jurisdiction, including the deep seabed, subject to amendments to the CBD to broaden its scope.

The provisions of the Plan of Implementation related to the sustainable development of oceans are also of relevance to activities undertaken in the deep seabed. In particular, Paragraph 32(a) calls upon States to maintain the productivity and biodiversity of important and vulnerable marine and coastal areas, including in areas beyond national jurisdiction. An element in maintaining productivity of those areas is to effectively manage the threats to, and impacts on, those ecosystems. This may include adopting regulations for marine scientific research and bioprospecting. Under the Plan, States are also encouraged to develop and facilitate the use of diverse approaches and tools, including the ecosystem approach and the establishment of representative networks of MPAs consistent with international law and on the basis of scientific information by 2012.429

5.5.3. Intergovernmental Oceanographic Commission of UNESCO

The purpose of the IOC is to promote international cooperation and coordinate programmes in research, services and capacity building related to the oceans.⁴³⁰

At its 19th Session in 1997, the Assembly of the Intergovernmental Oceanographic Commission established the Advisory Body of Experts on the Law of the Sea (ABE-LOS) to assist in carrying out its tasks. In 2001, the IOC Secretariat prepared a questionnaire to obtain information in order to: assess the problems encountered in the implementation of Part XIII of UNCLOS on MSR; assist States in establishing generally-accepted guidelines, criteria and standards for the transfer of marine technology; and inform the international community about the status of MSR and the transfer of marine technology and on the practical issues raised in implementing Parts XIII and XIV of UNCLOS. At the time of writing, the questionnaires were still being analyzed.

It is noteworthy that ABE-LOS considered criteria and guidelines on the transfer of marine technology. Interestingly, the guidelines define marine technology as instruments, equipment, vessels, processes and methodologies required to produce and use knowledge to improve the study and understanding of the nature and resources of the ocean and coastal areas. Considering the definition of marine technology, it would be the technology used to carry out pure marine scientific research. Hence, marine technology used to carry out commercially-oriented activities would be excluded from the term and possibly from the guidelines' scope. Such exclusion would seem unrealistic considering that the equipment to carry out marine scientific research and bioprospecting is the same. The guidelines further state that marine technology includes: information and data on marine sciences and related marine operations and services; sampling and methodology equipment; equipment for in situ and laboratory observations, analysis and experimentation; and expertise, knowledge, skills, technical/scientific/legal knowhow and analytical methods related to marine scientific research and observation.431

Activities undertaken within the IOC should be considered when assessing the need for, and eventually designing, an international regime on deep seabed bioprospecting, particularly with regard to the relation between bioprospecting and marine scientific research.

5.6. Non-governmental initiatives

5.6.1. Codes of conduct

Codes of conduct to address the impacts of marine scientific research in the deep seabed are being developed by the scientific community. Considering the current lack of regulatory framework for deep seabed bioprospecting activities, codes of conduct could be developed and used as an interim measure while awaiting the development of regulations or management plans.⁴³²

As noted in section 3 of this report, InterRidge is an initiative by scientists to facilitate international and multidisciplinary research associated with mid-ocean ridges through project coordination and information exchange and dissemination. It is developing a Code of Conduct for the Scientific Study of Marine Hydrothermal Vent Sites. The Code aims to minimize the impacts and maximize the efficiency of necessary research. It would apply to organizations and affiliated individuals undertaking marine scientific research and submarine-based tourism activities at hydrothermal vents located within and beyond the limits of national jurisdiction. These actors would commit to: identifying and complying with international, national and sub-national laws and policies; minimizing or eliminating adverse environmental impacts through all stages of an activity; minimizing or eliminating actual or potential conflicts or interference with existing or planned marine scientific research activities; and monitoring, evaluating and reporting on the Code's application. The Code also notes the need to reduce the impact of sampling at heavy use sites by encouraging the development of micro-analytical procedures, and alternatives to sampling.⁴³³ Such codes, besides emanating from the primary users of deep seabed ecosystems, thereby enhancing their efficiency, can allow pre-cruise planning and post-cruise assessment, provide for personal responsibility, and coordinate site visits.⁴³⁴

A code of conduct was also among the measures proposed by the Horta Workshop on the Management of Deep Sea Hydrothermal Vents at the Azores Triple Junction. The proposed code of conduct addresses scientific research, tourism, fisheries and commercial exploitation. Under the proposed code, scientific research should be undertaken in accordance with the approved MPA Management Plan and any other local and international regulations and follow prior clearance. A list of samples, preservation methods, numbers, destination, and person/lab responsible should be communicated to the MPA Management Committee following expeditions. Collection of non-target samples should be reported, and voucher specimens deposited in national collections. Proponents of the research should also indicate possible environmental impacts in their research proposals. The proposed code forbids all commercial exploitation inside the boundaries of the MPA. Exploitation outside the MPA, which might affect the area, should be subject to strict independent environmental assessment and may be prohibited.435

Although related to resources found within national jurisdiction, codes of conduct have also been developed to support implementation of the CBD provisions on access and benefit-sharing. An example is the Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC), addressing access to and benefitsharing regarding microbial resources.436 The Code, which is the result of a consensus between public and private sector representatives, recognizes that monitoring the transfer of microbial genetic resources is necessary to identify the individuals or groups that are entitled to be scientifically or financially rewarded for their contribution to the conservation and sustainable use of the resources. The Code includes provisions on access to in situ resources and, more interestingly in the context of deep seabed resources, on access to *ex situ* resources. There are also provisions on monitoring the distribution and utilization of microbial genetic resources, and terms of agreement on benefitsharing, access to technology, scientific and technical cooperation as well as technology transfer. The role of IPRs is also addressed. Such a code could be considered for access to, and sharing of benefits stemming from, deep seabed genetic resources.

5.6.2. Other initiatives

Draft Rules and Regulations on Protecting Biodiversity in International Waters have been proposed.⁴³⁷ The Regulations essentially address bioprospecting in the Area. While these Regulations are based on the assumption of an expanded mandate of the ISA, similar measures could be considered within any other institutional framework. Under the proposed Regulations, bioprospecting may be multipurpose and carried out in conjunction with prospecting for mineral resources and marine geological research. A notification process, similar to an authorization process, is provided for, as well as the need for access agreements prior to commencement of activities. Access agreements shall contain provisions on EIA, benefit-sharing, IPRs and confidentiality of data and information of a commercially sensitive nature. Benefit-sharing measures include participation of the ISA in bioprospecting activities, as well as deposition of samples to the ISA.

5.7 Reporting requirements under international instruments

Reporting not only provides information on the status of deep seabed ecosystems, but also allows identifying gaps in policies and legislation in place, as well as necessary technical and financial resources to fill these gaps. This section aims to assess the extent to which reporting requirements under the international instruments considered above provide a basis for information gathering regarding deep seabed bioprospecting. At the outset, it is worth noting that States have raised concerns within various fora, about the burden of increased reporting requirements for governments, in particular developing countries. A reporting mechanism with regard to deep seabed bioprospecting should therefore aim to consolidate information gathered through the requirements outlined below.

5.7.1. Reporting requirements under the UN Convention on the Law of the Sea

Part XII of UNCLOS on the protection and preservation of the marine environment contains a specific section on monitoring and environmental assessment. Under Section 4, States are required to publish or provide reports at appropriate intervals to the competent international organizations on the results of their observations, measures and analysis of the risks or effects of pollution of the marine environment. More particularly, when they have reasonable grounds to believe that planned activities under their jurisdiction or control may cause substantial pollution of, or significant and harmful changes to, the marine environment. States shall assess the potential effects of such activities on the marine environment and communicate the results of such assessments. This provision provides a basis for States to assess bioprospecting undertaken by vessels flying their flags in the Area.438

With regard to MSR undertaken in the Area, States are requested to disseminate the results of research and analysis when available, through the Authority or other international channels, under Article 143.

Under Article 160, the ISA's Assembly is mandated to examine periodic reports from the Council and from the Enterprise and special reports requested from the Council or any other organ of the Authority on activities undertaken in the Area. This would include activities undertaken by the Enterprise in the Area. Presumably, such reports could include information on the impacts of mining activities. Such reports could also be applied to bioprospecting activities, though a framework similar to that of the Area would be needed. Under Article 165, the ISA's LTC supervises, upon the Council's request, activities in the Area and reports to the Council. Although under the current regime this relates to mining activities, bioprospecting activities could be also included in such reports.

Under the Regulations on Polymetallic Nodules of the ISA, prospectors shall submit annual reports to the Authority on the status of prospecting. These reports shall contain: a general description of the status of prospecting and of the results obtained; and information on compliance with UNCLOS and relevant rules, regulations and procedures adopted by the ISA regarding cooperation in training programmes for MSR and technology transfer, and protection and preservation of the marine environment.439 Under Annex 4 on Standard Clauses for Exploration Contracts, contractors could be requested to submit annual reports containing information on: exploration work and its results; the equipment used; the implementation of training programmes; results obtained from environmental monitoring programmes; and the quantity of polymetallic nodules recovered as samples or for the purpose of testing.440 Moreover, under Regulation 31, each contractor undertaking exploration or exploitation is required to gather environmental baseline data and establish environmental baselines against which to assess the likely effects of its activities, as well as establish a programme to monitor and report on such effects. Regulation 32 requires the ISA's Secretary-General to immediately report on any incident resulting from, or caused by, a contractor's activities which has caused, or is likely to cause, serious harm to the marine environment. These measures could be considered for bioprospecting activities, within an appropriate institutional framework.

5.7.2. Reporting requirements under the Convention on Biological Diversity

Article 26 of the CBD requires Contracting Parties to submit reports, at intervals to be determined by the COP, on measures adopted to implement the Convention, as well as on the effectiveness of these measures to meet the objectives of the Convention. Presumably, this includes measures adopted by States to regulate activities and processes under their jurisdiction or control carried out beyond the limits of national jurisdiction, including deep seabed bioprospecting.

To date, two sets of national reports have been submitted by Parties to the CBD Secretariat, in 1998 and 2001 respectively. National reports are now to be submitted every four years, with the third set of reports to be submitted in 2005. Following adoption of a reporting format, Parties are requested to answer specific questions regarding their implementation of all the Convention's articles as well as thematic programmes, including the programme of work on marine and coastal biodiversity and related COP decisions. As it stands, the format, as revised following COP Decision VI/25, falls short of addressing specifically deep sea ecosystems as well as marine genetic resources beyond areas of national jurisdiction. However, revisions should take into account the revised programme of work on marine and coastal biodiversity at COP-7 and the inclusion of specific operational objectives on information-gathering activities regarding marine genetic resources in areas under and beyond national jurisdiction and on MPAs beyond the limits of national jurisdiction. In respect of genetic resources, at this stage, such information would presumably only provide information on information-gathering activities undertaken at the domestic level, not on the measures adopted to address activities undertaken with respect to those resources.

Parties are also invited to submit thematic reports on issues for in-depth consideration at COP meetings. Examples of such reports include thematic reports on: technology transfer; protected areas; and on access to, and benefitsharing arising from, genetic resources. Under the multiyear programme of work of the COP adopted at COP-7 (Decision VII/31), implementation of the programme of work on marine and coastal biodiversity will be subject to in-depth review at COP-10 in 2010. A thematic report on related issues, including items addressing deep sea ecosystems and related activities, could be considered.

5.7.3. Reporting requirements under other instruments

Article 22 of the OSPAR Convention requires Contracting Parties to report to the Commission at regular intervals on their legal, regulatory, and other measures for the implementation of OSPAR as well as the effectiveness of these measures. On the basis of Recommendation 2003/3 on a network of MPAs, Parties must report to the OSPAR Commission the areas that they have selected as components of the OSPAR Network, including information on the ecological and practical criteria for selection of the area as an MPA, the proposed management and protection status, and the management plan and measures adopted. Following this recommendation, Portugal will be required to report annually, after 2005, on implementation of the measures adopted for the management of the Lucky Strike and Menez Gwen MPAs. Presumably, such protected areas set up in the High Seas covered by the Convention Area on the basis of cooperation between Contracting Parties would also need to be subject to this reporting obligation.

The Noumea Convention is rather flexible regarding reporting. It only requires Parties to transmit to the Organization information on the measures adopted to implement the Convention "in such form and at such intervals as the Parties may determine." This would include reporting on measures adopted to address pollution resulting from exploration and exploitation of the seabed and its subsoil, such as bioprospecting.

Within the context of the Mediterranean Action Plan, under Article 23 of the 1995 Protocol to the Barcelona Convention, Parties are required to submit to the ordinary meetings of the Parties a report on their implementation of the Protocol, in particular on the status and the state of the areas included in the list of specially protected areas of Mediterranean importance. As noted above, Article III of the Antarctic Treaty requires Parties to, inter alia, exchange information regarding plans for scientific programmes, and exchange and make freely available scientific observations and results. Under Article 10 of Annex V to the Madrid Protocol, Parties have to collect and exchange records, including records of permits and reports of visits to Antarctic Specially Protected Areas and reports of inspection visits to Antarctic Specially Managed Areas, as well as on any significant change or damage to these areas. Parties also have to inform annually other Parties and the Committee of the number and nature of permits issued, and provide summary descriptions of the activities conducted by persons subject to their jurisdiction in the above mentioned areas. Observers designated under the system of observations and inspection set forth under CCAMLR must report on their inspections and observations.⁴⁴¹ Information regarding bioprospecting activities could be gathered on this basis.

6 Outline of domestic measures of selected countries

As outlined above, under UNCLOS and the CBD, flag States have the jurisdiction to adopt measures to regulate activities under their jurisdiction or control carried out beyond the limits of national jurisdiction, including for the purposes of ensuring that such activities do not cause damage to the marine environment. At the time of writing, no State had adopted any regulation addressing specifically bioprospecting or marine scientific research activities carried out by their nationals outside the limits of national jurisdiction. However, some States have adopted, or are in the process of adopting, regulations for marine scientific research or bioprospecting carried out within their jurisdiction. Moreover, Canada and Portugal, within the jurisdiction of which some hydrothermal vents have been discovered, have established MPAs around those sites.⁴⁴²

6.1 Domestic measures on marine scientific research and bioprospecting

Hydrothermal vents have been discovered in the South Pacific in the Manus Basin (including the Vienna Woods, PACMANUS, Su Su Knolls, Willaumez and Conical Seamount fields) and in the Woodlark Basin (including the Franklin Seamount). Some of these sites fall under the jurisdiction of Papua New Guinea (PNG), New Zealand, Fiji, the Solomon Islands, and Tonga, among others. Some of these States are considering granting, or have granted, permits for exploration and exploitation of mineral resources associated with hydrothermal vents within their territorial sea and/or EEZ.⁴⁴³ Some expeditions have sampled microbes from the Manus Basin and other locations such as Lihir Island and Rabaul, within PNG's territorial waters.⁴⁴⁴

There is currently no legislation addressing marine scientific research or access to PNG's genetic resources so far. However, PNG would be currently developing a policy on marine scientific research within its waters, as well as considering options for regulating bioprospecting.⁴⁴⁵ For the time being, individual requests for access to PNG's waters for pure marine scientific research and/or bioprospecting are dealt with on a case-by-case basis. In some cases, individual access and benefit-sharing agreements have been entered into with individual research organizations.⁴⁴⁶ Because PNG is also a Party to the Noumea Convention, it could also consider regulating access to these sites on this basis.

At least five hydrothermal vents are found under Fiji's jurisdiction.⁴⁴⁷ Fiji is currently drafting its bioprospecting legislation. Under the draft legislation, persons wishing to conduct biodiversity research would need to be granted access by the Conservation and Natural Parks Authority. Bioprospecting would be prohibited in any marine or terrestrial area without prior approval. Application forms for access would detail: area(s) of collection; organisms to be collected; and benefits for the resource owners. A statement on the nature of any IPRs that may be affected would also be required. Access would be granted by the Authority following advice, especially from the Fisheries Department when marine collections are proposed.⁴⁴⁸

Also in the South Pacific Region, New Zealand is host

to several hydrothermal vents, including Brothers Arc Caldera, Kermadec-Havre and Backarc System in the Lau Basin. New Zealand is currently developing an integrated bioprospecting policy as well as an oceans policy, which would address bioprospecting.⁴⁴⁹

Norway's waters host a hydrothermal vent, the Knipovich located in the Arctic Ocean. Norway has adopted regulations on marine scientific research undertaken within its waters and EEZ. Until adoption of a specific legislation on access to genetic resources, application for research related to marine genetic material is addressed under regulations in place for marine scientific research. Consent to marine scientific research projects is granted by the Directorate of Fisheries and research activities are controlled and surveyed by the Coast Guard, who may request to inspect a vessel or installation.⁴⁵⁰

6.2 Indirect regulation of bioprospecting: marine protected areas

6.2.1. Canada: the Endeavour Marine Protected Area

On the basis of the 1996 Oceans Act,⁴⁵¹ and following concerns over increasing pressure resulting from scientific interest for the area,⁴⁵² Canada established the Endeavour Hydrothermal Vent Marine Protected Area in 2003. The Area lays in Canadian waters, on the Juan de Fuca Ridge, southwest of Vancouver Island at depths of 2250 meters, covers 100 square kilometers of seabed and overlying water column, and is composed of four fields of large black smoker structures, namely the Main Endeavour Field, the Mothra Field, the High Rise Field and the SawIty Dawg Field.⁴⁵³

The Area is to be managed in accordance with the provisions of the 2003 Endeavour Hydrothermal Vent Marine Protected Area Regulations and the Endeavour Hydrothermal Vents Marine Protected Area Management Plan. The Management Plan aims at conserving Endeavour's ecological integrity as well as monitoring and coordinating activities through an access authorization process.⁴⁵⁴

Section 2 of the Regulations states that no person shall disturb, damage, destroy or remove from the MPA, any part of the seabed, including a venting structure, of the subsoil, or any living marine organism or part of its habitat. Activities, which are likely to result in the disturbance, damage, destruction or removal of these things, are also prohibited.

However, under Section 3, no person contravenes this prohibition if the disturbance, damage, destruction or removal is for scientific research for the conservation, protection and understanding of the area, and obeys certain conditions. It follows that pure marine scientific research is allowed within the MPA, subject to submission of a research plan to Fisheries and Oceans Canada no later than 90 days before the start of the expedition.⁴⁵⁵ The research plan must include: information regarding the ships and scientists involved in the research; commencement date, duration and itinerary of the research; a summary of the research to be carried out, including the data to be collected, sampling protocols to be used, and techniques to be used; and equipment to be moored, as well as the method of mooring.⁴⁵⁶ All licenses, authorizations or consents required under the Oceans Act, the Coastal Fisheries Protection Act, the Coasting Trade Act or the Fisheries Act in respect of scientific research have to be obtained prior to the expedition.⁴⁵⁷

Permission to undertake activities in the area are to be obtained through existing procedures. Foreign vessels must obtain permission through the Department of Foreign Affairs and International Trade under the 1992 Coasting Trade Act. Domestic vessels are subject to the provisions of the 1985 Fisheries Act regarding issuance of scientific permits. Requests for access authorization are reviewed by the Endeavour Management Committee,⁴⁵⁸ which advises Fisheries and Oceans Canada on whether to grant access or not.

The MPA has been divided into four zoned management areas centered on each of the four main hydrothermal fields. Different types of activity are permitted within each zone.⁴⁵⁹

The Management Plan also provides for the establishment of an information center to consolidate access to various data and information related to Endeavour, and facilitate information sharing.⁴⁶⁰ Monitoring of marine environmental quality on the basis of protocols and indicators is provided for under Management Objective 7. An education and outreach strategy is also set out in the Plan.⁴⁶¹

While scientific research is authorized and regulated within the MPA, the Management Plan and the Regulations remain silent regarding activities undertaken with a commercial purpose, such as bioprospecting, which seem to fall under the prohibition of Section 2 of the Regulations. The issue of sharing of scientific research results is taken into account, to a small extent, through the establishment of the information center. Implications of the Regulations and the Management Plan for expeditions involving both scientific research and bioprospecting remain unclear. Section 4 of the Regulations provides that no person contravenes section 2 by carrying out an activity in the Area by means or under conditions that are authorized under the Fisheries Act, the Coasting Trade Act, the Oceans Act, and the Coastal Fisheries Protection Act. To some extent, this may cover activities undertaken for commercial purposes such as bioprospecting.

6.2.2. Portugal: the Lucky Strike and Menez Gwen Marine Protected Areas

Four hydrothermal vent fields are found at the Azores Triple Junction in the Northeast Atlantic, stretching along the Mid-Atlantic Ridge to the Southwest of the Azores. Menez Gwen, Lucky Strike, Saldanha and Rainbow lie at depths between 850 and 2800 meters. Of these four sites, only Menez Gwen and Lucky Strike fall under Portugal's jurisdiction.⁴⁶²

Within the framework of the OSPAR Convention, the Azores Regional Government decided to establish an MPA around the Menez Gwen and Lucky Strike vent fields to "prevent degradation of and damage to species, habitats and ecological processes on the basis of the precautionary approach." Elements of a management plan for the MPA were identified by a workshop sponsored by the Government of the Azores.⁴⁶³

Both sites include the superjacent water column, the subsoil and sub-surface. The Workshop proposed that the Lucky Strike MPA comprise three areas: an integral reserve for observation only; a reserve for observation and monitoring; and an area for regulated sampling. The Menez Gwen MPA would comprise two areas: a conservation area for nonintrusive observation and non-destructive sampling; and an area for regulated sampling. Within both areas, only regulated scientific activities would be allowed.⁴⁶⁴

Access to the fields would be regulated, and a specific institution vested with the authority to grant access. Requests for access should include: information regarding the principal investigator or programme operator, the vessel, and participants; funding sources; the rationale for the expedition; the types of activities planned, including the anticipated number and type of samples to be collected; location of activities to be carried out; schedule and dates of the expedition; planned dissemination of research results; and an agreement to abide by the proposed code of conduct.⁴⁶⁵

Fisheries, tourism⁴⁶⁶ and all commercial activities, including mining and bioprospecting would be prohibited within the MPAs. Pure marine scientific research would be the only activity allowed, and subject to different regulation depending on the vent fields within which it would be carried out. It was proposed that, on the basis of a code of conduct, a list of sample species be made available to the MPA Management Committee after each expedition. The MPA Management Committee would encourage the publication of the research results, and publish an annual summary of research carried out in the area. The need for interdisciplinary research teams was noted, as was the need to report collection of non-target samples. It was proposed that sample specimens and reference collections be deposited in a natural history museum, as well as an MPA data bank.467

The administration of the MPA would be entrusted to a general assembly composed of government representatives and relevant stakeholders. An executive managers group would consider requests for vessel clearance, and be assisted by an advisory body.⁴⁶⁸

While non-target samples would have to be declared, the implications attached to such declaration are unclear. Moreover, apart from communication of research results to the MPA management authorities, no specific provisions are made regarding benefit-sharing and what would happen should economic gains ensue from the transfer of samples collected during pure marine scientific research expeditions to biotechnology companies.

7 Conclusions and possible approaches to bioprospecting in the deep seabed

This section takes stock of the main findings of the report, identifies areas for further study, and presents possible options to address deep seabed bioprospecting.

7.1 Main findings of the report

7.1.1. Status of, and threats to, deep seabed ecosystems

Oceans are an extremely rich ecosystem, home to many species and a huge biomass. 32 out of the existing 34 phyla are found in the oceans. Data indicate that the trends in discovery of new oceanic species, including deep sea species, are positive. This means that many more species of scientific and commercial interest are bound to be discovered.

Hydrothermal vents, which are of an ephemeral nature, are found almost ubiquitously along the world's mid-ocean ridges. Cold seeps, brine pools and other types of softbottom deep sea ecosystems exist in many ocean margins and continental shelves. The biodiversity of ocean floor sediments is extremely high.

Some deep seabed ecosystems and species are particularly sensitive to disturbances, including cold seeps and seamounts. The richness, extremely high sensitivity and poor resilience of seamount species, associated with their direct exposure to intensive deep sea fishing activities, call for a precautionary approach to their management. Specific studies are required on the impacts of oil drilling on cold seep ecosystems and species. Hydrothermal vents have various characteristics, depending on the intensity of local volcanic activity on the seafloor and hydrological conditions. A common feature is that hydrothermal vents act as center of irradiation of species towards virgin seabed areas. Specific management measures taking into account the dynamic nature of these ecosystems should be adopted.

Concern has grown over the impacts of both pure and applied scientific research in deep seabed areas. While it is impossible to quantify the damage caused by such research on the deep seabed environment, threats include the destruction of habitats, unsustainable collection, alteration of local hydrological and environmental conditions, and pollution of various nature. Similar activities can have very different impacts in various deep seabed ecosystems. Cumulative impacts over time, such as those associated with deep sea trawling, have already resulted in the extinction of species.

Technology is a key driver in deep sea research and monitoring. As technology evolves and becomes more accessible, including through the establishment of partnerships between governments and industry, scientific research in these areas is likely to increase.

This is likely to result in additional adverse impacts on the deep sea environment.

Aware of the potential impacts of marine scientific research on deep seabed ecosystems, many scientists have proposed establishing special scientific areas in the deep seabed. These areas are aimed to prevent or mitigate interference during the conduct of scientific expeditions, as well as avoid potential conflicting uses. Voluntary codes of conduct have also been developed to remedy the current lack of intergovernmentally-agreed measures.

Activities have recently been initiated at governmental level within the United Nations (UN) system by the General Assembly, including the Global Marine Assessment and the establishment of the *Ad hoc* Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction, as well as within the framework of the Convention on Biological Diversity (CBD). These initiatives will help further assess the status of, and threats to, deep seabed ecosystems and resources both within and beyond national jurisdiction, and help identify suitable management measures.

7.1.2. The value of deep seabed ecosystems and resources

There is a clear consensus among the scientific community that deep sea ecosystems perform important ecological functions, in spite of our limited knowledge about these ecosystems.

Deep seabed areas, especially hydrothermal vents, appear to be one of the nurseries of life on Earth. The peculiar characteristics of life in these extreme environments have offered hints about the evolution of life on Earth and how it could be shaped on other planets. Areas where methane hydrates are found play an important role in the maintenance of the global climate balance, as a result of their role as a greenhouse buffer. The role of hydrothermal plumes in supporting upper zooplankton communities demonstrates the importance of these ecosystems in the maintenance of the global carbon cycle. Ecological interlinkages have been observed between different deep seabed ecosystems, as well as between the ecosystems of different ocean realms. Moreover, some of the discovered deep seabed sites possess unique aesthetical features.

It is also widely recognized that deep seabed genetic resources, as a result of their particular biological characteristics that allow them to thrive in extreme conditions, hold great potential for various applications, including in the health sector, for industrial processes and bioremediation. Marine species have proven to be efficient in treating diseases such as carcinogenic tumors, and many experts concur in asserting that the potential of marine genes only commences to be unveiled. Once disclosed, the genome of many yet-to-be discovered deep seabed organisms will provide information that may be of crucial importance to various applications and sectors.

The features and potential of deep seabed ecosystems and resources should be taken into account when designing an appropriate management framework, which requires adopting a precautionary approach as well as the ecosystem approach. In designing a regime addressing the exploitation of deep seabed resources, consideration might also be given to the fact that private appropriation of these ecosystems and resources may not be appropriate with regard to their contributions to humankind, in terms of advancement of scientific knowledge and human welfare.

7.1.3. Trends in deep seabed research

Exploration of the deep seabed started as early as the 1870s, but it was not until 1977 that the first hydrothermal vents, one of the main features of the deep seabed, were discovered. Since then, deep seabed research activities have been conducted extensively.

Deep seabed expeditions are being undertaken at an increasing pace. It is estimated that at least 432 cruises to deep seabed sites have taken place in eleven years and that expeditions to deep seabed sites take place on a regular basis. These expeditions are carried out by scientists from a few nations, including the US, France, Japan, Germany and Canada. The most visited sites are vents located in the North-East Pacific, followed by those along the northern segment of the Mid-Atlantic Ridge, where one site alone, the Juan de Fuca Ridge, concentrates 72 cruises. Uncertainties remain regarding the jurisdiction within which vents are located. However, on the basis of the InterRidge Vent Database, it can be estimated that an even number of sites fall either within or beyond national jurisdiction.

The focus of ocean science is much more diversified than at the time of conventional oceanographic expeditions. Technological innovations, including satellite-based observations and the effective coupling of *in situ* and *ex situ* observations, have allowed the identification of new subject-areas for research, including the identification, development and commercialization of new products based on natural compounds. Section 4 showed the importance of marine resources in providing new sources of drugs, products and industries, and how this trend is likely to increase in the future, within the context of the global and regional biotechnology industry contexts.

Similarly, the focus of deep sea expeditions seems to be shifting from geological/geophysical purposes to ecological, biological, physiological and bioprospecting ones. Data indicate that deep seabed research activities are still mainly of a pure scientific research nature. However, promises of discoveries of novel organisms and products are likely to lead to an increase in commercially oriented research. This is all the more so since ocean expeditions and scientific programmes are increasingly designed and implemented on the basis of partnerships and joint ventures between public and private research institutions, governments and industry. As a result, modern oceanography is likely to become more interdisciplinary. This implies that distinguishing, in practice, between marine scientific research undertaken to advance knowledge of marine ecosystems, also called "pure scientific research," and marine scientific research undertaken for commercial purposes, also called "applied scientific research" - to which marine bioprospecting could be equated – is increasingly difficult.

Industry is not systematically involved in deep seabed exploration, but it is very interested in, and supportive

of, deep seabed research. Industry still largely depends on public research institutions which own the necessary technology and expertise to conduct deep seabed exploration. This reliance on public research institutions has allowed limiting multiple, potentially conflicting, uses of deep seabed resources and ecosystems. However, conflicting uses still exist, including between marine scientific research and fisheries activities, particularly deep sea trawling, and ocean drilling for the purposes of oil exploration and exploitation. Designing a comprehensive management regime for deep seabed ecosystems and resources will require taking into account these conflicts.

Following the general increase in the use of biodiversity for commercial purposes and the related growth in bioprospecting activities, bioprospecting for marine resources, including marine extremophiles, is likely to increase in the future. The advent of genomics and bioinformatics has paved the way for novel approaches to the identification of useful compounds and the development of new drugs, products and processes. This will also facilitate research on, and commercial development of, deep seabed genetic resources.

Section 3 showed that, following sampling and recovery from the deep seabed, various compounds from deep seabed organisms have been isolated, patented and developed for commercial application. Some products containing or developed on the basis of deep seabed genetic resources are already available on the market, and others may soon be commercialized. There are, however, difficulties in assessing the type of application and level of activity related to deep seabed genetic resources since information on origin and applications of the resources is not always readily available to the public or included in patent descriptions.

While public availability of research results of potential value for commercial applications remains limited, there seems to be an open exchange of information regarding research cruises, location of sites, and species discovered and identified. The scientific information thus disclosed is easily accessible through public, Internet-based databases, as well as relevant scientific publications. Such information has helped increase our knowledge of geological, biological, ecological, physiological and evolutionary processes related to the deep sea. It can also contribute to the development of new drugs, products and processes, and support the establishment of well-informed management and conservation measures. More particularly, the information gathered on deep seabed ecosystems and resources can support the work of various international organizations and institutions, such as the International Seabed Authority (ISA), the CBD, the Intergovernmental Oceanographic Commission of UNESCO (UNESCO-IOC), and regional marine-related bodies.

An increase in deep seabed bioprospecting remains subject to addressing the various technological and legal impediments that prevent a balanced development of activities related to deep seabed organisms, fruitful for all and respectful of the environment. Such impediments include ethical issues regarding patenting of inventions based on genetic resources, the high cost of necessary equipment and research expeditions, as well as the lack of a clear legal and institutional framework for access to these resources and sharing of the benefits arising out of their utilization. It is noteworthy that uncertainty over access procedures may act as major deterrent to investment in research, as may overly stringent conditions on access.

7.1.4. Current legal and policy framework

While science and technology evolve at a fast pace, the international legal and policy framework lags behind. Governments are still divided on whether, and if so, how to regulate deep seabed bioprospecting. This division is largely the result of knowledge gaps regarding the environmental impacts and economic potential of deep seabed bioprospecting, as well as questions regarding the relationship between marine scientific research – a High Seas freedom – and bioprospecting in areas beyond national jurisdiction, the legal status of genetic resources found in the Area as open-access or common heritage of humankind, and whether and how benefits should be shared from their recovery and use. To a large extent, the debate is reminiscent of that relating to deep seabed mineral resources several decades ago.

This section provides a brief summary of the international instruments relevant to deep seabed bioprospecting. By way of comparison, a brief overview is given of the framework for marine bioprospecting in areas within national jurisdiction.

7.1.4.1. Bioprospecting within national jurisdiction

Bioprospecting undertaken in the seabed within the limits of national jurisdiction is currently regulated by a set of measures found in the UN Convention on the Law of the Sea (UNCLOS), which determines States' jurisdiction, and rights and obligations in the oceans, as well as in the CBD, which provides for a specific set of measures on access to genetic resources and benefit-sharing.

On the basis of these instruments, bioprospectors intending to undertake research in a State's seabed are required to comply with this State's domestic legislation on marine scientific research, as well as its bioprospecting legislation, if such legislation has been adopted. While most States have adopted measures to regulate marine scientific research undertaken in their waters and seabed, only a handful of States have adopted legislation regulating access to, and exploitation of, their genetic resources, including their marine resources. Depending on the specific scope of legislation related to marine scientific research – i.e. addressing only pure scientific research or also dealing with applied research – bioprospecting could be regulated through this legislation in the absence of specific bioprospecting laws.

Some States have put in place measures, which, without specifically addressing bioprospecting, are aimed at ensuring the conservation and sustainable use of various deep seabed ecosystems, mainly hydrothermal vents. Canada established a marine protected area (MPA), within its waters, at the Endeavour site, Portugal, within the context of the Convention on the Protection of the Marine Environment of the North East Atlantic (OSPAR), proposed to establish an MPA for the Lucky Strike and Menez Gwen sites. Access to, as well as the type of research that can be undertaken within, these MPAs are strictly regulated on the basis of management plans and authorization procedures. To some extent, sharing of the results of pure research undertaken in those areas is provided for through the deposit of samples within a national collection and/or public dissemination of data and information. However, provisions for environmental impact assessment are absent.

Domestic measures susceptible to impact on the ability to undertake bioprospecting remain territorially based. As far as information available has allowed concluding, no State has adopted any legislation regulating pure marine scientific research or bioprospecting undertaken by their nationals or vessels under their control in international areas or under foreign jurisdiction.

7.1.4.2. Bioprospecting beyond national jurisdiction

There is currently no specific international regime addressing seabed bioprospecting carried out beyond national jurisdiction. Relevant measures are found in a number of international instruments, including UNCLOS, the CBD, various intellectual property rights (IPRs) instruments.

On the basis of the law of the sea framework set out in UNCLOS, the regulation of bioprospecting undertaken in marine areas beyond national jurisdiction falls within the jurisdiction of flag States. To date, no State has adopted any measure addressing bioprospecting undertaken by their nationals outside the limits of national jurisdiction. Moreover, legislation addressing marine scientific research tends to be territorially based.

What follows is a summary of the key issues and gaps that need to be addressed within relevant instruments.

The UN Convention on the Law of the Sea

- UNCLOS provides the legal framework to organize activities undertaken in the oceans in order to ensure, *inter alia*, the "equitable and efficient utilization of their resources, the conservation of their living resources, and the study, protection and preservation of the marine environment."
- The regime of the Area, defined as the seabed and ocean floor and subsoil thereof beyond the limits of national jurisdiction, is set out under Part XI of UNCLOS and the 1994 Implementation Agreement. The Area and its resources are recognized with the status of common heritage of humankind. However, the regime flowing from this principle and set out under Part XI does not apply to all resources of the Area, but only to mineral resources. The main features of the regime are those of: non-appropriation over the Area or its resources; international management through an international institution; peaceful use of the Area and its resources;

and sharing with humankind of the benefits resulting from activities related to the Area or its resources.

- Does the exclusion of living resources from the regime set out under Part XI on the Area imply that genetic resources located in the Area fall under the regime governing the High Seas, as organized under Part VII? The answer is not a clear-cut case. The language of UNCLOS regarding living resources, including such terms as "harvestable stage" or "sedentary" is applicable to macrofauna such as fisheries. However, this language is not appropriate with regard to microorganisms such as genetic resources, which are collected or sampled, but not "harvested." Moreover, these microorganisms can be either sedentary or not depending on their biological/physiological characteristics.
- The question arises whether the distinction made in Article 77 between living species that are sedentary and those that are not, is also applicable to living resources found in the Area. If it is, a fragmented regime ensues between genetic resources which then would fall under the regime of the High Seas (because belonging to the water column) and those that should be regulated by the regime of the Area (because belonging to the seabed and its subsoil).
- Distinguishing, in practice, between pure marine scientific research and research undertaken for commercial purposes is difficult. The lack of clear definition, within the context of UNCLOS, of marine scientific research as well as of prospecting, to which bioprospecting could be compared, contributes to this difficulty.
- Currently, deep seabed bioprospecting falls under flag States' legislation. It is not addressed *per se* under UNCLOS.
- The distinction between bioprospecting and marine scientific research, if any and appropriate, should be clearly articulated in order to define the regime that ensues with regard to treatment of information and data acquired during research. Marine scientific research undertaken in the Area should be carried out for the benefit of humankind as a whole, and research results made public and disseminated. This has to be reconciled with the need for confidentiality of data gathered for commercial purposes, such as in the case of bioprospecting. There are provisions for data confidentiality in the case of prospection for mineral resources in the Area, but there is no counterpart regarding confidentiality of data and exclusive rights in the case of prospection for biological resources in the Area.
- The provisions of UNCLOS related to the protection of the marine environment, as well as those related to technology transfer apply, presumably, to bioprospecting activities and technology.

The Convention on Biological Diversity

 The CBD provides a framework for the conservation and sustainable use of biological resources, including marine resources, as well as for the equitable sharing of the benefits arising from their utilization. With regard to marine areas, the CBD is to be implemented consistently with States' rights and obligations under the framework of the law of the sea.

- Under the CBD, genetic resources located in areas beyond national jurisdiction are only dealt with to the extent that processes and activities carried out under the control or jurisdiction of a State, within or beyond national jurisdiction, have or are likely to have a significant adverse impact on such resources or areas. With regard to deep seabed genetic resources, this implies that flag States are under the obligation to regulate bioprospecting or marine scientific research undertaken by their nationals or vessels flying their flag, within the framework of the law of the sea, only when such activities present a risk of significant adverse impact on the marine environment.
- With regard to conservation and sustainable use measures, this raises the issue of the threshold required for action: what is considered to be an adverse impact? What is a "significant" adverse impact? The level of what can be deemed significant clearly differs depending on factors such as the ecosystem to which it applies, since what may cause irreversible damage in the deep seabed may only cause moderate damage in the water column, for example. Would repeated collection and sampling at hydrothermal vent sites be considered as a significant adverse impact? The answer depends on the type and level of impacts that such activities bear on the resources themselves, as much as on the surrounding environment.
- With regard to access to, and sharing of the benefits arising from, deep seabed genetic resources, the CBD and the Bonn Guidelines on Access and Benefit-Sharing provide a useful model, including such procedures as prior informed consent of the owner of the resources, and arrangements for sharing of ensuing benefits. However, such a model, which remains of a bilateral nature and based on the assumption of national sovereignty over resources, would require being adapted to the multilateral framework of deep seabed activities and open-access resources. Section 7.3. further elaborates on how access and benefit-sharing measures under the CBD could be adapted to deep seabed genetic resources.

Intellectual property rights instruments

- Instruments on IPRs, including the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, and the Agreement on Trade-Related Aspects of Intellectual Property Rights of the World Trade Organization, have a role in regulating the use of information, data, and inventions ensuing from biological material, including deep seabed genetic resources.
- These instruments lack a clear definition of what can be considered as microorganisms or resources suitable for patentability.
- As they are currently designed, patent classification systems and databases do not permit clearly tracking and identification of marine microorganisms.
- There is a need to define precisely what is covered by an invention, and whether describing the sequence of a genome can be considered an invention, for example.
- IPRs instruments and traditional systems of protection of intellectual property may be inadequate with regard

to inventions stemming from biological resources, which are of common public interest.

- By way of benefit-sharing mechanisms, disclosure requirements, within patent applications, may be considered with regard to genetic resources considered as open-access or common heritage of humankind. Such disclosure could be implemented through deposit of samples within designated public collections, as in the case of the Budapest Treaty.
- There is a need for further economic analysis of the benefits and disadvantages of patentability of life forms, including its effects on promoting research and innovation.

7.2. Issues to be addressed and areas requiring further study

This report has brought to light a number of issues that need clarification and/or further work. The following are some of the main questions to be addressed:

- There is a need to further research the content and nature of, and trends in, patent claims with regard to deep seabed genetic resources, in order to better assess and monitor trends in the use of such organisms. This requires greater responsiveness from patent classification systems and databases, including through the adoption of classifiers relating to marine organisms.
- 2) Further study regarding public-private partnerships for deep seabed bioprospecting is also necessary. Such study could explore the role of publicly-funded and private research institutions in the discovery and development of deep seabed valuable compounds, the types of partnerships established, and issues related to IPRs and benefit-sharing.
- 3) There is a need to clearly identify and define what bioprospecting covers, as well as develop criteria and guidelines to assist States in ascertaining the nature and implications of marine scientific research, as called for under Article 251 of UNCLOS. Should marine scientific research and bioprospecting be treated differently, considering practical difficulties in establishing the difference? Should researchers/academia and private companies be treated differently in terms of access to deep seabed genetic resources? Clarifying these issues is particularly important considering that, while marine scientific research is among the most direct threats to deep seabed ecosystems, it is also necessary to increase our knowledge of these ecosystems.
- 4) Parties to UNCLOS need to make the political decision whether living resources associated with the seabed beyond national jurisdiction fall within the regime of the High Seas, and are therefore openly accessible, or within the regime of the Area, and are therefore a common heritage of humankind.
- 5) Additional uncertainty regarding the regime applicable to deep seabed genetic resources and related activities carried out in the deep seabed results from the fact that claims to an extended continental shelf, beyond the 200

nautical miles, are still being filed. This implies that the precise delineation of the Area is not yet defined, and that uncertainty exists as to whether specific deep seabed bioprospecting activities fall under the regulation of national legislation or remain currently unregulated.

- 6) Because conservation measures are necessary, as a precaution, and are likely to impact on deep seabed bioprospecting and vice-versa, it is important to see how such measures, including possibly the establishment of MPAs, can accommodate the needs of pure and applied science, as well as States' rights within international areas.
- 7) In order to adequately assess the type and level of conservation measures required, further international scientific programmes, including monitoring activities, should be designed, implemented and adequately funded. Authoritative scientific assessments of deep seabed ecosystems and deep seabed genetic resources should be produced regularly. In addition to independent scientific assessments, reporting requirements, within the UNCLOS and CBD frameworks, as well as within regional frameworks, provide a basis upon which deep seabed bioprospecting activities can be assessed and monitored.
- 8) The benefits and role of voluntary initiatives in implementing conservation and sustainable use measures, including voluntary codes of conduct, should be taken into account. These could be used as temporary measures while regulations are being developed.
- 9) Issues related to technology transfer, including "clean technology," need to be considered. These issues relate, among others, to the modalities of the transfer, as well as to the desirability of such transfer with regard to conservation needs. If transfer of technology related to deep seabed bioprospecting is deemed undesirable, sharing of benefits should be ensured through the widest possible dissemination of research results.
- 10) Several aspects of the role of IPRs with regard to deep seabed genetic resources, including their socioeconomic and ethical aspects, need to be further studied. The role of IPRs in stimulating research, contributing to a sustainable use of resources and ensuring sharing of benefits resulting from the use of deep seabed genetic resources, cannot be taken for granted but cannot be overlooked. The need for a *sui generis* system of IPRs should be explored, should it be decided that these resources are the common heritage of humankind.
- Adequately defining what genetic resources are and what the scope of intellectual property instruments covers (e.g. broad or restricted definition of microorganisms) is also required.
- 12) There is a need to ensure consistency between the rules related to IPRs and those related to sharing of information resulting from marine scientific research in the Area. This is intimately linked to clarifying the

distinction between marine scientific research and bioprospecting.

13) The question of how sharing of benefits can be organized should be further studied. Monetary as well as nonmonetary benefits, including technology transfer and capacity building need to be explored. Issues to consider regarding benefit-sharing include the modalities to ensure that the sharing is fair and equitable, as well as whom the beneficiaries should be. A requirement of disclosure of origin, within patent applications, may ensure that benefits are shared equitably. These questions are intimately linked to the status of deep seabed genetic resources.

7.3. Feasible approaches to designing a regime for bioprospecting in the deep seabed

The international community will be able to determine the desirability and modalities of an international regime for deep seabed bioprospecting, on the basis of the clarifications obtained on the above-mentioned issues. These clarifications can be obtained through further work and cooperation within such fora as the UN Informal Consultative Process on Oceans and the Law of the Sea (ICP), the UN *Ad hoc* Working Group on biodiversity beyond national jurisdiction, the CBD and UN-Oceans. The UN General Assembly, due to its large participation and broad mandate under the UN Charter, seems to be the most appropriate forum to determine ways forward regarding discussions on possible options for a regime. Some available options are exposed below.

It should be noted, at the outset, that a wide range of actors have a key interest in the way deep seabed resources and ecosystems are managed and used. While the most obvious of these remain academia and industry, including the chemical, health, energy, food, and pharmaceutical sectors, governments also have various interests in the issues related to deep seabed ecosystems, ranging from compliance with treaty obligations (e.g. UNCLOS, environmental agreements, IPRs instruments, etc.) to a share in the benefits ensuing from the development and use of deep seabed resources. For a successful regime to be designed and implemented, it is therefore necessary to involve all relevant actors in the process, i.e. governments, academia, industry, indigenous representatives, and civil society.

7.3.1. Retaining the status quo

Retaining the *status quo* would entail that access to, and use of, deep seabed genetic resources remain unregulated and open. As it stands, the responsibility to adopt measures to regulate activities carried out in the Area or in the High Seas lays with flag States.

Advantages

• The CBD-UNDOALOS Study pointed to the stimulation of research and investment.

Disadvantages

- Risks of over-exploitation and destruction of habitats are not negligible if no conservation and sustainable use measures are put in place.
- Provided that flag States adopt relevant measures, such an approach may entail the adoption of uncoordinated, if not contradictory, measures. This would be inappropriate with respect to conservation needs related to deep seabed ecosystems.
- It appears that lack of a clear regulatory framework and procedures act as a deterrent to investment in research.
- The *status quo* favors the minority of those that have the technology and financial resources to access deep seabed ecosystems. While provisions for technology transfer and capacity building are provided for under UNCLOS with regard to marine scientific research, practical steps in this regard have been limited.
- There is currently no organized framework for an equitable sharing of the benefits resulting from the exploitation of genetic resources which are, to a large extent, deemed of public interest. This approach would therefore be inappropriate with regard to benefit-sharing needs, should States agree that deep seabed genetic resources are the common heritage of humankind.
- Issues associated with the patenting of deep seabed organisms would also remain unresolved.

If the *status quo* is maintained, it would be worth considering expanding the mandate of the ISA with respect to the Area's biodiversity in order to allow it to regulate activities related to living resources of the Area, in addition to those related to mineral resources only.

7.3.2. Using regional frameworks

As a first step towards an integrated regime, the use of regional instruments for the protection of the marine environment could be contemplated. Such instruments provide a framework to organize cooperation and harmonize management measures within their respective geographical area.

Advantages

- Using regional instruments would ensure that measures adopted to regulate activities undertaken within deep seabed ecosystems, including the establishment of MPAs, are in conformity with the law of the sea framework.
- Regional instruments often include requirements for prior environmental impacts assessments, as well as monitoring activities regarding the status of, and threats to, the marine environment.

Disadvantages

- Regional instruments cover a relatively small part of areas beyond national jurisdiction.
- Not all regional frameworks presented in this report cover all relevant aspects associated with deep seabed bioprospecting. Particularly, the issue of sharing of information and data, as well as benefits ensuing

from the use of such resources, if such use is allowed, may not be adequately covered.

• The institutional framework of some instruments may be weak, e.g. lack of periodicity in meetings of the Parties, lack of a permanent structure mandated with operational and organizational responsibilities, lack of adequate scientific input...

Among the various regional instruments that could be used as models *per se* to regulate deep seabed bioprospecting, it is worth highlighting the framework of the Antarctic Treaty System (ATS), the key aspects of which include:

- planning and notification of research activities undertaken in the area covered by the Antarctic Treaty;
- information sharing;
- a set of conservation principles and measures, including the establishment of MPAs;
- an institutional framework, under the Convention for the Conservation of Antarctic Marine Living Resources, made up of: a Commission mandated to, *inter alia*, facilitate research, disseminate information, and revise conservation measures; and a Scientific Committee for consultation and information exchange purposes;
- priority accorded to scientific research over any other activity;
- detailed provisions for environmental impact assessments under the Madrid Protocol on Environmental Protection;
- a system of inspections;
- a system of authorization regarding prospecting, exploration and exploitation of mineral resources under the Convention on the Regulation of Antarctic Mineral Resources Activities; and
- the confidential treatment of data and information that have potential commercial value.

While the ATS may be used as a model to address bioprospecting in the deep seabed, it should be stressed that its provisions are based on conflicting claims to sovereignty over parts of the Antarctic and its waters. Any regime on bioprospecting, modeled on the ATS, would have to take into account the fact that the Area is common heritage of humankind, over which no sovereignty claims can be exercised. Such a regime should also be adapted to the legal status of deep seabed genetic resources – i.e. open-access, common heritage of humankind, or of a *sui generis* status. Moreover, it should be borne in mind that the issue remains open as to whether some of the provisions of the system (i.e. those of the Madrid Protocol) are applicable to the deep seabed.

7.3.3. Adoption of guidelines by the General Assembly

Among the options available, the UN General Assembly could adopt a resolution containing guidelines or principles on deep seabed bioprospecting. Such guidelines or principles, which could be prepared by the ICP or the UN *Ad hoc* Working Group on biodiversity beyond national jurisdiction, could be used as a temporary framework until a binding regime is developed, if such a regime was deemed desirable.

Advantages

- This approach would accommodate the urgency to take action, since it would facilitate the conciliation of diverging views within a relatively shorter timeframe than if a convention or treaty were considered.
- The adoption of guidelines or principles by the UN General Assembly would reflect broad governmental support to addressing deep seabed bioprospecting.

Disadvantages

- The guidelines or principles would remain nonlegally binding.
- Guidelines or principles do not allow for a great level of details. Such guidelines should therefore be complemented by a code of conduct setting out ways to operationalize the guidelines or principles.

Based on the current patchwork framework, guidelines or principles could focus on organizing cooperation and coordination between flag States and, drawing upon existing global and regional instruments, including measures on conservation, sustainable use, cooperation in marine scientific research, information sharing and capacity building, monitoring, as well as certain principles regarding sharing of ensuing benefits, and the use of voluntary codes of conduct. The guidelines should clearly address the distinction between pure marine scientific research and bioprospecting. The resolution should consider an appropriate institutional framework to coordinate implementation of the guidelines. The regulations of the ISA relating to prospecting could be used as a valuable input in the elaboration of the guidelines.

With regard to conservation measures, the guidelines may address: MPAs; procedures of notification or authorization to regulate access to deep seabed ecosystems; collection/ sample quotas and regulation of equipment; and environmental impact assessments.

With regard to benefit-sharing, several aspects would need to be addressed, including:

- the treatment of information and data collected during marine scientific research, as well as the procedure for maintaining confidentiality or disseminating information;
- the possible use of a disclosure mechanism similar to that set out in the Budapest Treaty;
- the modalities for technology transfer and capacity building; and
- with regard to monetary benefits, the possible establishment of a common fund financed by a share in the profits ensuing from the development and commercialization of deep seabed genetic resources.

7.3.4. Using the framework of the Convention on Biological Diversity

The CBD provides a framework within which the ethical, socioeconomic and environmental aspects of deep seabed activities can be reconciled, through a balanced implementation of the three objectives of the Convention.

Advantages

- •The CBD provides a framework to coordinate flag States activities for the conservation and sustainable use of deep seabed genetic resources.
- A substantial amount of work and activities undertaken within CBD fora are of relevance to deep seabed bioprospecting, including work on: conservation measures, including MPAs; access and benefit-sharing, including the Bonn Guidelines on Access and Benefit-Sharing; the role of IPRs with regard to biological resources; technology transfer; and exchange of information, through the Clearing-House Mechanism. Such work provides a good starting point to elaborate a specific regime for bioprospecting in the deep seabed.

Disadvantages

- Activities related to deep seabed genetic resources are only regulated under the CBD in so far as they have or are likely to have a significant adverse impact on the marine environment. In order to ensure that deep seabed bioprospecting is regulated, regardless of its impacts, notably with regard to the issue of benefit-sharing, amendments would be required.
- The institutional framework of the CBD is not appropriate to address issues of access to, and sharing of the benefits arising from, deep seabed genetic resources, which fall beyond national jurisdiction. If a system of prior notification is envisioned, the Secretariat could receive such notifications. However, if a system of authorization is favored, a structure with the political authority to grant such access would be needed. While the Conference of the Parties (COP) has such authority, the frequency of its meetings does not seem appropriate to consider access applications. The Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) could be such a structure, considering its mandate regarding scientific, technical and technological matters. Amending Article 25, which sets out the responsibilities of the SBSTTA, would be necessary. With regard to benefit-sharing, a smaller permanent structure may be more desirable in order to negotiate arrangements with bioprospectors and act as a mechanism for the distribution of such benefits. Such a structure could be a new subsidiary body.
- Amending the CBD or adopting a Protocol is likely to be a lengthy endeavor considering States' reluctance to address the issue of deep seabed bioprospecting. Moreover, consensus is far from being achieved on the legitimacy, for the CBD, to address issues related to resources found in areas beyond national jurisdiction, particularly with regard to marine areas.
- As for UNCLOS, the US, one of the major actors in marine scientific research, is not a Party to the CBD.

If amendments were considered by Parties, the following articles merit attention:

- Article 2 to include a definition of bioprospecting;
- Article 8(I) to remove the threshold required for conservation action;
- Article 15, on access to genetic resources, to specify that

access to resources found in international areas may require prior notification to/authorization from the national government of the applicants or from a designated institutional structure within the CBD framework (e.g. the Secretariat, the SBSTTA or a new subsidiary body);

- Article 19, on handling of biotechnology and distribution of its benefits, to ensure that benefits arising out of the utilization of genetic resources from international areas are shared with all other Parties;

- Article 24 to expand the mandate of the Secretariat; and - Article 25 to expand the mandate of the SBSTTA.

Other amendments may be required, as appropriate, depending on the level and type of regulation desired. Such amendments would need to be proposed by any Party to the Convention, and adopted by the COP by consensus, or failing which, by a two-third majority (Article 29). The adoption of a Protocol (Article 28) is also a possibility, particularly if a specific institutional framework to grant access authorization and negotiate benefit-sharing arrangements is envisioned.

7.3.5. Applying the regime of the Area

The regime of the Area could be used as a model or be applied *per se* to the bioprospecting following appropriate amendments to UNCLOS, since this regime only applies to non-living resources as it stands.

Under the regime of common heritage of humankind, deep seabed genetic resources would not be subject to private appropriation, should only be used for peaceful purposes, and would be managed by an international institution. The benefits ensuing from the utilization of these resources should also be shared with humankind as a whole.

Advantages

- Through the concept of common heritage of humankind, this regime covers all the issues associated with deep seabed activities, i.e. ethical, socioeconomic and environmental ones.
- The regime includes provisions for organizing and controlling exploration and exploitation activities, as well as measures for the sharing of benefits, through technology transfer and knowledge and information sharing.
- An institutional framework, the International Seabed Authority (ISA), is already in place and is operational.
- Management of deep seabed genetic resources by the ISA would respond to the needs of the ecosystem approach to conservation and sustainable use.

Disadvantages

 Bringing living resources within the scope of the Area's regime and the International Seabed Authority's (ISA) mandate, would require either: amending UNCLOS; adopting a Protocol; developing an implementing agreement; or adopting an agreed interpretation of UNCLOS by States Parties, stating that genetic resources found in the Area fall under the regime of either Part XI or Part VII, and clarifying the relation between MSR and (bio)prospecting.

- These options to bring living resources within the scope of the Area's regime are likely to prove time consuming and difficult to negotiate since States are still divided on whether the regime of the Area and ISA should deal with living resources.
- It is also noteworthy that the US, one of the major States involved in deep seabed activities, is not a Party to UNCLOS.

In amending UNCLOS, the following articles should be considered:

Article 1 (Part I) to include definitions for: MSR, prospecting, exploration and exploitation, as well as bioprospecting; and living resources, to include genetic resources;
Article 77 (Part VI) to remove the distinction between sedentary and non-sedentary living resources; and
Article 133 (Part XI) to include living resources within the scope of the resources covered by the regime of the Area.

Depending on the extent to which Parties intend to regulate bioprospecting and the desired institutional framework, other amendments would be required regarding, among others, provisions addressing publication and dissemination of information, as well as the responsibilities of the ISA.

It is noteworthy that pursuant to Article 312 of UNCLOS, amendments, other than those related to activities in the Area, should be proposed by a Party. A conference, mandated with considering such amendments, would be convened if not less than half of the Parties replied favorably to the proposals within a year. A simplified procedure is also provided for (Article 313). The voting procedure shall be that used during the Third UN Conference on the Law of the Sea.

With regard to amendments of the provisions relating exclusively to activities in the Area (Article 314), a Party

makes proposals for amendments, which are subject to approval by the ISA. Under the 1994 Implementation Agreement (Section 4), the Assembly of the ISA may undertake a review of the provisions of Part XI and relevant Annexes at any time. The voting procedure shall be that used during the Third UN Conference on the Law of the Sea.

Considering the difficulties associated with bringing living resources within the scope of the Area's regime, this regime could be used as a model to develop a standalone regime for activities carried out with respect to living resources of the Area, in conformity with UNCLOS. Similarly, the regulations developed by the ISA can be used as models to address the impacts of bioprospecting activities. However, as for the previous options, negotiating such a framework is likely to prove time consuming.

A new institution, possibly modeled on the ISA, could be set up with the mandate to adopt conservation measures, authorize or receive notification of access to deep seabed genetic resources, act as a focal point for the transfer of technology and information exchange, as well as the designated authority to receive samples of resources collected, negotiate benefit-sharing arrangements, and supervise a system of inspections. The framework within which such institution would be established remains to be determined, but options include a subsidiary body of the UN General Assembly and a standalone organization outside the UN system.

Whether and how the various options set out above should be explored shall be decided by the UN General Assembly on the basis of solid, comprehensive information about all the aspects of the issue. Further studies should be undertaken cooperatively within the UN system in order to address the various ethical, socioeconomic, environmental, scientific and legal aspects of the issue. It is hoped that this report provided a useful starting point for these studies.

Endnotes

1 Ametasearch of the databases of relevant authoritative scientific journals, including Nature, Nature Biotechnology, Science and Deep-Sea Research, using various keywords (e.g. bioprospecting, cold seeps, deep sea bioprospecting, deep sea ecosystems, deep sea genetic resources, deep seabed bioprospecting, deep seabed ecosystems, deep seabed genetic resources, extremophiles, gas hydrates, hot vents, hydrothermal vents, marine extremophiles, methane hydrates, seamounts, seeps), has led to the identification of more than 400 scientific articles. These articles contained references to other relevant studies. It is therefore possible to conclude that a large body of scientific literature on deep seabed ecosystems, generally supported by a very high degree of evidence, is available.

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4 The technology requirements associated with the exploration and exploitation of deep seabed organisms, including those necessary for their isolation and culture, are described in section 3 of this report.

5 Hydrothermal vents are also located in unstable systems, as these are areas that are geologically very active.

6 Continental slopes belong to the same oceanic realm as the sediments of the abyssal plain. The two together constitute the realm of hidden boundaries (source: Baseline Report of the Census of Marine Life).

7 Art.76, United Nations Convention on the Law of the Sea, hereafter referred to as "UNCLOS."

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66 Nisbet, E.G., "The Realms of Archean Life" (2000) Nature 405, 625-626.

67 InterRidge is an international initiative by scientists, which aims at promoting coordination for all aspects of mid-ocean ridges (scientific activities, operations, information exchange, etc.). See: http://interridge.org/>.

68 Hannington, M.D., Petersen, S., Herzig, P.M. & Jonasson, I.R., "A Global Database of Seafloor Hydrothermal Systems, Including a Digital Database of Geochemical Analyses of Seafloor Polymetallic Sulfides Prepared for the International Seabed Authority, Central Data Repository," (2002) Version 1.0. Available at: http://www.cdr.isa.org.jm/doc/data-rep/vents-sulphides/documentation_ver1.doc> (last visited on 1 December 2004).

69 ISA's Hydrothermal Vent Systems and Sulphide Database is available at <http://www.cdr.isa.org.jm/servlet/page?_ pageid=326,328&_dad=portal30&_schema=PORTAL30> (last visited on 15 December 2004). Polymetallic massive sulfide deposits are typically associated with high-temperature (ca. 350°C) black smoker vents that occur in areas of active or recently active volcanism (e.g. deep sea mid-ocean ridges, sedimented ridges, mid-plate seamounts, arc volcanoes, backarc rift environments). Low temperature hydrothermal vents and associated mineral deposits are typically found at the margins of high temperature vent fields or in shallow water settings adjacent to volcanically active landmass.

70 See <http://www.interridge.org>.

71 Glowka, L., "Bioprospecting, Alien Invasive Species, and Hydrothermal Vents: Three Emerging Legal Issues in the Conservation and Sustainable Use of Biodiversity" (2000) Tulane Environmental Law Journal 13(2), 329-360.

72 Korn, H., Friedrich, S., *et al.*, "Deep Sea Genetic Resources in the Context of the Convention on Biological Diversity and the United Nations Convention on the Law of the Sea", 2003, German Federal Agency for Nature Conservation, 83 pp. Also Leary, D.K., "Emerging Legal Regimes Regulating Bioprospecting for Thermophiles and Hyperthermophiles of Hydrothermal Vents" (2003) Journal of Marine Biotechnology (forthcoming).

73 Art.12(b), Convention on Biological Diversity, hereafter referred to as "CBD."

74 "Progress Report on the Implementation of the Programmes of Work on the Biological Diversity of Inland Water Ecosystems, Marine and Coastal Biological Diversity, and Forest Biological Diversity - Information on Marine and Coastal Genetic Resources, Including Bioprospecting" (UNEP/CBD/COP/5/INF/7). The Encyclopedia of Biodiversity defines bioprospecting as the "systematic search for genes, natural compounds, designs, and whole organisms in wild life with a potential for product development by biological observation and biophysical, biochemical, and genetic methods, without disruption to nature." (Academic Press, 2001, p.471).

75 Glossary, New Zealand Biodiversity Strategy, 2000.

76 Glossary of the European Community Clearing-House Mechanism <http://biodiversity-chm.eea.eu.int/ CHMIndexTerms/Glossary/B/bioprospecting> (visited on 16 November 2004).

77 Art.1, Act No.10 of 2004: National Environmental Management: Biodiversity Act.

78 Section 5(a), Wildlife Resources Conservation and Protection Act, Republic Act No.9147 of 19 March 2001.

79 It has been proposed to distinguish between "biodiscovery"

and "bioprospecting." Biodiscovery would cover the first phase of scientific research, and be equivalent, in this regard, to prospecting for mineral resources. Bioprospecting would cover the subsequent phases of re-collection of the resources for purposes of further investigation and eventual commercial application, and be closer, in this respect, to exploration and exploitation of mineral resources. It is assumed that the regime for authorizing access in both sets of circumstances would differ as well as the regime for, and modalities of, benefit-sharing. See Workshop on Bioprospecting in the High Seas (28 - 29 November 2003, Dunedin, New Zealand), report available at <http://www.fish. govt.nz/current/deepsea/workshop-report-bioprospecting-inthe-high-seas.doc>, hereafter referred to as "Dunedin Workshop Report." Queensland's 2004 Biodiscovery Act seems to use the term biodiscovery as a synonym of bioprospecting, defining biodiscovery as "a) research or b) the commercialization of native biological material or a product of biodiscovery research." Biodiscovery research is "the analysis of molecular, biochemical or genetic information about native biological material for the purpose of commercializing the material" (Schedule, Biodiscovery Act 2004 (No.19)).

80 Art.246(5), UNCLOS.

81 Art.251, UNCLOS.

82 "Study of the Relationship between the Convention on Biological Diversity and the United Nations Convention on the Law of the Sea with Regard to the Conservation and Sustainable Use of Genetic Resources on the Deep Seabed" (UNEP/CBD/ SBSTTA/8/INF/3/Rev.1), hereafter referred to as "CBD-UNDOALOS Study."

83 Regulation 1(3)(e), Regulations on Prospecting and Exploration for Polymetallic Nodules, hereafter referred to as "Polymetallic Nodules Regulations."

84 Regulations 6 and 35, Polymetallic Nodules Regulations.

85 Art.2(2), Annex III, UNCLOS; Regulation 2(a), Polymetallic Nodules Regulations.

86 Para 420 and 422, "Oceans and the law of the sea. Report by the Secretary-General" (A/57/57).

87 A Dictionary of Biology, Oxford University Press, 2000.

88 Nee, S., "More than Meets the Eye" (2004) Nature 429, 804-805.

89 Oldham, P., Global Status and Trends in Intellectual Property Claims: Microorganisms, 2004, Centre for Economic and Social Aspects of Genomics, 42 pp.

90 Many of these research programmes are reported in the InterRidge MOR & BAB Cruise Database, available at http://www.interridge.org.

91 See http://www.mpch-mainz.mpg.de/~geo/Arctic/ Cruise2001/> (last visited on 22 December 2004).

92 See <http://www.challengerexpedition.com/> (visited on 7 March 2005).

93 Using DNA technology, the Census will retrieve gene sequences from old preserved samples of formaldehyde obtained during the Continuous Plankton Recorder campaigns dating back 70 years. 94 The Census of Marine Life reports that 11 seamount research programmes are currently being carried out.

95 The European Commission-funded project HERMES will form the nucleus of the Continental Margins activities.

96 Two other categories of activities complete current efforts under the Census of Marine Life: the Drifters activities, including the Census of Marine Zooplankton (CMarZ, coordinated by the US, Japan and Germany); and the Swimmers activities, including on Tagging of Pacific Pelagics (TOPP, coordinated by the US).

97 See <http://www.esf.org/esf_article.php?language=o&articl e=127&domain=3&activity=7> (visited on 22 December 2004). 98 Ifremer, Annual Report 2003, 80 pp. See also <http://www.

ifremer.fr/droep>. 99 See <http://www.pmel.noaa.gov/vents/> (last visited on 22

December 2004). 100 See: http://www.sorcerer2expedition.org/version1/HTML/main.htm, visited on 12 May 2005.

101 See: http://www.venterinstitute.org/press/news/news_

2005_02_24.php, visited on 12 May 2005.

102 See <http://www.marbec.org/index.asp> (last visited on 16 December 2004).

103 See http://www.amnh.org/nationalcenter/expeditions/blacksmokers/> (visited on 16 December 2004).

104 See <http://www.ocean.washington.edu/outreach/revel> (last visited on 6 March 2005).

105 In addition to conducting Internet-based research, the authors of this report sought information from the main private and public entities identified as either holding relevant patents or having commercialized products based on deep seabed genetic resources. A questionnaire was sent out to clarify the nature, level and modalities of public-private partnerships. Out of the dozen entities contacted, only one responded.

106 Rappuoli, R., "Reverse Vaccinology, a Genome-based Approach to Vaccine Development" (2001) Vaccine 19, 2688-2691. Also, Rappuoli, R. & Covacci, A., "Reverse Vaccinology and Genomics" (2003) Science 302, 602.

107 Oldham, P., Global Status and Trends in Intellectual Property Claims: Microorganisms, 2004, Centre for Economic and Social Aspects of Genomics, 42 pp.

108 A summary of views, prepared by the WTO Secretariat in 2002, regarding the relationship between the WTO TRIPS Agreement and the CBD offers an account of the debate regarding patentability of genetic material ("The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity - Summary of Issues Raised and Points Made. Note by the Secretariat" (IP/C/W/368)). One view is that allowing patents to be granted in respect of genetic material would limit access to such genetic material and may conflict with countries' sovereign rights over their genetic resources. It has also been noted that failure to fulfill closely the criteria for patentability, namely those of novelty, inventive step (or non-obviousness) and industrial applicability (or usefulness) may lead to: granting patents covering genetic material in their natural state, considering that some countries define inventions to include discovery of naturally-occurring matter; and granting patents for genetic material that has been merely isolated from nature without having undergone any genetic modification from man's hands. In response, the summary notes that holding a patent on isolated or modified genetic materials does not amount to ownership of the genetic materials themselves, nor does it provide property rights with regard to the source from which the original material was obtained. It also notes that life forms in their natural state would not satisfy the criteria for patentability in the TRIPS Agreement, unless the subject-matter of a patent has involved sufficient human intervention, such as production by means of a technical process or isolation or purification, and if the isolated or purified subject is not of a previously recognized existence (Para 14-19).

 109
 See
 http://www.newscientist.com/news/print.jsp?id=ns99991503> (last visited on 12 December 2004).

110 See <http://www.sederma.fr>, 'Patent corner' (visited on 10 November 2004). Also: Mas-Chamberlin, C., Mondon, P., Lamy, F., Scocci, S., De Givry, L., Vissac, F. & Lintner, K., "Heat- and UV-stable Cosmetic Enzymes from Deep Sea Bacteria" (2002) Cosmetics & Toiletries 117(4), 22-30. Lintner, K., Lamy, F., Mas-Chamberlin, C., Mondon, P., Scocci, S., Buche, P. & Girard P., "Heat-Stable Enzymes from Deep Sea Bacteria: A Key Tool for Skin Protection Against UV-A Induced Free Radicals" (2002) IFSCC Magazine 5(3), 195-200.

111 The name of the specific product derived from *T. thermophilus* was not specified in information retrieved from http://www.californiatan.com/> (visited on 12 December 2004).

112 See <http://www.roche-diagnostics.com/ba_rmd/patent_ list.html> (last visited on 14 December 2004).

113 See <http://www.diversa.com/inteprop/issupate.asp> (visited on 10 November 2004).

114 See <http://www.diversa.com/corpinfo/corpalli.asp> (last visited on 22 December 2004).

115 See <http://www.diversa.com/presrele/2004/view_release. asp?id=20041122> (visited on 13 December 2004).

116 See <http://www.diversa.com/markprod/prod/pyro.asp>

(last visited on 14 December 2004).

117 See <http://www.invitrogen.com/content.cfm?pageid=3450> (visited on 14 December 2004).

118 See <http://www.neb.com/nebecomm/products/ productM0258.asp> (visited on 15 December 2004). Also, Wirsen, C.O., Molyneaux, S.J. & Langworthy, T.A., "Comparative Physiological Studies on Hyperthermophilic Archaea Isolated from Deep-Sea Hot Vents with Emphasis on Pyrococcus Strain GB-D" (1992) Applied and Environmental Microbiology 58, 3472-3481.

 119
 See
 <http://www.neb.com/nebecomm/products/</th>

 productMo261.asp> (visited on 15 December 2004).

120 See <http://www.aquaartis.com> (visited on 19 January 2005).

121 See <http://oceanexplorer.noaa.gov/explorations/03bio/ background/medicines/medicines.html> (visited on 19 January 2005). The Harbor Branch Oceanographic Institution holds the following patents related to the discovery of discodermolide compounds and methods for their use: AT0486565 (Austria); BE0486565 (Belgium); 3,008,985 (Canada); DK0486565 (Denmark); FR0486565 (France); P69018901.5 (Germany); GB0486565 (Great Britain); IT0486565 (Italy); 2,056,412 (Japan); LU0486565 (Luxembourg); NL0486565 (The Netherlands); ES0486565 (Spain);SE0486565 (Sweden);P0486565 (Switzerland); and 5,681,847, 5,840,750, 4,939,168, 5,010,099 (United States).

122 See <http://www.hytest.fi/tuotteet388.php> (last visited on 14 December 2004).

123 See <http://www.promega.com/catalog/CatalogProducts. asp?catalog%5Fname=Promega%5FProducts&category%5Fnam e=Tth+DNA+Polymerase&description%5Ftext=%3Ci%3ETth%3C %2Fi%3E+DNA+Polymerase> (visited on 14 December 2004).

124 See <http://v3.espacenet.com/textdoc?CY=ep&LG=en&F= 4&IDX=WO03093434&DB=EPODOC> (visited on 7 December 2004).

125 See <http://v3.espacenet.com/textdoc?CY=ep&LG=en&F= 4&IDX=US2003235902&DB=EPODOC> (visited on 7 December 2004).

126 Japanese Unexamined Patent Publication 2001-288103, Japanese Unexamined Patent Publication 2001-520027, and Japanese Unexamined Patent Publication 2000-103743.

127 See <http://v3.espacenet.com/textdoc?CY=ep&LG=en&F= 4&IDX=US2003129734&DB=EPODOC> (visited on 1 November 2004).

128 See <http://v3.espacenet.com/textdoc?CY=ep&LG=en&F =4&IDX=U55989587&DB=EPODOC> (visited on 12 December 2004).

129 See <http://appft1.uspto.gov/netacgi/nph-Parser?Sect1=PT O1&Sect2=HITOFF&d=PG01&p=1&u=/netahtml/PTO/srchnum. html&r=1&f=G&l=50&s1='20020106660'.PGNR.&OS=DN/ 20020106660&RS=DN/20020106660> (last visited on 14 December 2004).

130 See <http://ep.espacenet.com/search97cgi/s97_cgi.exe?A ction=FormGen&Template=ep/en/advanced.hts> (visited on 3 November 2004).

131 See http://www.hboi.edu/dbmr/dbmr_patents.html (visited on 5 November 2004). The list is limited to issued and allowed patents as of 6 February 2002.

132 Leary, D.K., "Bioprospecting and the Genetic Resources of Hydrothermal Vents on the High Seas: What is the Existing Legal Position, Where are we Heading and What are our Options?" (2004) Macquarie Journal of International and Comparative Environmental Law 1, 137-178.

133 The Resolution also "calls upon States and international financial institutions, including through bilateral, regional and global cooperation programmes and technical partnerships, to continue to strengthen capacity-building activities, in particular in developing countries, in the field of marine scientific research by, *inter alia*, training the necessary skilled personnel, providing the necessary equipment, facilities and vessels and transferring environmentally sound technologies." It is assumed that these provisions also apply to deep sea MSR.

134 Baseline Report of the Census of Marine Life. Also, Broad, W.J., The Universe Below, 1997, Simon & Schuster, 415 pp.

135 Baseline Report of the Census of Marine Life.

136 This estimation is based on anticipated scientific efforts regarding phyla (phyla are the first hierarchical subdivisions of life domains) and to sampling intensity in this realm, knowing that most of the marine species are contained in a few phyla and that practically all phyla are represented in the marine environment.

137 For a legal definition of acoustic pollution in the oceans, see Dotinga, H.M. & Oude Elferink, A.G., "Acoustic Pollution in the Oceans: The Search for Legal Standards" (2000) Ocean Development and International Law 31, 151-182. Regarding light in the deep sea bed, see Jinks, R.N., Markley, T.L., Taylor, E.E., Perovich, G., Dittel, A.I., Epifanio, C.E. & Cronin, T.W., "Adaptive Visual Metamorphosis in a Deep-sea Hydrothermal Vent Crab" (2002) Nature 420, 68-70. It has been discovered that species inhabiting vent sites such as the crab Bythograea thermydron, which has a planktonic larval stage, undergo adaptive visual metamorphosis while settling down in the vent environment. These adaptations demonstrate not only that light exists in the deep seabed but also that it plays a role as a factor orientating post-larval settlement. 138 In addition to MSR, the other main threats to deep seabed ecosystems are mining and tourism. The impacts of mining result from drilling, excavation and disposal of associated waste, as well as construction, operation and maintenance of the necessary infrastructure. Tourism in the deep sea is still at very early stages but is a potentially growing activity. As an example, the Russian Academy of Sciences, which operates the MIR submersible vehicles, has partnered with the tour operator Deep Ocean Expeditions in providing tourists with the opportunity to visit deep seabed sites in the Azores in the context of official scientific missions. A cruise took place in June 2002, and costed participating tourists US\$ 55,000 per head. See Glowka, L., "Putting Marine Scientific Research on a Sustainable Footing at Hydrothermal Vents" (2003) Marine Policy 27(4), 303-312.

139 Glowka, L., "Putting Marine Scientific Research on a Sustainable Footing at Hydrothermal Vents" (2003) Marine Policy 27(4), 303-312.

140 Mullineaux, L., Desbruyeres, D. & Juniper, K.S., "Deep-sea Hydrothermal Vents Sanctuaries: A Position Paper" (2001) InterRidge News 7, 15-16.

141 See <http://earthobservations.org/docs/DRAFT%20GEOSS% 20Plan%20Reference%20Document%20203-1.pdf> (last visited on 16 December 2004).

142 See <http://beaufix.ipgp.jussieu.fr/rech/lgm/MOMAR/> (last visited on 16 December 2004).

143 Copley, J., "Oceanography: All Wired Up" (2004) Nature 427, 10-12.

144 See <http://www.pmel.noaa.gov/vents/nemo/index.html> (last visited on 16 December 2004).

145 See <http://195.37.14.189/public_html/reser-db.htmto> (last visited on 22 December 2004).

146 See <http://195.37.14.189/public_html/res-epr.htm> (last visited on 22 December 2004).

147 See <http://195.37.14.189/public_html/res-mar.htm> (last visited on 22 December 2004).

148 Correspondence from Dr. Alex Rogers, British Antarctic Survey.

149 An example of such difficulties lays in the fact that deep sea organisms change in shape once brought to the surface.

150 A few countries operate manned or unmanned vehicles needed for deep sea exploration, including France (Nautile, Victor 6000, Aster), Russia (Mir I and II), and the US (Alvin, ABE and others). For an comprehensive review of the main deep sea manned or unmanned vehicles see <http://www.oceanexplorer. noaa.gov/technology/subs/subs.html>.

151 In some cases, the technology is owned by the military but operated by a research institution. Such is the case for the Deep Submersible Vehicle Alvin, owned by the US Navy, and operated as a national oceanographic facility by the Woods Hole Oceanographic Institution in the US. Alvin reaches the depth of 4,500 meters . Further details are available online at <http://seawifs.gsfc.nasa.gov/OCEAN_PLANET/HTML/alvinspecs.html> (visited on 6 November 2004).

152 Stoeckle, M., "Taxonomy, DNA and the Bar Code of Life" (2003) Bioscience 53(9), 2-3.

153 In their 2000 review of search and discovery strategies for biotechnology, Bull, Ward and Goodfellow state that "[b]iotechnology in a great many and probably most instances has a requirement for real, not virtual organisms, and thus research on ways and means of bringing as yet uncultured organisms into culture should be given much greater prominence." in Bull, A., Ward, A.C. & Goodfellow, M., "Search and Discovery Strategies for Biotechnology: the Paradigm Shift" (2000) Microbiology and Molecular Biology Reviews 64(3), 575-606.

154 For example, the Harbor Branch Oceanographic Institution, a not-for-profit oceanographic research and education organization based in Florida, US, owns and operates the Johnson Sea Link I and II manned submersibles, which can reach depths of about 1,000 meters. For further details, see http://www.hbbi.edu/marineops/jsl1.html#> (visited on 5 November 2004). Some of the Harbor Branch Oceanographic Institution's deep sea missions, which include benthic and/or mid-water observations, photo/video documentation, and collection of organisms, are funded or co-funded by the US National Science Foundation and the National Oceanic and Atmospheric Administration.

155 This section is based on a visit to the headquarters of the Japan Agency for Marine-Earth Science and Technology (JAMSTEC), Yokosuka, Japan on 8 November 2004.

156 Pamphlet on the Extremobiosphere Research Center, 2004. Japan Agency for Marine-Earth Science and Technology, Yokosuka, Japan, 14 pp.

157 For specifications, see <http://www.jamstec.go.jp/jamstece/ships/shinkai3.html> (visited on 6 November 2004). JAMSTEC also used to operate the SHINKAI 2000 (maximum depth of operation: 2,000 meters), which is now retired from service for financial reasons (personal communication with the Deputy-Manager of the JAMSTEC-XBR Center). For specifications on SHINKAI 2000, see <http://www.jamstec.go.jp/jamstec-e/ships/ shinkai1.html> (visited on 6 November 2004).

158 For specifications, see <http://www.jamstec.go.jp/jamstec-e/ rov/3k.html and http://www.jamstec.go.jp/jamstec-e/rov/hyper. html> (visited on 9 November 2004).

159 Another ROV, called KAIKO, was able to sample sediments from the Mariana Trench – the deepest point in the world ocean at the depth of 10,898 meters. KAIKO was lost during one of its missions.

160 For specifications, see <http://www.jamstec.go.jp/jamstece/rov/auv ex1.html> (visited on 9 November 2004).

161 For specifications, see <http://www.jamstec.go.jp/jamstec.e/ odinfo/sdsreport.html> (visited on 9 November 2004).

162 See <http://www.jamstec.go.jp/jamstec-e/bio/exbase.html> (visited on 9 November 2004).

163 The UK has a deep-sea research programme and ROV

technology capable to reach 6,500m (correspondence from Dr. Alex Rogers, British Antarctic Survey).

164 See <http://www.ifremer.fr and www.whoi.edu>.

165 "Scientific Information on Biodiversity in Marine Areas Beyond the Limits of National Jurisdiction," Information document presented at the first meeting of the *Ad hoc* Openended Working Group on Protected Areas of the Convention on Biological Diversity (UNEP/CBD/WG-PA/1/2/INF/1).

166 Resilience is the capacity of an ecosystem to resist changes and includes the pace at which an ecosystem may be able to recover following changes.

167 "Management of Risks to the Biodiversity of Seamounts and Cold-water Coral Communities Beyond National Jurisdiction," Information document presented at the seventh meeting of the Conference of the Parties to the Convention on Biological Diversity (UNEP/CBD/COP/7/INF/25).

168 "Scientific Information on Biodiversity in Marine Areas

Beyond the Limits of National Jurisdiction," Information document presented at the first meeting of the Ad hoc Openended Working Group on Protected Areas of the Convention on Biological Diversity (UNEP/CBD/WG-PA/1/2/INF/1).

169 Baseline Report of the Census of Marine Life. According to this report, the abyssal plain is rich and diversified in species. Life there is possible thanks to the continuous falling of the remaining of marine organisms from the upper water column, also known as 'marine snow.'

170 Cold seeps cover much larger portions of the continental margins and may be easier to study since they are associated with systems that present an interest for offshore drilling.

171 Seewald, J.S., Doherty, K.W., Hammar, T.R., & Liberatore, S.P., "A New Gas-tight Isobaric Sampler for Hydrothermal Fluids" (2001) Deep-Sea Research I 49, 189-196. Also Phillips, H., Wells, L.E., Johnson II, R.V., Elliott, S. & Deming, J.W., "LAREDO: a New Instrument for Sampling and in situ Incubation of Deep-sea Hydrothermal Vent Fluids" (2003) Deep-Sea Research I 50, 1375-1387.

172 Doerries, M.B. & Van Dover, C.L., "Higher-taxon Richness as a Surrogate for Species Richness in Chemosynthetic Communities" (2003) Deep-Sea Research I 50, 749-755.

173 Beyond Borders: A Global Perspective. The Global Section of the Ernst & Young Global Biotechnology Report 2004 series, 2004, EYGM Limited, 1-17.

174 Beyond Borders: A Global Perspective. The Global Section of the Ernst & Young Global Biotechnology Report 2004 series, 2004, EYGM Limited, 1-17.

175 According to an interview with the CEO of the Switzerlandbased company Serono, the situation faced by the European biotechnology industry is due to too stringent a political and regulatory framework, as well as to a complex approach to the approval of biotechnology products. On the other hand, European biotechnology companies excel in the establishment of crossborder partnerships, i.e. partnerships with biotechnology from other sectors and pharmaceutical companies. This would indicate a good degree of dynamism of the European biotechnology industry (source: Beyond Borders: A Global Perspective. The Global Section of the Ernst & Young Global Biotechnology Report 2004 series, 2004, EYGM Limited, 1-17).

176 On the Threshold: The Asia-Pacific Perspective. Ernst & Young Global Biotechnology Report 2004 series, 2004, EYGM Limited, 42 pp.

177 On the Threshold: The Asia-Pacific Perspective. Ernst & Young Global Biotechnology Report 2004 series, 2004, EYGM Limited, 42 pp.

178 On the Threshold: The Asia-Pacific Perspective. Ernst & Young Global Biotechnology Report 2004 series, 2004, EYGM Limited, 42 pp.

179 This approach has been exacerbated with the adoption, by many companies, of the 'NRDO - no research, development only' working philosophy (source: Resurgence: The Americas Perspective. Ernst & Young Global Biotechnology Report 2004 series, 2004, EYGM Limited, 61 pp).

180 Interview with Lori Rafield, a general partner at Apax Partners (source: Resurgence: The Americas Perspective. Ernst & Young Global Biotechnology Report 2004 series, 2004, EYGM Limited, 61 pp).

181 Refocus: The European Perspective. Ernst & Young Global Biotechnology Report 2004 series, 2004, EYGM Limited, 55 pp. 182 Resurgence: The Americas Perspective. Ernst & Young Global

Biotechnology Report 2004 series, 2004, EYGM Limited, 61 pp.

183 Resurgence: The Americas Perspective. Ernst & Young Global Biotechnology Report 2004 series, 2004, EYGM Limited, 61 pp.

184 Resurgence: The Americas Perspective. Ernst & Young Global Biotechnology Report 2004 series, 2004, EYGM Limited, 61 pp.

185 Oldham, P., Global Status and Trends in Intellectual Property Claims: Genomics, Proteomics and Biotechnology, 2004, Centre for Economic and Social Aspects of Genomics, 60 pp.

186 Oldham, P., Global Status and Trends in Intellectual Property Claims: Genomics, Proteomics and Biotechnology, 2004, Centre for Economic and Social Aspects of Genomics, 60 pp.

187 Oldham, P., Global Status and Trends in Intellectual Property Claims: Genomics, Proteomics and Biotechnology, 2004, Centre for Economic and Social Aspects of Genomics, 60 pp.

188 Resurgence: The Americas Perspective. Ernst & Young Global Biotechnology Report 2004 series, 2004, EYGM Limited, 61 pp.

189 Oldham, P., Global Status and Trends in Intellectual Property Claims: Genomics, Proteomics and Biotechnology, 2004, Centre for Economic and Social Aspects of Genomics, 60 pp.

190 Dunedin Workshop Report. 191 Dunedin Workshop Report.

192 "Chapter 10: New Products and Industries from Biodiversity," Millennium Ecosystem Assessment - Condition and Trends Assessment, (in press), Island Press, 54 pp.

193 "Chapter 10: New Products and Industries from Biodiversity," Millennium Ecosystem Assessment - Condition and Trends Assessment, (in press), Island Press, 54 pp.

194 Oldham, P., Global Status and Trends in Intellectual Property Claims: Genomics, Proteomics and Biotechnology, 2004, Centre for Economic and Social Aspects of Genomics, 60 pp. See also <http://ep.espacenet.com>.

195 Oldham, P., Global Status and Trends in Intellectual Property Claims: Genomics, Proteomics and Biotechnology, 2004, Centre for Economic and Social Aspects of Genomics, 60 pp.

196 Oldham, P., Global Status and Trends in Intellectual Property Claims: Genomics, Proteomics and Biotechnology, 2004, Centre for Economic and Social Aspects of Genomics, 60 pp.

197 Oldham, P., Global Status and Trends in Intellectual Property Claims: Genomics, Proteomics and Biotechnology, 2004, Centre for Economic and Social Aspects of Genomics, 60 pp.

198 "Chapter 10: New Products and Industries from Biodiversity," Millennium Ecosystem Assessment - Condition and Trends Assessment, (in press), Island Press, 54 pp.

199 Fenical, W., Carter, G.T., Jordan, M.A., Wilson, L., Walsh, P.J. & Moore, B.S., "Drug Discovery and Development," in Marine Biotechnology in the Twenty-First Century: Problems, Promise and Products, 2002, 45-64.

200 Dunedin Workshop Report.

201 Gorina-Ysern, M., "Legal Issues Raised by Profitable Biotechnology Development Through Marine Scientific Research" (2003) American Society of International Law Insights, available at <http://www.asil.org/insights/insigh116.htm>.

202 Greer, D. & Harvey, B., Blue Genes: Sharing and Conserving the World's Aquatic Biodiversity, 2004, Earthscan.

203 Fenical, W., Carter, G.T., Jordan, M.A., Wilson, L., Walsh, P.J. & Moore, B.S., "Drug Discovery and Development," in Marine Biotechnology in the Twenty-First Century: Problems, Promise and Products, 2002, 45-64.

204 Fenical, W., Carter, G.T., Jordan, M.A., Wilson, L., Walsh, P.J. & Moore, B.S., "Drug Discovery and Development," in Marine Biotechnology in the Twenty-First Century: Problems, Promise and Products, 2002, 45-64.

205 Greer, D. & Harvey, B., Blue Genes: Sharing and Conserving the World's Aquatic Biodiversity, 2004, Earthscan.

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207 Greer, D. & Harvey, B., Blue Genes: Sharing and Conserving the World's Aquatic Biodiversity, 2004, Earthscan.

208 Dunedin Workshop Report.

209 Dunedin Workshop Report.

210 Greer, D. & Harvey, B., Blue Genes: Sharing and Conserving the World's Aquatic Biodiversity, 2004, Earthscan.

211 Fenical, W., Carter, G.T., Jordan, M.A., Wilson, L., Walsh, P.J. & Moore, B.S., "Drug Discovery and Development," in Marine Biotechnology in the Twenty-First Century: Problems, Promise and Products, 2002, 45-64.

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219 This section draws on the United Nations University -Institute of Advanced Studies (UNU-IAS) report The International Regime for Bioprospecting: Existing Policies and Emerging Issues for Antarctica, 2003, UNU-IAS, 24 pp.

220 Cavicchioli, R. & Thomas, T., 'Extremophiles' in Lederberg, J., (Ed.) Encyclopedia of Microbiology (2000), Academic Press, San Diego, 317-337.

221 Rothschild, L.J. & Mancinelli, R.L.,"Extremophilic Organisms Adapt to Life in Incredibly Harsh Environment" (2001) Nature 409, 1092-1101.

222 Bowman, J.P., "Antarctica a Global 'Hot Spot': Biodiversity and Biotechnology," available at <http://www.atse.org.au/ publications/symposia/proc-2001p9.htm>.

223 Cheng, C.C. & Cheng, L., "Evolution of an Antifreeze Glycoprotein" (1999) 401 Nature, 443-444. See also, "Antifreeze Proteins – Secrets for Mankind?," available at http://www. nsf.gov/od/lpa/nsf50/nsfoutreach/htm/n50_z2/pages_z3/04_ pg.htm>.

224 "Antifreeze Proteins - Secrets for Mankind?," available at <http://www.nsf.gov/od/lpa/nsf50/nsfoutreach/htm/n50_z2/ pages_z3/04_pg.htm>.

225 Preamble, UNCLOS.

226 Art.1(1), UNCLOS.

227 States can regulate activities taking place within their internal waters, including prohibiting passage of foreign vessels (Art.2(1) and Art.3, UNCLOS). In the territorial sea, States exercise their sovereignty, subject to the right of innocent passage for foreign ships (Art.17, UNCLOS). In their Exclusive Economic Zone (EEZ), coastal States have sovereign rights to explore for, exploit, conserve and manage living and non-living natural resources, and regulate other activities for the economic exploitation and exploration of the EEZ (Art.56(1)(a), UNCLOS). Within the EEZ, States also have jurisdiction over the establishment and use of artificial islands, installations and structures, marine scientific research (MSR) and the protection and preservation of the marine environment (Art.56(1)(b), UNCLOS). On the continental shelf, coastal States have sovereign rights to explore and exploit non-living resources as well as living organisms belonging to sedentary species. These sovereign rights are subject to the rights of other States, including the right of navigation and to lay submarine cables and pipelines (Art.77, Art.78(2) and Art.79, UNCLOS).

228 Art.4, Annex II, UNCLOS. To date, claims have been deposited by the Russian Federation, Brazil and Australia.

²²9 "Oceans and the law of the sea. Report of the Secretary-General to the 59th session of the UN General Assembly" (A/59/62), Para 47. In relation to deposit of charts and coordinates, the Secretary-General notes that "the international community and the users of the seas and oceans need to know the limits of the maritime zones in which a coastal State exercises its sovereignty or sovereign rights and jurisdiction, in view of the different legal regimes applicable. Ultimately, through the delineation of the outer limits of the continental shelf and, where appropriate, the [EEZ], the international community should be able to determine the boundaries of the international seabed area (the Area), which is subject to the regime of the common heritage of humankind." 230 According to Art.31 of the 1966 Vienna Convention on the Law of Treaty, a treaty shall be interpreted in light of its object and purpose.

231 Art.77(4), UNCLOS.

232 Farrier, D. & Tucker, L., "Access to Marine Bioresources: Hitching the Conservation Cart to the Bioprospecting Horse," (2001) Ocean

Development and International Law 32, 213-239.

233 Art.86 and 87, UNCLOS.

234 Art.117-119, UNCLOS.

235 The Status of Natural Resources on the High Seas, WWF/IUCN, Gland, Switzerland, 2001, 93 pp.

236 Agreement Relating to the Implementation of Part XI of the United Nations Convention on the Law of the Sea of 10 December 1982 (A/RES/48/263), hereafter referred to as "1994 Part XI Agreement."

237 Preamble, UNCLOS.

238 Art.136 and 137, UNCLOS.

239 Art.1(3), UNCLOS.

240 Art.133, UNCLOS.

241 Art.156 and 157, UNCLOS.

242 Art.156-170, UNCLOS and Section II, 1994 Part XI Agreement. 243 Art.153(1), UNCLOS.

244 Art.140(2), UNCLOS.

245 Art.143(2), UNCLOS.

246 Art.144(1), UNCLOS.

247 Art.145, UNCLOS.

248 Art.162(2)(z), UNCLOS.

249 Art.153(3), UNCLOS.

250 Art.8, Annex III, UNCLOS.

251 Point 7, Section I, 1994 Part XI Agreement.

252 Section II, 1994 Part XI Agreement.

253 Reports of the Chairmen of the Legal and Technical Commission to the Council (ISBA/9/C/4 and ISBA/10/C/4). 254 Para 15-17, Report of the Chairman of the Legal and Technical

Commission (ISBA/9/C/4). 255 "Seabed Authority's Legal and Technical Commission, in First

Open Meeting, Discusses Biodiversity in Deep Seabed Area," Press Release (SB/10/8).

256 This is also one of the options presented in the CBD-UNDOALOS Study.

257 The ISA is currently associated with the Kaplan Project, designed to measure biodiversity, species range, and gene flow in the Clarion-Clipperton Zone in the Northeast Pacific. The information gained will be used to determine the potential risks resulting from mining of manganese nodules for marine life. The first set of results and analyses should be available in 2005. The outputs will include the establishment of a database of some of the important species found in the Clarion-Clipperton Zone, including their genetic sequences. The Authority will also promote work undertaken by the Chemosynthetic Ecosystems Group (known as ChEss) and the Seamounts Group (known as CenSeam) within the Census of Marine Life. Both cover the environments where polymetallic sulphides and cobalt-rich crusts are found, namely hydrothermal vents and seamounts. See Statement by the ISA's Secretary-General at the 59th session of the UN General Assembly, 17 November 2004.

258 The workshop's presentations are available at <http://www. isa.org.jm/en/default.htm>.

259 Decision of the Assembly of the International Seabed Authority relating to the Regulations on Prospecting and Exploration for Polymetallic Nodules in the Area (ISBA/6/A/18), hereafter referred to as "Polymetallic Nodules Regulations."

260 Regulation 1(4), Polymetallic Nodules Regulations.

261 Regulation 2(2), Polymetallic Nodules Regulations. 262 Regulation 2(4), Polymetallic Nodules Regulations.

263 Regulations 24(1) and 26(1), Polymetallic Nodules Regulations.

264 Regulation 30, Polymetallic Nodules Regulations.

265 Regulation 31(3) and (4), Polymetallic Nodules Regulations.

266 Regulation 31(7), Polymetallic Nodules Regulations.

267 Regulation 35(3), Polymetallic Nodules Regulations.

268 "Draft regulations on prospecting and exploration for polymetallic sulphides and cobalt-rich ferromanganese crusts in the Area. Proposed by the Legal and Technical Commission" (ISBA/10/C/WP1), hereafter referred to as " Draft Polymetallic Sulphides Regulations."

269 Regulations 16-19, Draft Polymetallic Sulphides Regulations.

270 Para.39, CBD-UNDOALOS Study.

271 Art.256 and 257, UNCLOS.

272 Art.240, UNCLOS.

273 Art.245 and 246(1), UNCLOS.

274 Art.248, Art.249(1)(a) and (c), and Art.249(2), UNCLOS.

275 Art.143(1), UNCLOS.

276 Art.143(2), UNCLOS.

277 Art.143(3), UNCLOS.

278 Para 53, CBD-UNDOALOS Study.

279 Gorina-Ysern, M., "Legal Issues Raised by Profitable Biotechnology Development Through Marine Scientific Research" (2003) American Society of International Law Insights, available at <http://www.asil.org/insights/insight16.htm>.

280 Art.269, UNCLOS.

281 Art.273, UNCLOS.

282 Section 5(1)(a), (b), and (c), 1994 Part XI Agreement.

283 Art.1(4), UNCLOS.

284 Art.194(3)(c), UNCLOS. Art.196 specifically refers to pollution resulting from the use of technologies under States' jurisdiction or control.

285 Art.194(5) and (4), UNCLOS.

286 Preamble, Declaration of Principles Governing the Seabed and the Ocean Floor, and the Subsoil Thereof, Beyond the Limits of National Jurisdiction (UN General Assembly Resolution 2749(XXV)).

287 Para 9, UN General Assembly Resolution 2749 (XXV).

288 Para 1(a), UN General Assembly Resolution 2750 (XXV) on the reservation exclusively for peaceful purposes of the seabed and the ocean floor and the subsoil thereof, underlying the High Seas beyond the limits of present national jurisdiction and use of their resources in the interests of humankind, and the convening of a conference on the law of the sea.

289 Increasing attention to the issue of exploitation of the living resources of the deep seabed, including within the CBD framework, prompted the UN Secretary-General, in its 1995 annual report on developments regarding the law of the sea to the 50th session of the UN General Assembly, to draw the General Assembly's attention to the issue (see Annual Report by the Secretary-General on developments regarding the law of the sea (A/50/713)). Following adoption of Decision II/10 by the COP to the CBD, in his annual report to the 51st session of the UN General Assembly, the Secretary-General particularly drew attention to the fact that "[t]he topic [i.e. the issue of access to the genetic resources of the deep seabed] touches not only to the protection and preservation of the marine environment, including that of the international seabed area, but also on such matters as the operation of the consent regime for [MSR], (...), the duties of conservation and management of the living resources of the High Seas, the sustainable development of the living resources of the High Seas and the sustainable development of living marine resources generally. The specific issue of access points to the need for the rational and orderly development of activities relating to the utilization of genetic resources derived from the deep seabed area beyond the limits of national jurisdiction" (Annual report by the Secretary-General on developments regarding the law of the sea (A/51/645)).

290 Para 16, 56 and 62, "Oceans and the law of the sea" (A/ RES/57/141).

291 Para 420 and 422, "Oceans and the law of the sea. Report by the Secretary-General" (A/57/57).

292 Para 18, "Oceans and the law of the sea. Report by the Secretary-General" (A/58/65).

293 Para 195, Doc. A/58/65.

294 Para 147, Doc. A/58/65.

295 Para 250, "Oceans and the law of the sea. Report of the Secretary-General to the 59th session of the UN General Assembly" (A/59/62).

296 Para 264 and 266, Doc. A/59/62.

297 Para 260-262, Doc. A/59/62.

298 Para 266, Doc. A/59/62.

299 Para 2, "Results of the review by the Commission on

Sustainable Development of the sectoral theme of 'Oceans and seas': international coordination and cooperation" (A/ RES/54/33).

300 Para 20, "Report on the work of the United Nations Openended Informal Consultative Process on Oceans and the Law of the Sea at its third meeting" (A/57/80).

301 Para 23-24, Doc. A/57/80.

302 Part C, Doc. A/57/80.

303 Para 16, 56 and 62, "Oceans and the law of the sea" (A/ RES/57/141).

304 Para 98-100, "Report on the work of the United Nations Openended Informal Consultative Process on Oceans and the Law of the Sea at its fourth meeting" (A/58/95), hereafter referred to as "ICP Report – Fourth meeting."

305 Para 103-106, ICP Report – Fourth meeting.

306 Para 20, ICP Report – Fourth meeting.

307 Para 22, ICP Report – Fourth meeting.

308 Para 51-54, "Oceans and the law of the sea" (A/58/240). 309 Para 68, Doc. A/58/240.

310 "Report on the work of the United Nations Open-ended Informal Consultative Process on Oceans and the Law of the Sea at its fifth meeting" (A/59/122), hereafter referred to as "ICP Report – Fifth meeting."

311 Para 90-94, ICP Report – Fifth meeting.

312 Para 5, ICP Report – Fifth meeting.

313 Para 7, ICP Report – Fifth meeting.

314 Para 97, ICP Report – Fifth meeting.

315 Press release GA/10298 of 16 November 2004.

316 Press release GA/10299 of 17 November 2004.

317 Para 68-72, "Oceans and the law of the sea" (A/RES/59/24).

318 Para 73-74, Doc. A/RES/59/24.

319 Para 84-87, Doc. A/RES/59/24.

320 Art.1, CBD. Article 2 (Use of terms) defines biological diversity as "the variability among living organisms from all sources, including terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part." Sustainable use is defined as "the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations." For the definitions of genetic resources and genetic material, see section 3.2 of this report.

321 Art.3, CBD.

322 For possible definitions, see section 3.2. of this report. Doc. UNEP/CBD/COP/5/INF/7 defined bioprospecting as "the exploration of biodiversity for commercially valuable genetic and biochemical resources" and further as "the process of gathering information from the biosphere on the molecular composition of genetic resources for the development of new commercial products." The CBD-UNDOALOS Study endorses this definition (Para 49) and notes other definitions (Para 79, note 102).

323 Art.4, CBD.

324 Art.5, CBD.

325 Art.22, CBD. As of 12 November 2004, there were 188 Parties to the CBD and 145 Parties to UNCLOS.

326 The CBD-UNDOALOS Study provides a detailed account of how each provision impacts on the regulation of bioprospecting undertaken with regard to deep seabed genetic resources (Para 77-96).

327 Report of the First Meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) (UNEP/ CBD/COP/2/5). Following recommendations by a workshop on marine biodiversity held prior to SBSTTA-1, Recommendation I/8 of the SBSTTA related to scientific, technical and technological aspects of the conservation and sustainable use of coastal and marine biological diversity, recommended that the next meeting of the SBSTTA consider questions related to bioprospecting on the deep seabed, including access to its genetic resources. For a brief account of discussions, see Glowka, L., "Genetic Resources, Marine Scientific Research and the International Seabed Authority," (1999) Review of European Community and International Environmental Law 8(1), 56-66.

328 Decision II/10 "Conservation and sustainable use of marine and coastal biological diversity."

329 Para 12, Decision II/10.

330 Annex to CBD Decision IV/5. The programme of work as adopted by COP-4 included elements on: integrated marine and coastal area management; marine and coastal living resources; marine and coastal protected areas; mariculture; and alien species and genotypes.

331 Para 103, CBD-UNDOALOS Study.

332 Para 104, CBD-UNDOALOS Study.

333 Para 72, CBD-UNDOALOS Study.

334 Earth Negotiations Bulletin, Thursday 13 March 2003, Vol.09, No.250.

335 Section D, SBSTTA Recommendation VIII/3 "Marine and coastal biodiversity: review, further elaboration and refinement of the programme of work."

336 Section B, Para 19, SBSTTA Recommendation VIII/3.

337 Earth Negotiations Bulletin, Thursday 19 February 2004, Vol.09, No.282; Earth Negotiations Bulletin, Friday 29 February 2004, Vol.09, No.283.

338 Earth Negotiations Bulletin, "Summary of the Seventh Conference of the Parties to the Convention on Biological Diversity," Vol.09, No.284.

339 Para 54-56, Decision VII/5 "Marine and coastal biological diversity."

340 Para 57-62, Decision VII/5.

341 Para 30-31, Decision VII/5.

342 Para 21, Decision VII/5 and programme element 3 of the elaborated programme of work on marine and coastal biodiversity.

343 Articles 15 to 21 deal respectively with: access to genetic resources; access to and transfer of technology; exchange of information; technical and scientific co-operation; handling of biotechnology and distribution of benefits; financial resources; and financial mechanism.

344 Over 50 Parties have reported efforts to develop national legislation or policies to implement the provisions of the CBD relating to access to, and use of, genetic resources. Regional efforts to apply these provisions have been made under the Andean Pact, Association of South East Asian Nations, European Union, South Pacific Regional Environment Programme, Central American Fund for Environment and Development: Account for the Global Environment, Southern African Biodiversity Support Programme, Pan-European Biological and Landscape Diversity Strategy, Pan-European Ecological Network, and the South Asia Cooperative Environment Programme.

345 Art.15(2) and (4), CBD.

346 Art.15(6) and (7), CBD.

347 Glowka, L., "Genetic Resources, Marine Scientific Research and the International Seabed Area," (1999) Review of European Community and International Environmental Law 8(1), 56-66. 348 Art.2 and 16(1), CBD.

349 Art.16(1), CBD.

350 Art.16(2), CBD.

351 Art.16(4), CBD.

352 Art.16(5), CBD.

353 Art.19(1) and (2), CBD.

354 "Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of their Utilization" (Annex to Decision VI/24 'Access and benefit-sharing as related to genetic resources'), hereafter referred to as "Bonn Guidelines." 355 Para 7, Bonn Guidelines.

356 Part I, Section D, Bonn Guidelines.

357 Para 5, Bonn Guidelines.

358 Para 24, Bonn Guidelines.

359 Para 41, Bonn Guidelines.

360 Para 43, Bonn Guidelines.

361 Para 44, Bonn Guidelines.

362 Para 45-50, Bonn Guidelines.

363 Para 51-61, Bonn Guidelines.

364 Para 1, Part C, Decision VI/24.

365 Part D, Decision VI/24.

366 Part B, Decision VII/19 "Access and benefit-sharing as related to genetic resources (Article 15)."

367 Part C, Decision VII/19.

368 Paragraph 44(o) of the Plan of Implementation of the World Summit on Sustainable Development calls for action to "negotiate within the framework of the Convention on Biological Diversity, bearing in mind the Bonn Guidelines, an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources. Resolution 57/260 of 20 December 2002, adopted by the UN General Assembly, invites the COP to the CBD to take appropriate steps with regard to the commitment made at the World Summit on Sustainable Development.

369 Para 1, Part D, Decision VII/19. Terms of reference for the ABS Working Group to carry out its task are annexed to the Decision. 370 Preamble, Para 7, Part E, Decision VII/19.

371 Evans-Illidge, E.A. & Murphy, P.T., "A New Approach to Benefit Sharing in Bioprospecting," available at <http://www.biodiv.org/ doc/case-studies/abs/cs-abs-au.pdf>.

372 Para 98, CBD-UNDOALOS Study.

373 Para 100 and 133, CBD-UNDOALOS Study.

374 Oldham, P., Global Status and Trends in Intellectual Property Claims: Genomics, Proteomics and Biotechnology, 2004, Centre for Economic and Social Aspects of Genomics, 60 pp.

375 Oldham, P., Global Status and Trends in Intellectual Property Claims: Genomics, Proteomics and Biotechnology, 2004, Centre for Economic and Social Aspects of Genomics, 60 pp.

376 This section draws on a similar section from the United Nations University - Institute of Advanced Studies (UNU-IAS) report The International Regime for Bioprospecting: Existing Policies and Emerging Issues for Antarctica, 2003, UNU-IAS, 24 pp.

377 "Contractual practices and clauses relating to intellectual property, access to genetic resources and benefit-sharing. Document prepared by the Secretariat" (WIPO/GRTKF/IC/5/9), hereafter referred to as "Contractual Practices."

378 Para 34, Contractual Practices.

379 Para 38, Contractual Practices.

380 "Draft Technical Study on Disclosure Requirements related to genetic resources and traditional knowledge. Document prepared by the Secretariat" (WIPO/GRTKF/IC/5/10), hereafter referred to as "Disclosure Requirements Study."

381 Para 24, Disclosure Requirements Study.

382 Para 91, Disclosure Requirements Study.

383 Para 130, Disclosure Requirements Study.

384 Para 102, Disclosure Requirements Study.

385 As of 25 February 2005, there were 60 Parties to the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, hereafter referred to as "Budapest Treaty."

386 Art.3(1), Budapest Treaty.

387 Art.7 and 6(2), Budapest Treaty.

388 Rules 6, 2, 9 and 11, Budapest Treaty Regulations.

389 Oldham, P., Global Status and Trends in Intellectual Property Claims: Microorganisms, 2004, available at http://www. cesagen.lancs.ac.uk>.

390 Art.27(1), Agreement on Trade-Related Aspects of Intellectual Property Rights, hereafter referred to as "TRIPS Agreement."

391 For an account of diverging views on how to interpret the provisions of Article 27(3), see the note prepared by the WTO Secretariat in 2002, "Review of the Provisions of Article 27.3(b) - Summary of Issues Raised and Points Made. Note by the Secretariat" (IP/C/W/369).

392 Art.29, TRIPS Agreement.

393 Article 7 states that "the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and
economic welfare, and to a balance of rights and obligations."

394 Article 8 states, *inter alia*, that: members may adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socioeconomic and technological development; and appropriate measures may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain or adversely affect the international transfer of technology.

395 Para 19, Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

396 WTO website: <http://www.wto.org/english/tratop_e/trips_ e/art27_3b_background_e.htm>.

397 For a summary of views on the issue of disclosure, see Para 20-28, "The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity – Summary of Issues Raised and Points Made. Note by the Secretariat" (IP/C/W/368).

398 The Convention for the Protection of the Marine Environment of the North-East Atlantic (hereafter referred to as "OSPAR") combined and updated the 1972 Oslo Convention on Dumping of Waste at Sea and the 1974 Paris Convention on Land-based Sources of Marine Pollution.

399 There are currently 15 Contracting Parties to OSPAR: Belgium, Denmark, the European Community, Finland, France, Germany, Iceland, Ireland, the Netherlands, Norway, Portugal, Spain, Sweden and the United Kingdom of Great Britain and Northern Ireland, Luxembourg and Switzerland.

400 Art.1(a), OSPAR.

401 2003 Strategies of the OSPAR Commission for the Protection of the Marine Environment of the North-East Atlantic (Agreement 2003-21).

402 List of Threatened and/or Declining Species and Habitats, Agreement 2004-06.

403 Appendix 1, Proceedings of the Workshop "Planning the Management of Deep-sea Hydrothermal Vent Fields MPA in the Azores Triple Junction," Horta, 18-20 June 2002, hereafter referred to as "Horta Workshop Proceedings."

404 Preamble, 1986 Convention for the Protection of the Natural Resources and Environment of the South Pacific Region, hereafter referred to as "Noumea Convention."

405 Art.2(a), Noumea Convention. The Parties, the EEZ of which are concerned, are: American Samoa, Australia (East Coast and Islands to eastward including Macquarie Island), Cook Islands, Federated States of Micronesia, Fiji, French Polynesia, Guam, Kiribati, Marshall Islands, Nauru, New Caledonia and Dependencies, New Zealand, Niue, Northern Mariana Islands, Palau, Papua New Guinea, Pitcairn Islands, Toeklau, Tonga, Tuvalu, Vanuatu, Wallis and Futuna and Western Samoa.

406 Art.3, Barcelona Convention for the Protection of the Marine Environment and the Coastal Region of the Mediterranean, hereafter referred to as the "Barcelona Convention."

407 Art.12, Barcelona Convention.

408 Art.16, Barcelona Convention.

409 Para 280, "Oceans and the law of the sea. Report of the Secretary General to the 59th session of the UN General Assembly - Addendum" (A/59/62/Add.1).

410 Art.2(1), 1995 Protocol concerning Specially Protected Areas and Biological Diversity in the Mediterranean, hereafter referred to as "1995 SPA Protocol."

411 Art.3 and 5, 1995 SPA Protocol.

412 Art.6, 1995 SPA Protocol.

413 InterRidge database at <http://interridge.org/>.

414 United Nations University – Institute of Advanced Studies (UNU-IAS) report The International Regime for Bioprospecting: Existing Policies and Emerging Issues for Antarctica, 2003, UNU-IAS, 24 pp.

415 Art.II, Antarctic Treaty.

416 Art.VII(5)(a), Antarctic Treaty.

417 Art.II(1) and (2), Convention on the Conservation of Antarctic Marine Living Resources, hereafter referred to as "CCAMLR." 418 Art.I(1), CCAMLR.

419 Art.IX(1), CCAMLR.

420 Art.XIV and XV, CCAMLR.

421 Art.2, Protocol Environmental Protection to the Antarctic Treaty, hereafter referred to as "Madrid Protocol."

422 Art.3(1) and (3) and Art.7, Madrid Protocol.

423 Art.3(1) and (2), Madrid Protocol.

424 Art.6, Madrid Protocol.

425 Art.2-4, Annex V to the Protocol on Environmental Protection to the Antarctic Treaty Area Protection and Management.

426 Bastmeijer, K., The Antarctic Environmental Protocol and its Domestic Legal Implementation, 2003, Kluwer Law International, 517 pp.

427 Art.37(2), 39(1) and 53(1), Convention on the Regulation of Antarctic Mineral Resources Activities.

428 Para 44(0), Plan of Implementation of the World Summit on Sustainable Development, hereafter referred to as "WSSD Plan of Implementation," available at <http://www. johannesburgsummit.org/html/documents/summit_ docs/2309 planfinal.htm>.

429 Para 32(c), WSSD Plan of Implementation.

430 Art.2, Statutes of the Intergovernmental Oceanographic Commission (IOC) (SC-2000/WS/57).

431 IOC Criteria and Guidelines on the Transfer of Marine Technology (IOC/ABE-LOS IV/Inf.3).

432 Glowka notes that "without (1) direct measures taken by individual researching States to regulate the conduct of their marine scientific researchers in the Area, (2) a new international treaty or (3) voluntary oversight by the scientific community itself, there is very little that international law and institutions can directly offer at present to minimize the potential use conflicts and the threats MSR may pose to the most visited sites," in "Putting Marine Scientific Research on a Sustainable Footing at Hydrothermal Vents," (2003) Marine Policy 27(4), 303-312.

433 InterRidge News (2003) 12(1), available at http://195.37.14.189/ public_html/irn121a.pdf>; "InterRidge Working group meeting report – Mid-ocean ridge ecosystems," February 2004, available at http://195.37.14.189/public_html/Mid%20Ocean%20Ridge %20ecosystems/IRBio_FINAL2004.pdf; Juniper, S.K., "Scientific Research Results from the Deep Seabed: Discoveries, Applications and Conservation Issues at Hydrothermal Vents," Presentation at

and Conservation issues at Hydrothermal vents, Presentation at the Fifth Meeting of the UN Informal Consultative Process on Oceans and the Law of the Sea (June 2004), available at <http:// www.un.org/depts/los/consultative_process/5thmeetingpanel. htm>.

434 Devey, C., "The Work of InterRidge and its Potential Relevance to the Establishment of Environmental Baselines, Including the Voluntary Code of Conduct for Scientific Research at Hydrothermal Vents, and Potential Collaborations with the Authority," Presentation at the ISA Workshop on the establishment of environmental baselines at deep seafloor cobalt-rich crusts and deep seabed polymetallic sulphide mine sites in the Area for the purpose of evaluating the likely effects of exploration and exploitation on the marine environment, 6-10 September 2004, available at <http://www.isa.org.jm/en/default.htm>.

435 Horta Workshop Proceedings.

436 Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct, 2000, available at http://www.belspo.be/bccm/mosaicc/.

437 Mann Borgese, E., "Bioprospecting and Access to Genetic Resources in the Area" (fax to the Secretariat of the Convention on Biological Diversity, 20 May 2001 – on file with the authors). 438 Art.204, 205 and 206, UNCLOS.

439 Regulation 5, Polymetallic Nodules Regulations.

440 Section 10, Annex 4, Polymetallic Nodules Regulations. 441 Art.XXIV, CCAMLR.

442 While the majority of hydrothermal vents are located in the Area, some are found in areas within national jurisdiction, including those of Portugal, Canada, Papua New Guinea, Fiji, New Zealand and the US. See the InterRidge database at <http:// interridge.org/>.

443 Leary, D.K., "Emerging Legal Regimes Regulating Bioprospecting for Thermophiles and Hyperthermophiles of

Hydrothermal Vents" (2003) Journal of Marine Biotechnology (forthcoming). Also, Leary, D.K., "Bioprospecting and the Genetic Resources of Hydrothermal Vents on the High Seas: What is the Existing Legal Position, Where are we Heading and What are our Options?" (2004) Macquarie Journal of International and Comparative Environmental Law 1, 137-178.

444 Research has been undertaken by Australia's Commonwealth Scientific and Industrial Research Organization, Ifremer and JAMSTEC among others. In 2000, the PACMANUS site was drilled as part of the Ocean Drilling Programme Leg 193. See Leary, D.K., "Emerging Legal Regimes Regulating Bioprospecting for Thermophiles and Hyperthermophiles of Hydrothermal Vents" (2003) Journal of Marine Biotechnology (forthcoming).

445 Leary, D.K., "Emerging Legal Regimes Regulating Bioprospecting for Thermophiles and Hyperthermophiles of Hydrothermal Vents" (2003) Journal of Marine Biotechnology (forthcoming). Also, Leary, D.K., "Bioprospecting and the Genetic Resources of Hydrothermal Vents on the High Seas: What is the Existing Legal Position, Where are we Heading and What are our Options?" (2004) Macquarie Journal of International and Comparative Environmental Law 1, 137-178.

446 Leary, D.K., "Emerging Legal Regimes Regulating Bioprospecting for Thermophiles and Hyperthermophiles of Hydrothermal Vents" (2003) Journal of Marine Biotechnology (forthcoming).

447 See the InterRidge Database at <http://interridge.org/>.

448 Aalbersberg, W.G., "Bioprospecting and its Regulation by the Government of Fiji," available at http://www.worldwildlife.org/bsp/bcn/whatsnew/fijigov.htm.

449 For details, see <http://www.med.govt.nz/ers/nat-res/ bioprospecting/index.html> and <http://www.oceans.govt. nz/>.

450 Statement by the Norwegian delegation at the second meeting of the ICP, May 2001.

451 Under section 35(1) of the Oceans Act, a marine protected area is "an area of the sea that forms part of the internal waters of Canada, the territorial sea of Canada or the [EEZ] of Canada and has been designated for special protection for one or more of the following reasons: 1) the conservation and protection of commercial and non-commercial fishery resources, including marine mammals, and their habitats; 2) the conservation and protection of endangered or threatened marine species, and their habitats; 3) the conservation and protection of unique habitats; 4) the conservation and protection of marine areas of high biodiversity or biological productivity; and 5) the conservation and protection of any other marine resources or habitat as is necessary to fulfill the mandate of the Minister."

452 Fisheries and Oceans Canada, Regulatory Impact Analysis Statement, Endeavour Hydrothermal Vents Marine Protected Area Regulations (Draft), Canada Gazette Part I, (9 June 2001). Endeavour is visited by one to several MSR expeditions per year. In July 1998 the American Museum of Natural History contracted the University of Washington to recover parts of several chimneys for display and specimen study. This joint project of American and Canadian scientists removed up*per sec*tions of four chimneys, parts of which are now on display in museums in the US (source: Leary, D.K., "Law Reaches New Depths: The Endeavour Hydrothermal Vents Marine Protected Area," In Beumer, J.P., Grant, A. & Smith, D.C. (Eds.), Aquatic Protected Areas. What Works Best and How do we Know? Proceedings of the World Congress on Aquatic Protected Areas, 2002, Cairns, Australia, Australian Society for Fish Biology, University of Queensland, 85-96).

453 Endeavour Hydrothermal Vents Marine Protected Area Management Plan, 2001, Fisheries and Oceans Canada,

available at <http://www.pac.dfo-mpo.gc.ca/oceans/Endeavour/ management_e.htm>.

454 Management Objectives 1 and 2, Endeavour Hydrothermal Vents Marine Protected Area Management Plan.

455 Para 3(1)(b), Endeavour Hydrothermal Vents Marine Protected Area Regulations, available at http://canadagazette.gc.ca/partll/2003/20030312/html/sor87-e.html. 456 Para 3(2), Endeavour Hydrothermal Vents Marine Protected Area Regulations.

457 Para 3(1)(c), Endeavour Hydrothermal Vents Marine Protected Area Regulations.

458 Section 6, Endeavour Hydrothermal Vents Marine Protected Area Management Plan. The Management Committee will be responsible for the overall management of the MPA. Chaired by Fisheries and Oceans Canada, and composed of stakeholders and relevant federal government agencies, the Management Committee has the following tasks: identifying and evaluating emergent or critical issues regarding use of the MPA's resources; reviewing plans for research and other activities, such as submarine tourism; identifying educational opportunities; providing advice to Fisheries and Oceans Canada on the MPA's development and evaluation; and reviewing applications for research and other activities within the MPA.

459 The Management Plan defines the various activities allowed in each site. Only observation and non-invasive research techniques will be permitted in the Salty Dawg field, where activities will be limited to infrequent water sampling and annual visits for monitoring instruments in areas on or near the seafloor, acoustic imaging, water column investigations that have no impact on the seafloor or benthic/near-bottom ecosystems, and activities in the area that contribute to the knowledge and understanding of environmental impacts of human activities on hydrothermal vent ecosystems. The High Rise Field will be a site for research, associated with long term monitoring, and will be utilized as part of the education/outreach strategy of the MPA. Most scientific research will be confined to the Mothra and Main Endeavour fields, where observational and intensive sampling operations will continue to be permitted subject to consistency with the Regulations.

460 Management Objective 6, Endeavour Hydrothermal Vents Marine Protected Area Management Plan.

461 Management Objective 8, Endeavour Hydrothermal Vents Marine Protected Area Management Plan.

462 Horta Workshop Proceedings. Lucky Strike is the largest hydrothermally active area known in the world's oceans with 21 active chimney sites spreading throughout 150 square kilometers at a depth of 1700 meters around a fossil lava lake. The Menez Gwen vent field hosts a 700 meters high volcano and active sites at 850 meters depth.

463 Horta Workshop Proceedings. The goals of the Workshop were to, *inter alia*: identify threats to the sites; draw up a zonation plan of the area; develop a code of conduct; design a management plan; and strike a balance between conservation of the sites and activities such as tourism and scientific research.

464 Horta Workshop Proceedings.

465 Horta Workshop Proceedings.

466 The Workshop proposed that access for tourism be prohibited within defined zones (e.g., experimental areas and highly sensitive sites) and accessible areas be restricted considering, *inter alia*, mode of operation, vessel type and size. It was proposed that: tour operators provide on-board ship access to MPA officials; biological and geological specimen collection be prohibited; photographic and video images be only for private use; professional photographers be charged a fee and their images provided to an MPA data bank; tour operators submit independent environmental assessments; tour operators be licensed and a license fee be set up. (source: Horta Workshop Proceedings).

467 Horta Workshop Proceedings. 468 Horta Workshop Proceedings.

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