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Recent Developments in Biological Prospecting Relevant to Antarctica

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Prepared by

United Nations University Institute of Advanced Studies

1. Introduction

ATCM XXVII considered biological prospecting in Antarctica under item 17 of its agenda. The record of the discussion noted that a “number of Parties emphasized the increasing importance of this topic for the ATCM and urged interested Delegations to introduce working papers at the next ATCM, so that consideration of this important subject can progress. The need for the ATCM to be informed of developments on this topic in other international fora was stressed.”

This Paper responds to this request for more information, in particular the need for information of developments in other international fora. The report builds upon previous reports prepared for the ATCM on this topic, in particular, Information Paper 106 *Industry Involvement in Antarctic Bioprospecting*, prepared for ATCM XXVII and Information Paper 75 *Bioprospecting*, prepared for ATCM XXVI.

Section 2 of this Paper provides a review of recent trend in Biological Prospecting of interest. Section 3 looks at general trends in biotechnology. Section 4 outlines developments regarding biological prospecting in other international fora.

The United Nations University Institute of Advanced Studies (UNU-IAS) in May 2005 published a study considering biological prospecting of genetic resources of the seabed beyond national jurisdiction (*Bioprospecting of Genetic Resources in the Deep Seabed: Scientific, Legal and Policy Aspects*). The study provides an overview of relevant scientific, legal and policy aspects and explores various policy options that exist to address deep seabed bioprospecting at the international level. The study was peer reviewed by numerous experts and representatives of international organisations, including the Secretariat of the Convention on Biological Diversity, the Secretariat of the International Seabed Authority, the United Nations Department of Economic and Social Affairs, the United Nations Division for Ocean Affairs and the Law of the Sea and the United Nations Educational Scientific and Cultural Organization. This Paper is based on that study.

2. Biological Prospecting

The UNU-IAS study demonstrates that bioprospecting for deep seabed genetic resources is taking place and that related commercial applications are being marketed. Although it was not possible to determine whether any of these resources were collected from the deep seabed under or near the Southern Ocean, it is unlikely that they were. Nevertheless as was pointed out in earlier studies, they demonstrate the growing interest in extremophiles research, which is prevalent in Antarctica.

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 bacteria¹ to develop commercial skin protection products providing higher resistance to UV and heat exposure. These inventions have been the object of patents.² 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.³

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 US5455170), a thermostable polymerase from *Pyrodictium sp.* (patent US5491086), and a thermostable polymerase from *Thermosiphon africanus* (patent US 5968799)⁴. 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.⁵ 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.⁶ As of November 2004, Diversa has commercialized several products developed on the basis of deep sea organisms⁷, including: the Pyrolase™ 160 enzyme, derived from a hydrothermal organism and used in industry to reduce viscosity;⁸ and the thermostable ThermalAce™ DNA Polymerase, derived from a non-declared Archaea species, and used in DNA sequencing.⁹

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

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

2 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.

3 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).

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

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

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

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

8 See <<http://www.diversa.com/markprod/prod/pyro.asp>> (last visited on 14 December 2004).

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

genes, *Pyrococcus sp.* – a hydrothermal vent species found at 2010 meters of depth and growing at temperatures of up to 104°C;¹⁰ and the *Therminator^a DNA Polymerase*, obtained from a genetically-engineered form of the DNA polymerase of *Thermococcus sp.*¹¹

The company Aquaartis, based in France, has developed *BactoScreenTM* – 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.¹²

The United States National Oceanic and Atmospheric Administration (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 *Forcepia*, commonly found in deep sea habitats in the Gulf of Mexico. Reference is also made to the discovery of discodermolide, a potent anti-tumor agent, isolated from a deep sea sponge by the Harbor Branch Oceanographic Institution, Inc. (HBOI), a not-for-profit 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.¹³

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.

3. General Trends in Biotechnology

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%.¹⁴ New investments, including from governments, are directed towards the biotechnology sector.

10 See <<http://www.neb.com/nebecomm/products/productM0258.asp>> (visited on 15 December 2004). Also, Wirsén, C.O., Molyneux, 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.

11 See <<http://www.neb.com/nebecomm/products/productM0261.asp>> (visited on 15 December 2004).

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

13 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); P69018991.5 (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).

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

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.¹⁵ 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.¹⁶

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).¹⁷ 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. 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.¹⁸

The development of genomics has been promoted by the development of bioinformatics, which is the application of information technologies to biodiversity studies. 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.¹⁹ 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.²⁰ 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.²¹

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

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

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

17 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.

18 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.

19 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.

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

21 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.

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 2002-2003.²² 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.²³ This may lead to greater examination of novel genetic resources and biochemical processes as part of the product development phase of various sectors.

The Millennium Ecosystem Assessment (MA) was launched in March 2005 and represents the most significant international environmental assessment of the past few years. The MA was carried out between 2002 and 2005 to assess the consequences of ecosystem change for human well-being and to analyze options available to enhance the conservation and sustainable use of ecosystems and their contributions to human well-being. The MA responds to government requests for information received through four international conventions (Convention on Biological Diversity, UN Convention to Combat Desertification, Ramsar Convention on Wetlands, and the Convention on Migratory Species) and is also designed to meet needs of other stakeholders including business, civil society, and indigenous peoples. It has been carried out by approximately 1,300 experts from 95 countries through four working groups and encompassed both a global assessment and a series of sixteen sub-global assessments. An independent review board has overseen an extensive review by governments and experts. Each working group and each sub-global assessment has produced detailed technical assessment reports. It found that 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.²⁴ 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.

4. Developments in other international fora

There have been a number of recent developments in other international fora of relevance to biological prospecting in Antarctica. The most important of these, namely the UN General Assembly and the UN Informal Consultative Process on Oceans, the International Seabed Authority (ISA) and the Law of the Sea United Nations Convention on Law of the Sea (UNCLOS), the Convention on Biological Diversity (CBD), the World Intellectual Property Organisation (WIPO) and the World Trade Organisation (WTO), are outlined in this Section.

22 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-in-the-high-seas.doc>>, hereafter referred to as “Dunedin Workshop Report.”

23 Dunedin Workshop Report.

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

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

By Resolution 54/33, the General Assembly established an open-ended informal consultative process to undertake an annual review of developments in oceans affairs. The General Assembly 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.

There have been five meetings of this process, known as the United Nations Open-ended informal consultative process on oceans and the law of the sea (ICP). ICP considered bioprospecting at its fifth meeting in June 2004. Delegates had different views regarding the legal status and the regime for bioprospecting in the deep seabed beyond national jurisdiction.

Delegates who favoured developing policies to regulate bioprospecting in the Area emphasized that, pursuant to article 143 of United Nations Convention on the Law of the Sea (UNCLOS), all marine scientific research in the Area had to be carried out exclusively for peaceful purposes and for the benefit of mankind as a whole. They argued that all marine resources on the seabed beyond national jurisdiction, including the marine biodiversity, constitutes the common heritage of mankind and should be dealt with within the legal regime for the Area in Part XI of UNCLOS, given the symbiotic relationship of biodiversity and the deep seabed and its resources. It was also pointed out that there are complementarities between UNCLOS and the CBD, as both instruments emphasize the fair and equitable distribution of benefits from the resources. Thus, commercially-oriented activities in the Area regarding biological diversity should be subject to these legal frameworks. Access to the biodiversity and genetic resources in the Area should be equitable and subject to the regime of marine scientific research. The derivatives of such research should be subject to benefit-sharing, on a non-discriminatory basis. Several delegations stressed that the improper use of intellectual property rights was prejudicial to countries that had not yet achieved the advanced level of technology necessary to carry out bioprospecting, depriving those countries' present and future generations of the benefits derived from such activity in the Area.

Delegates expressing reservations about developing policies for bioprospecting pointed out that UNCLOS contains only general principles set out in article 240 of UNCLOS which do not include any conditions or restrictions on the freedom to conduct marine scientific research and bioprospecting on the high seas. UNCLOS excludes marine living resources, such as fish, marine mammals, plants and other living organisms, from the legal regime of the Area and the regime of the common heritage of mankind does not apply to them. Consequently, these resources are not owned until they are taken into possession. Despite the work being done by International Seabed Authority (ISA) to promote and encourage marine scientific research in the Area and exploration of its resources with due regard for the protection of the marine environment, it was pointed out that no organization had, or should have, authority to regulate marine scientific research on the high seas. Several delegations expressed their reservations with regard to paragraphs 260 to 262 of the report of the Secretary-General on oceans and the law of the sea. Among others, they pointed out that UNCLOS did not provide a definition of marine scientific research and did not mention bioprospecting. It was also noted that the distinction between pure and applied marine scientific research had never been accepted universally, since there was no perceivable difference in the activity or method.

Delegates discussed whether ICP was the best forum to consider bioprospecting. Some delegations expressed the view that there is a legal lacuna in respect of deep sea biodiversity.

While UNCLOS contains provisions for marine scientific research, including in areas beyond national jurisdiction, it is unclear about bioprospecting. A number of delegations expressed the view that ISA should be considered as a possible forum where matters related to bioprospecting of other resources could be examined. Other delegations stated that a comprehensive study of the issues involved, including the nature of the resources and their potential use has to be undertaken before any legal provisions or any other actions could be taken.

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.²⁵ 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.²⁶ The ICP also identified genetic resources as an issue that may benefit from further work by the General Assembly.²⁷

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.²⁸ 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.²⁹

The General Assembly in its annual resolution on the oceans (A/RES/59/24) 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.

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

²⁵ Para 5, ICP Report – Fifth meeting.

²⁶ Para 7, ICP Report – Fifth meeting.

²⁷ Para 97, ICP Report – Fifth meeting.

²⁸ Press release GA/10298 of 16 November 2004.

²⁹ Press release GA/10299 of 17 November 2004.

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 60th session of the General Assembly, which should address these issues.³⁰

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 58/240.³¹ Presumably, this assessment would include an assessment of the state of deep seabed biodiversity.

4.2 *Bioprospecting in the Area: Part XI and the role of the International Seabed Authority*

As has been noted in previous Papers the regulations developed by the ISA to address the impact of mining on the Area's marine environment are of relevance for addressing the impacts of bioprospecting activities in the Area and Antarctica.

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.³² 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.³³

The regime of the Area only applies to "activities of exploration for, and exploitation of, the resources of the Area,"³⁴ which are defined as "solid, liquid or gaseous mineral resources *in situ* in the Area at or beneath the seabed, including polymetallic nodules."³⁵ 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.³⁶

Part XI requires prospective miners to submit a plan of work for approval to the Council,³⁷ which shall indicate two sites proposed for exploration and/or exploitation,³⁸ and be accompanied by an assessment of the potential environmental impacts of the proposed activities.³⁹ Upon approval of the work plan, the Authority's Enterprise has the right to decide

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

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

32 Preamble, UNCLOS.

33 Art.136 and 137, UNCLOS.

34 Art.1(3), UNCLOS.

35 Art.133, UNCLOS.

36 Art.156 and 157, UNCLOS.

37 Art.153(3), UNCLOS.

38 Art.8, Annex III, UNCLOS.

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

which of the two sites it wishes to mine.⁴⁰ 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.⁴¹ 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.⁴² 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.⁴³

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.⁴⁴

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.⁴⁵ 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.⁴⁶

At its sixth session in 2000, the ISA adopted Regulations on Prospecting and Exploration for Polymetallic Nodules in the Area.⁴⁷ 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.⁴⁸

Under Regulation 2, prospecting is not to be undertaken if substantial evidence indicates a risk of serious harm to the marine environment.⁴⁹ Regulation 2 also states that prospecting does not confer rights on the prospector with respect to resources, but that the prospector may

40 Section II, 1994 Part XI Agreement.

41 Reports of the Chairmen of the Legal and Technical Commission to the Council (ISBA/9/C/4 and ISBA/10/C/4).

42 Para 15-17, Report of the Chairman of the Legal and Technical Commission (ISBA/9/C/4).

43 “Seabed Authority’s Legal and Technical Commission, in First Open Meeting, Discusses Biodiversity in Deep Seabed Area,” Press Release (SB/10/8).

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

45 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.

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

47 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.”

48 Regulation 1(4), Polymetallic Nodules Regulations.

49 Regulation 2(2), Polymetallic Nodules Regulations.

“recover a reasonable quantity of minerals, being the quantity necessary for testing and not for commercial use.”⁵⁰

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.⁵¹ 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.⁵²

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.⁵³ 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.”⁵⁴

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 prospecting, 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.⁵⁵

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.”⁵⁶ 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

⁵⁰ Regulation 2(4), Polymetallic Nodules Regulations.

⁵¹ Regulations 24(1) and 26(1), Polymetallic Nodules Regulations.

⁵² Regulation 30, Polymetallic Nodules Regulations.

⁵³ Regulation 31(3) and (4), Polymetallic Nodules Regulations.

⁵⁴ Regulation 31(7), Polymetallic Nodules Regulations.

⁵⁵ Regulation 35(3), Polymetallic Nodules Regulations.

⁵⁶ “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.”

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.⁵⁷ 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.

4.3 *Bioprospecting under the Convention on Biological Diversity*

The CBD contains measures addressing access to genetic resources, transfer of technologies, technical and scientific cooperation, funding and handling of biotechnology.⁵⁸

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 2002,⁵⁹ 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.

The Guidelines, which are voluntary,⁶⁰ are to be applied in a manner that is mutually supportive of the work undertaken by other fora.⁶¹ It is specifically stated that nothing in the Guidelines should be interpreted to assign any rights over genetic resources beyond those provided in accordance with the CBD.⁶² 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 benefit-sharing arrangements. Section IV identifies steps in the access and benefit-sharing process.

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

⁵⁷ Regulations 16-19, Draft Polymetallic Sulphides Regulations.

⁵⁸ 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.

⁵⁹ "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."

⁶⁰ Para 7, Bonn Guidelines.

⁶¹ Part I, Section D, Bonn Guidelines.

⁶² Para 5, Bonn Guidelines.

national definitions of such terms as “access to genetic resources,” “benefit-sharing,” “commercialization,” “derivatives,” “provider,” “user,” “stakeholder,” and “*ex situ* collection.”⁶³ All these are particularly relevant in the case of activities related to use of genetic resources in Antarctica, 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.⁶⁴

On the basis of calls from the World Summit on Sustainable Development (WSSD) and the UN General Assembly,⁶⁵ 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.⁶⁶

The ABS Working Group met in March 2004 in Bangkok. The ABS Working Group initiated negotiations on an international regime on ABS. The ABS Working Group also addressed: the use of terms not defined in the CBD; additional approaches to complement the Bonn Guidelines on ABS, such as an international certificate of origin/source/legal provenance; measures to ensure compliance with prior informed consent (PIC) of Parties providing genetic resources and with mutually agreed terms (MAT) for granting access.

The report of the ABS Working Group, as well as discussions during the meeting, focused on the international ABS regime. The complexity of the matters, such as the relationship with intellectual property rights (IPRs), the difficulty to develop a common vision regarding the nature of the regime or even its necessity, and the unclear international framework, means that it will take some time before even the outline of the international regime will become clear and its details will take even longer. Some options were identified under the scope and potential objectives of the regime, while its potential elements were grouped according to their subject matter, to set the groundwork for more structured deliberations in the future. A matrix was also developed to identify and analyze the gaps in international instruments and indicate ways to address them. Finally, the meeting made specific calls for government submissions on the matrix and broader ABS regime, which many see as crucial to further clarify positions and set the baseline for the ABS Working Group. The meeting was described as a success by ENB which described it as “brainstorming session to allow for consolidation of country and regional positions and to prepare for the next Working Group session”, which will be in January 2006. The results of the ABS Working Group will be considered by COP 8 in Brazil in March 2006.

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

64 Part C, Decision VII/19.

65 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.

66 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.

4.4 Activities of the World Intellectual Property Organization

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. 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.

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.⁶⁷ 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.⁶⁸ 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.⁶⁹

Responding to an invitation from COP-6 (April 2002), WIPO prepared a technical study on patent disclosure requirements related to genetic resources and traditional knowledge,⁷⁰ which was subsequently adopted by WIPO's General Assembly and presented to COP-7 in February 2004. Disclosure of origin is particularly relevant to Antarctic genetic resources, the status of which is uncertain. 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 Prior Informed Consent.

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).⁷¹ The study notes the need to clarify the link between input, i.e. the source genetic material, and invention

⁶⁷ "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."

⁶⁸ Para 34, Contractual Practices.

⁶⁹ Para 38, Contractual Practices.

⁷⁰ "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."

⁷¹ Para 24, Disclosure Requirements Study.

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.⁷² 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.⁷³

A distinctive disclosure mechanism of particular relevance to Antarctic genetic resources (because of their extremely difficult to access *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 Antarctic genetic resources, the written disclosure of the invention might be considered insufficient.⁷⁴

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 1980.⁷⁵ According to the Budapest Treaty, Contracting Parties recognize a deposit made in specified culture collections, or International Depository Authorities (IDA), as adequate for the purposes of their patent procedure.⁷⁶ 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.⁷⁷ The Treaty contains procedures governing the behavior of depositors and IDAs, the duration of storage of microorganisms and the mechanism for providing samples.⁷⁸ 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

⁷² Para 91, Disclosure Requirements Study.

⁷³ Para 130, Disclosure Requirements Study.

⁷⁴ Para 102, Disclosure Requirements Study.

⁷⁵ 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.”

⁷⁶ Art.3(1), Budapest Treaty.

⁷⁷ Art.7 and 6(2), Budapest Treaty.

⁷⁸ Rules 6, 2, 9 and 11, Budapest Treaty Regulations.

online sequence listing of WIPO, may facilitate tracking such origin and conditions.⁷⁹ 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.

4.5 *The Agreement on Trade-Related Aspects of Intellectual Property Rights of the World Trade Organization*

The Agreement on Trade-Related Aspects of Intellectual Property Rights of the World Trade Organization (TRIPS) establishes minimum standards on the protection of intellectual property rights for WTO Member States.

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.⁸⁰

Pursuant Article 27(3), plants or animals are excluded from patentability, but microorganisms and microbiological and non-biological processes can be subject to patents.⁸¹

Article 28 requires that a patent confer 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 subject-matter 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.⁸²

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

⁷⁹ Oldham, P., *Global Status and Trends in Intellectual Property Claims: Microorganisms*, 2004, available at <<http://www.cesagen.lancs.ac.uk>>.

⁸⁰ Art.27(1), Agreement on Trade-Related Aspects of Intellectual Property Rights, hereafter referred to as “TRIPS Agreement.”

⁸¹ 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).

⁸² Art.29, TRIPS Agreement.

on these topics is to be guided by the objectives of the TRIPS Agreement set out in Article 7⁸³ and its principles embedded in Article 8,⁸⁴ and should take development issues into account.⁸⁵

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.⁸⁶ The focus of discussions on this issue is main to do with the implications of the TRIPS Agreement on the use and misuse of traditional knowledge. Discussions are ongoing in the TRIPS Council as part of the Doha Round on all of these issues.⁸⁷

83 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."

84 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.

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

86 WTO website: <http://www.wto.org/english/tratop_e/trips_e/art27_3b_background_e.htm>.

87 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).