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UNU/IAS Report

The International Regime for Bioprospecting

Existing Policies and Emerging Issues for Antarctica

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August 2003

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1 Introduction

An increasing amount of the scientific research on the flora and fauna of Antarctic is underway with a view to identifying commercially useful genetic and biochemical resources. This type of research is likely to increase.

The need to consider bioprospecting has been raised in the Scientific Committee on Antarctic Research (SCAR), the Committee for Environmental Protection (CEP), and the Antarctic Treaty Consultative Meeting (ATCM). Most recently, the matter was considered at the last meeting of the CEP and ATCM based on a Working Paper submitted by the United Kingdom (WP–043).

The CEP concluded that biological prospecting needed to be discussed during the next CEP meeting and included it on its agenda for its sixth meeting (Item 7). Members were encouraged to submit papers on biological prospecting for consideration at CEP VI. The ATCM agreed with the CEP that biological prospecting was a very important matter. The ATCM also agreed that biological prospecting raised legal and political issues, in addition to environmental issues. As a result, the ATCM urged Parties to be prepared to consider these matters at the XXVIth meeting of the ATCM.

This paper has been prepared in order to assist Parties in their preparations on the matter of biological prospecting in Antarctica for ATCM XXVI and CEP VI.

The Paper takes as its starting point the issues raised in Working Paper-043.

The Paper begins by reviewing bioprospecting activities in Antarctica to ascertain the nature and scope of existing Antarctic bioprospecting activities before considering similar bioprospecting activities in other regions. The relevant legal provisions of the Antarctic Treaty System (ATS) are then outlined and a brief overview of the ATS bodies relevant activities undertaken. Next, relevant international policies are considered before briefly addressing the questions raised at the last ATCM and CEP. Finally, some possible next steps are outlined.

2 Review of Biological Prospecting Activities in Antarctica

This section will consider the types of institutions engaged in Antarctic bioprospecting, review several notable commercially valuable discoveries, provide an indication of commercial investment into Antarctic bioprospecting, and outline a number of commercial applications arising there from.

The preliminary desktop review undertaken for this study has shown that without further in–depth research it is not possible to ascertain the precise extent of current Antarctic bioprospecting activities. The information below was obtained from publicly available information on the internet. It is evident from such a search an initial search that more bioprospecting is actually taking place, a finding supported by observations of scientists active in Antarctica. Determining the exact extent of such activities, their commercial value, and likely trends will require more active surveying of the relevant activities in Antarctica, the sectors using genetic material from Antarctica, research programmes most directly involved, and records of the appropriate patent offices.

So far, biological prospecting activities in Antarctica have been carried out by universities, research centres, and biotechnology and pharmaceutical companies, such as the University of Bordeaux (France), the Australian Academy of Technological Sciences and Engineering, Genencor International (multinational), and Merck Sharp & Dohme (multinational). Bioprospecting activities in Antarctica tend to be carried out by consortia comprising a mixture of public and private bodies, making it difficult to draw a clear distinction between scientific research and commercial activities. MICROMAT, for example, is an academic–industrial consortium, whose partners include the University of Nottingham (UK), University of Liège (Belgium), University of Ghent (Belgium), University of Bordeaux (France), Genencor International (multinational), Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (Germany), Merck Sharp & Dohme (multinational), and BioSearch Italia SPA (Italy).[1] In addition to public–private consortia, scientists on a strictly academic project may identify and exploit an organism's valuable use, thus blurring the line between scientific research and commercial activity. (i.e. see paragraph 14 and the case of the protease isolated from the thermophilic bacillus).

Bioprospectors' interest in Antarctica stems from 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 hyper–saline lakes, and antifreezes in sea–lakes.[2]

Amongst the many examples of commercially useful compounds discovered, is a glycoprotein, which functions as the 'antifreeze' that circulates in some Antarctic fish, preventing them from freezing in their sub–zero environments.[3] The glycoprotein was discovered in the early 1970s by National Science Foundation (NSF) funded research conducted by Chi–Hing C Cheng and Liangbiao Cheng from the University of Illinois. The application of this glycoprotein in a range of processes is being considered, including increasing the freeze tolerance of commercial plants, improving farm–fish production in cold climates, extending the shelf life of frozen food, improving surgery involving the freezing of tissues, and enhancing the preservation of tissues to be transplanted.[4] It should be noted that this discovery was based on research into the Southern Ocean, highlighting the importance both of the Southern Ocean and the Antarctic continent as sources of commercially useful genetic resources. Other discoveries include the enzyme–producing ability of an Antarctic fungus [5] based on research carried out in 1995 by M Fenice, L Selbmann, L Zucconi and S Onofri from the University of Tuscia.

Attracted by such potentially useful discoveries the private sector has started to include Antarctic flora and fauna in its product development programmes. Examples of companies' activities include a contract signed in 1995 between the Antarctic Cooperative Research Centre, University of Tasmania, Australia, and AMRAD Natural Products, an Australian pharmaceutical company. According to the contract, AMRAD is given the right to screen some 1,000 Antarctic microbial samples per year in search for natural antibiotics and other human pharmaceutical products.[6] Another example is Cerylid Biosciences, an Australian biotechnology company engaged in the discovery of new lead compounds for the development of new anti–cancer and anti–inflammatory medicines. Cerylid bases its discovery work on a biodiversity library containing 600,000 extracts from naturally occurring sources, which includes samples of plants, microbes, and marine organisms collected amongst others in Antarctica. Finally, Genencor International, a global biotechnology company with more than $300 million in revenue in 1999 and over 3,000 owned and licensed patents and applications, also sources materials from Antarctica.[7] One prominent Antarctic scientist estimated that the private sector has provided $1 million funding for Antarctic microbiology and biotechnology since 1997.[8]

In some cases, these research activities have lead to commercial applications. Patents are one indicator of the application of this research, and have been referred to in this regard by the 27th meeting of SCAR. Patents applied for or granted so far based on the bioprospecting of Antarctic biota are manifold. Preliminary investigation of the Database of the European Patent Office identified sixty–two Patents that had relied upon Antarctic biodiversity. A preliminary examination of the US Patent Office Database identified over 300 references to Antarctica. A recent example is a patent granted in 2002 from the Spanish Patent Office for the wound healing, and skin, hair and nail treating characteristics of a glycoprotein extracted from the Antarctic bacteria *Pseudoalteromonas antarctica*.[9] An extract from the green algae *Praiola crispa ssp. antarctica* has been patented in 2002 in Germany for its utility in cosmetic skin treatment.[10] In 1997, a patent was granted by the Russian patent office to for the production of biologically active substances with anti–tumour properties gained from strain 356 of the Antarctic black yeast *Nadsoniella nigra var. hesuelica*.[11]

The database of the US Patent Office revealed there were ninety–two applications for patents that referred to Antarctica. A typical example, is a patent application that has been filed with the US Patent Office relating to, *inter alia*, the process for preparing novel anti–freeze peptides and to peptides obtained from some Antarctic bacteria, which can be incorporated into frozen food products such as frozen vegetables and ice cream.[12] Another interesting example is the application filed in the US for a process that provides cellular transformation, directed evolution, and screening methods for creating novel transgenic organisms having desirable properties, which will be particularly helpful for identifying mutations associated with disease, and for forensic, epidemiological, and evolutionary studies[13]. This example is of particular interest because the invention is dependant upon the protease of a thermophilic *Bacillus* that was apparently isolated in a scientific expedition in 1980[14]. This example illustrates how difficult it is to distinguish commercial activity from scientific research.

Quantifying the actual value of these patents or indeed the overall benefit that companies have derived from Antarctic biodiversity has not been possible. Compiling such figures, if possible, will be a lengthy task that will require the cooperation of the institutions involved and the relevant governments. Given the constraints of this study, it has not been possible to ascertain many other basic facts that need to be known about bioprospecting before rational decisions can be made about its regulations. For example, the extent that the natural biological process contributed to the discovery, whether that patent holders collected the samples from Antarctica or relied upon *ex–situ* samples collected by others, how companies have accessed them and assert their right to use them, the type of non–monetary benefits, and how the monetary and non–monetary benefits have been distributed.

It has not been possible to come to any conclusions about the physical impact that bioprospecting has had on the biodiversity of Antarctica. It has not been possible to ascertain if there has been a rise in collecting biodiversity components and whether the activity has resulted in damage to the Antarctic environment components. The bioprospecting examined for the purposes of this survey has only used Antarctic biodiversity for its information value. The survey did not find any instances of commercial harvesting of Antarctic biodiversity by companies or individuals for biotechnological purposes.[15]

Despite these limitations, some preliminary conclusions and observations can be drawn about bioprospecting in Antarctica.

It appears there is considerable interest in conducting further research into commercially useful genetic resources and biochemical processes in Antarctica. The potential of bioprospecting activities can be illustrated by two additional examples. It has for example been found that many of the newly discovered Antarctic Actinobacteria species, including Streptomyces, Nocardia, and Micromonospora, belong to genera with strong track records for producing pharmaceutically active compounds. The adaptation of various cellular processes to a permanently cold environment represents potential biotechnology products for exploitation. Two examples of such adaptation are the production of polyunsaturated fatty acids (PUFA) and of cold–active enzymes by bacteria inhabiting Antarctic ice.

The bioprospecting that has been conducted in Antarctica appears to be similar in terms of process to that carried out elsewhere. Development of commercial products from naturally occurring genetic resources or biochemical processes has been typically a long, expensive, and uncertain process. Key stages of bioprospecting usually include:

- organism discovery through collection, screening and description
- product development involving isolation, purification, modification and clinical testing
- manufacturing
- marketing

The time between collection and marketing can be very long – sometimes more than twenty years. The cost of developing a successful product can require an investment of hundreds of millions of dollars. The marketed product is often a result of many different ideas and contributions, with the initial discovery of the natural resource contributing only partially to the product. Intellectual property rights, such as patents, have been applied for as soon as possible in the process.

Questions that have arisen in the development of products include:

- how can ownership be properly acquired
- what procedures need to be followed to ensure that the use is legitimate
- what if any approvals are necessary to ensure that the patent application is valid
- is benefit sharing required and if so with whom

GlaxoWellcome Viridian, for example, was apparently reluctant to support some Antarctic biopropspecting activities, due to the lack of clarity surrounding benefit–sharing.[16]

3 Overview of Biological Prospecting Trends Elsewhere

General industry trends in bioprospecting and biotechnology provide some indication as to the likely future of biological prospecting activities in Antarctica.

3.1 General Industry Trends

Industry sectors involved in bioprospecting include biotechnology, waste, agriculture, pharmaceuticals, and cosmetics. All of these sectors are increasingly using biotechnology to develop new products.

Although every sector relies upon natural processes in different ways, some general observations are relevant. Development of commercial products from naturally occurring genetic resources or biochemical processes is typically a long, expensive, and uncertain process.

The accounting firm Ernst & Young publishes the most respected survey of the biotechnology sector annually. In its most recent survey, it concluded that the biotechnology industry continues to experience significant growth despite the downturn in global market. According to the report, the global biotech industry comprises 4,284 companies (622 public; 3,662 private) in 25 nations. In 2001, the 622 public companies generated revenues of $35 billion, spent $16 billion in R&D and employed more than 188,000 people. While seventy–two per cent of the public company revenues were generated by companies in the US, emerging biotech sectors in Europe, Canada, and the Asia/Pacific region have experienced significant growth in the number of companies as new technologies increasingly make their way from research labs into privately funded enterprises. The report estimates that by 2005 the European biotech market could double from current valuations to more than $100 billion. These figures are supported by other surveys of sector. For example, the *Far Eastern Economic Review* estimated the number of 'bioventures' in the US, Europe, and Asia at 1,500, 1,300, and 1,200, respectively.[17]

Quantifying the contribution that natural genetic resources make to this market is difficult for many reasons. Figures, for example, 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.

Nevertheless, the magnitude of the commercial use of biodiversity can be illustrated by considering some examples:

- Annual sales derived from traditional knowledge using genetic resources are US$ 3 billion for the cosmetic and personal care industry, US$ 20 billion for the botanical medicine sector, and US$ 75 billion for the pharmaceutical industry;[18]
- Sixty–two per cent of cancer drugs approved by the US Food and Drug Administration are of natural origin or modelled on natural products.[19]

The continued growth of the biotechnology sector and the increased pervasiveness of biotechnology in other sectors will lead to greater examination of novel genetic resources and biochemical process as part of the product development phase of various sectors. A consequence of this trend is that naturally occurring genetic resources and biochemical processes will most likely receive greater attention from the private sector. In other words, based on the global biotechnology trends, it can be assumed that bioprospecting is likely to increase.

Despite this potential commercial utility, the actual use of genetic resources by industry is complex and affected by numerous factors. Kerry ten Kate and Sarah Laird carried out the most recent comprehensive survey of the private sector's use of naturally occurring genetic resources and biochemical processes[20] from 1997–1998. They examined the commercial use of biological diversity by the pharmaceutical industry, crop protection industry, seed companies developing major crops, horticulture industry, companies developing botanical medicines, cosmetics and personal care industry, and the commercial use of biotechnology in fields other than healthcare and agriculture.

They note, *inter alia,* that while the pharmaceutical industry continues to be interested in natural products, natural product drug discovery is slow and costly in comparison to drug development based on synthetic compounds, and may therefore lead to a decrease in the pharmaceutical industry's reliance on natural compounds.[21] Regarding the development of major crops by the seed industry, ten Kate and Laird highlight that despite plant breeders' use of, and interest in, foreign germaplasm, future trends may see a decrease in the demand for exotic materials due to obstacles in gaining access to genetic resources and the challenge faced in comprehending the many intellectual property rights and material transfer agreement requirements.[22]

The authors note that industry commonly cites two factors in determining future commercial demand patterns for access to genetic resources, namely advancements in science and technology, and trends in law and policy. Reasons cited for a possible decrease in the demand for access to genetic resources are alternative approaches to discovering and developing products, the more selective and targeted selection of samples aimed at complementing existing collections, and increased

reliance of the latter. Regarding law and policy trends, increasing bureaucracy, legal uncertainty, and lack of clarity, as well as unrealistic expectations for benefit–sharing are at the centre of decreasing demand for access to genetic resources. Similar conclusions have been made in other reviews (i.e. Reports of the CBD Panel of Experts on Access and Benefit–Sharing).[23]

The authors do, however, note that there are persuasive reasons why demand for genetic resources, and thus for bioprospecting, may increase in the future, including consumer demand for natural products and the development of new tools to explore and develop genetic resources.[24]

The authors argue that general future industry trends regarding bioprospecting are likely to decrease as the number and complexity of rules and regulations continues to grow. Their view is that decision–makers must therefore be encouraged to adopt and implement simple, streamlined, and flexible regulations on access to genetic resources.[25]

3.2 Bioprospecting for Extremophiles

As noted above, bioprospecting for extremophiles is currently the main focus of bioprospecting in Antarctica. Novel extremophiles and their biochemical process are likely to remain the most important commercial application of the genetic resources of Antarctica.

Extremophiles, microorganisms thriving in extreme conditions such as high temperature, pressure, and salt concentration, or low pH, nutrient concentration, or water availability, inhabit a variety of environments including arid deserts, hot springs, shallow submarine hydrothermal systems, alkaline soils, soda lakes, salterns, deep–sea sediments, and Alpine glaciers. Some examples include the nitrate–reducing achaean, *Pyrolobus fumarii*, which can grow at temperatures of 113 °C. The green algae *Dunaliella acidophila* survives at pH 0, an acidity level that is close to that of ten per cent hydrochloric acid and stands in contrast to the pH level of seawater, pH 8.[26]

The application of extremophiles in industrial processes ranges from their use in liposomes for drug delivery and cosmetics, waste treatment, molecular biology, and to the food industry. A eukaryotic homologue of the *myc* oncogene product from halophilic archaea, for example, is being utilised to screen cancer patients' sera.[27] The greatest commercial impact so far has been made by enzymes from extremophiles, alkaline proteases derived from alkaliphilic species being one example. Due to the species' robust nature, the enzymes can be exposed to harsh conditions such as bleach chemicals and high temperature, and have been successfully used as protein degrading additives in detergents. The significance of this is illustrated by the fact that the market for enzymes used for detergents represents approximately thirty per cent of all enzymes produced. Enzymes isolated or adapted from extremophiles are also used in clinical chemistry, pulp industries, food processing, cleaning, dyeing technologies, or refining and bioremediation.[28]

The best known example of the commercial applicability of extremophiles is the DNA polymerase of *Thermus aquaticus* called Taq polymerase.[29] This polymerase, which is central in the polymerase chain reaction (PCR) as it survives the reaction's successive heating cycles,[30] is widely used in medical diagnosis and forensics, and is at the basis of a US$ 300,000,000 industry.[31] In 1991, the Swiss pharmaceutical company Hoffman–Laroche bought the exclusive world rights to the PCR process for $300 million from Cetus Corporation, the biotechnology company that invented the PCR process and discovered the use of *Thermus aquaticus*. According to one source "worldwide sales of PCR enzymes are in the range of $50–$100 million, and the market for biotechnology enzymes derived from extremophiles is forecast to grow at 15–20% per year".[32]

Bioprospecting for these microbes continues to date, with current research focusing on extremophiles' ability to produce antibiotics, thought research into other potential uses of extremophiles, (e.g. for the treatment of industrial effluents) is also being undertaken. Because the majority of effluents stemming from the synthesis of industrial chemicals are currently treated using expensive and environmentally questionable technologies, the utility of organisms able to treat these wastes is apparent.[33] Advancements in this area have already been accomplished with the engineering of a recombinant strain of *Delinococcus radiodurans* to degrade organopollutants in radioactive, mixed waste environments.[34] With the aim of determining how extremophiles can be more productive in order to develop innovative products and new industrial processes, the European Commission supported a three–year–long project on 'extremophiles as cell factories' with the contribution of some 7 million ECU.[35]

The sustained importance of novel organisms is illustrated by the fact that Diversa Corporation, a US–based biotechnology company, obtained exclusive rights to all commercial applications derived from a recently discovered microbe inhabiting a submarine hydrothermal vent in the Kolbeinsy ridge, north of Iceland.[36] Maloney notes the "urgent need for new antimicrobial agents, given the increase in drug resistance in many common bacterial pathogens and changes in the spectrum of pathogens, together with the emergence of new diseases".

Despite general market trends, it appears that the commercial use of naturally occurring extremophiles is likely to increase, even dramatically, in the near future.

4 Bioprospecting and the Antarctic Treaty System (ATS)

4.1 Legislative Background

The Antarctic Treaty System (ATS) does not directly regulate biological prospecting activities. Nevertheless, provisions relevant in considering the issue of bioprospecting are contained in the Antarctic Treaty, its Protocol on Environmental Protection (Madrid Protocol) and the Convention on the Conservation of Antarctic Marine Living Resources (CCAMLR). The Convention on the Regulation of Antarctic Mineral Resources Activities (CRAMRA) may also provide some guidance for developing measures for regulating bioprospecting activities.

4.1.1 The Antarctic Treaty

The Antarctic Treaty stipulates that Antarctica shall be used for peaceful purposes only and provides for freedom of scientific investigations. It advocates the promotion of international co–operation in this regard.[37] Article III (a)–(c) outlines the specific measures that Parties agree to pursue to this end. Accordingly, Contracting Parties agree that, to the greatest extent feasible and practicable:

a. information regarding plans for scientific programs in Antarctica shall be exchanged to permit maximum economy of and efficiency of operations

b. scientific personnel shall be exchanged in Antarctica between expeditions and stations

c. scientific observations and results from Antarctica shall be exchanged and made freely available

Bioprospecting in Antarctica will mostly be confined to the act of collecting and discovering novel biological resources, thus remaining an activity that is largely scientific even if it is for some ultimate commercial purpose. Accordingly, bioprospecting activities will fall within the remit of Article III addressing co–operation with regard to scientific programmes, scientific personnel, scientific observations, and results. Reporting requirements should provide information about many of these activities but are unlikely to provide information about the commercial application of these resources. Concerns have been raised about reconciling the desire for commercial confidentiality and patents with the legal requirements of Article III. In this regard, it is worth recalling that intellectual property rights are generally understood as a mechanism to promote and encourage exchange of scientific information.

Commercialising most research coming from Antarctica requires a considerable investment of resources. As a result, important issues relate to the ownership of genetic resources and to the need of ensuring that the resources have been legitimately acquired. A lack of clarity about these matters has already affected companies' involvement in work on the genetic resources found in Antarctica. Therefore, Article IV will need to be considered, in particular the provision that "[n]o acts or activities taking place while the present Treaty is in force shall constitute a basis for asserting, supporting or denying a claim to territorial sovereignty in Antarctica or create any rights of sovereignty in Antarctica".

Jurisdictional issues are also of crucial importance in determining ownership and the relevant existing policies governing bioprospecting. Accordingly, Article VI is relevant, stating that the Antarctic Treaty applies to the area south of 60° South Latitude, including all ice shelves, but does not prejudice or affect the rights of any State under international law with regard to the high seas within that area.

4.1.2 Madrid Protocol

The 1991 Madrid Protocol, which entered into force in January 1998, aims to protect comprehensively the Antarctic environment and dependent and associated ecosystems. It designates Antarctica as a natural reserve, devoted to peace and science, and prohibits any activities relating to mineral resources, other than scientific research.[38]

The Protocol sets out a series of environmental principles which, *inter alia*, stipulate that activities in the treaty area are to be planned and conducted so as to limit adverse environmental impacts, avoid detrimental changes in the distribution, abundance or productivity of species or populations of species of fauna and flora,[39] "accord priority to scientific research, and to preserve the value of Antarctica as an area for the conduct of such research".[40] Article 6 reinforces the Antarctic Treaty's provisions on co–operation, noting that Parties shall co–operate in the planning and conduct of activities, where appropriate undertake joint expeditions and share the use of stations and other facilities, and, to the extent possible, share information that may be helpful in planning and conducting activities.

The Protocol includes provisions on environmental impact assessment, outlined in Annex I to the Protocol. Thus, prior assessments of the environmental impacts of activities planned pursuant to scientific research programmes, tourism, and all other governmental and non–governmental activates must be carried out.[41] As a result, bioprospecting activities will need to be subjected to an assessment of any potential environmental impacts they may have on the Antarctic environment. The

Environmental Impact Assessment would examine, *inter alia*, whether the collection of material for bioprospecting would negatively affect specific species or habitats. It is worth noting in this context that the EIA is the responsibility of the State whose nationals undertake the expedition or of the State on whose territory the expedition is organised or proceeds from.[42]

4.1.3 Convention on the Conservation of Antarctic Marine Living Resources (CCAMLR)

As noted before, bioprospecting in Antarctica is being carried out in the Southern Ocean as well as on the continent. The 1980 Convention on the Conservation of Antarctic Marine Living Resources, which entered into force in October 1982 and whose objective is the conservation of Antarctic marine living resources,[43] applies to "the Antarctic marine living resources of 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".[44] Pursuant to Article 2, any harvesting shall be regulated to prevent the decrease in size of harvested populations to levels below their maximum sustainable yield as well as of non–target species and the marine ecosystem as a whole.[45] Article 7 establishes a Commission, whose activities include the formulation, adoption, and revision of conservation measures on the basis of the best scientific evidence available.[46]

The Convention also sets out reporting requirements according to which Parties must annually provide such statistical, biological, and other information as the Commission and its subsidiary Scientific Committee may require. Information about harvesting activities and on steps taken to implement conservation measures must also be submitted upon request to the Commission.[47]

Although harvesting for the purposes of bioprospecting is unlikely to affect populations to such an extent as to fall under the scope of Article 2 of the CCAMLR, the Convention's reporting requirements outlined in Article 20 could include bioprospecting. As noted before, ownership and rights to use are important issues. Jurisdictional questions of the Southern Ocean are made complex due to the various overlapping and competing claims.

4.1.4 Convention on the Regulation of Antarctic Mineral Resources Activities (CRAMRA)

The Convention on the Regulation of Antarctic Mineral Resources Activities (CRAMRA) was adopted in 1988 but is unlikely to enter into force due to the subsequent entry into force of the Madrid Protocol. Although CRAMRA was negotiated to manage and regulate another commercial enterprise in Antarctica, namely mining, the instrument is nevertheless worth considering in this Paper, in particular its provisions regulating mineral resource activities, its institutional structure, and the manner in which it addresses sovereignty. How CRAMRA deals with the treatment of data and information that have potential commercial value also provide some indication as to possible approaches for bioprospecting.

CRAMRA's area of applicability is the "continent of Antarctica and all Antarctic islands, including all ice shelves, south of 60° south latitude and in the seabed and subsoil of adjacent offshore areas up to the deep seabed". [48] By excluding from its jurisdiction mineral resource activities beyond the geographic extent of Antarctica's continental shelf, it ensures that its regulations do not apply to mining activities that could be conducted in accordance with the 1982 United Nations Convention on the Law of the Sea and overseen by the International Seabed Authority.[49]

According to Article 37(2), prospecting activities, which do not require prior authorisation by the Convention's institutions, are to be authorised by Sponsoring States who must ensure that the activities are carried out in compliance with the Convention. Regarding exploration and development activities, the Convention provides for the express authorisation by the bodies it establishes.[50]

The Convention provides for a Commission, which is mandated to act as the plenary body responsible for the overall functioning of the regulatory mechanism established and decide by consensus on areas to be identified for exploration and development.[51] The treaty provides that once the Commission identifies an area for exploration and development, it shall establish a Regulatory Committee, which is to comprise ten members and adopt decisions with a two–thirds majority. The Committee's task is to develop, in line with the Convention's standards, regulations governing the possible exploration and development activities of possible operators.[52]

CRAMRA encourages international participation by interested Parties, particularly from developing countries and notes, similarly to Article IV of the Antarctic Treaty, that nothing in the Convention constitutes a basis for asserting, supporting, or denying claims to territorial sovereignty.[53] Key in addressing the different concerns of claimant and non–claimant States was the establishment of the limited membership Regulatory Committees, composed of claimant and non–claimant States,[54] as well as the power granted to the Commission.[55]

With regard to availability and confidentiality of data and information, 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".

Article 37 in turn notes in this regard that

11. The Sponsoring State shall ensure that basic data and information of commercial value generated by prospecting are maintained in archives and may at any time release part of or all such data and information, on conditions which it shall establish, for scientific or environmental purposes.

12. The Sponsoring State shall ensure that basic data and information, other than interpretative data, generated by prospecting are made readily available when such data and information are not, or are no longer, of commercial value and, in any event, no later than 10 years after the year the data and information were collected, unless it certifies to the Commission that the data and information continue to have commercial value. It shall review at regular intervals whether such data and information may be released and shall report the results of such reviews to the Commission.

13. The Commission may adopt measures consistent with this Article relating to the release of data and information of commercial value including requirements for certifications, the frequency of reviews and maximum time limits for extensions of the protection of such data and information.

One subject matter not addressed by CRAMRA is the allocation of financial profits derived from mineral resource activities in Antarctica.

4.2 Activities of ATS Bodies

In addition to the provisions developed by the ATS, a number of relevant recommendations have been made by various ATS bodies.

4.2.1 Scientific Committee on Antarctic Research (SCAR)

The Scientific Committee on Antarctic Research (SCAR), and in particular SCAR's Working Group on Biology, have been alert to the issue of bioprospecting in Antarctica for some time. In a report on Scientific Research in the Antarctica (Information Paper XXIII ATCM/IP 123 SCAR (1999)), SCAR reported that:

At present there appear to be no provisions in the Antarctic Treaty to deal with exploitation of biological resources in the Antarctic, with the exception of fisheries. There have already been collections of micro–organisms for pharmaceutical purposes and a biological prospecting interest in the Antarctic is developing rapidly. The implications of biological prospecting, and the patenting of biological products, for biological research and conservation is of concern to the Working Group on Biology and the meeting agreed that these issues should be raised with SCAR and with CCAMLR.

The Twenty–seventh Meeting of the Scientific Committee on Antarctic Research (XXVII SCAR), held in Shanghai, China, in July 2002 noted the following under agenda items 6 & 7 on ATCM Scientific Matters and the Group of Specialists on Environmental Affairs and Conservation:

9. Although bioprospecting had been discussed at the WGB previously, this issue requires further attention. Bioprospecting occurs at two levels, viz. the study of genetic materials and determination of commercially important genetic codes and the harvesting of in situ organisms for extraction of biochemicals. A patent had been filed for a protein (marinomonin) isolated from a bacterium collected from an Antarctic lake sediment. Such patent efforts might well restrict the use of this knowledge by Antarctic scientists. While no current instance of harvesting for biotechnology is known, there are obvious environmental ramifications of the taking of animals and plants as a commercial venture. No action is recommended at present, but it was noted by GOSEAC that developments related to bioprospecting should be closely monitored as they might develop into important pressures on Antarctic resources. The Working Group noted that the Antarctic Treaty System (ATS) might need to be extended to include regulation of bioprospecting, and indeed all the provisions of the Convention on Biological Diversity....[56]

4.2.2 Committee for Environmental Protection (CEP)

The Committee for Environmental Protection (CEP) took up the issues raised in Working Paper WP–043 submitted by the UK to XXV ATCM. Under agenda item 4(d) "Matters covered by Annex II (Conservation of Antarctic Fauna and Flora)" of the fifth session of the CEP, the following was recorded:

(58) The United Kingdom presented Working Paper (XXV ATCM/WP43) on biological prospecting in Antarctica. The Meeting congratulated the United Kingdom on their paper, which raised a series of important questions resulting from advances in biotechnology.

(59) Several delegates pointed out that the subject of biological prospecting is complex, and includes legal and political issues. Comments from members covered items such as commercial confidentiality, cross–convention aspects, the legal basis for biological prospecting, intellectual property and patents etc., as well as consistency with Article III of the Antarctic Treaty.

(60) ASOC stated that biological prospecting would represent a further penetration of commercial and economic interest into Antarctica, and argued against accepting biological prospecting as a fait accompli.

(61) The CEP concluded that the complexities and rapid developments in this field were strong reasons for the Antarctic community to be pre–emptive on this issue and that biological prospecting needed to be discussed during the next CEP meeting. The CEP, however, is not in a position to address all the problems. It was suggested that many issues require consideration by the ATCM. Members were encouraged to submit papers on biological prospecting for consideration at CEP VI.

The CEP agreed that biological prospecting should be added as agenda item 7 to the Agenda of CEP VI. This was approved subsequently by the ATCM (see paragraph 70).

4.2.3 The Antarctic Treaty Consultative Meeting (ATCM)

Pursuant to Agenda Item 6: Report of the Committee for Environmental Protection, the 25th session of the Antarctic Treaty Consultative Meeting (ATCM) noted the following in paragraph 68 of its report:

Referring to paragraphs 58–61 of the Report, the ATCM agreed with the CEP that biological prospecting was a very important matter. The Meeting agreed that biological prospecting also raised legal and political issues, as well as environmental issues. In this respect the Meeting urged Parties to be prepared to consider these matters at XXVI ATCM.

In paragraph 70 of its report the ATCM "approved the draft preliminary agenda for CEP VI".

Subsequent to the XXVth ATCM Gateway Antarctica held a workshop on bioprospecting in Antarctica from 7–8 April 2003 in Christchurch, New Zealand. Participants at the workshop heard presentations on, *inter alia*, the potential for commercial success arising from Antarctic bioprospecting; relevant international policies; patents and property rights; and ethical and equity issues. Discussion centred around scientific and commercial interests, environment, ethics and equity, and on international and commercial law aspects. Issues that come up in this meeting include:

i. Who owns these resources?
ii. How can scientists working in these areas legitimately acquire these resources?
iii. What measures do scientists have to take to protect these resources?
iv. Is benefit sharing feasible and if so with whom?
v. Who owns the commercial products resulting from these resources?
vi. The relationship between the ATS and other international policies
vii. Is bioprospecting contrary to Article III of the Treaty?

5 International Policies Governing Bioprospecting Activities

This Section examines international policies that address various aspects of bioprospecting activities. The examination is confined to those instruments of most relevance to bioprospecting in Antarctica, focusing in particular on the United Nations Convention on the Law of the Sea, the Convention on Biological Diversity, the World Intellectual Property Organization, and the International Treaty on Plant Genetic Resources for Food and Agriculture. In the interest of brevity many other international measures and instruments that deal with various aspects of bioprospecting, but are less relevant than the above, are not considered here.[57]

5.1 United Nations Convention on the Law of the Sea (UNCLOS)

The 1982 United Nations Convention on the Law of the Sea (UNCLOS), which entered into force on 16 November 1994, was adopted in order 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.[58]

UNCLOS, like the ATS, applies to an international area, including to the Southern Ocean. It is particularly noteworthy that it has developed regulations on the prospecting and exploitation of resources in this international area. Accordingly, it is relevant to examine pertinent provisions established under this Convention.

5.1.1 Part XI of UNCLOS, as modified by the 1994 Agreement: The Area

Part XI of UNCLOS (as modified) establishes principles applicable to the Area, defined as the seabed and ocean floor and subsoil thereof beyond the limits of national jurisdiction. Accordingly, the Area and its resources are identified as the common heritage of humanity, and it is amongst others agreed that States shall not claim or exercise sovereignty over the Area, and that no such claims or exercises shall be recognised.[59]

It establishes the International Seabed Authority, which organises and controls activities in the Area concerned with seabed minerals, notably with a view to administering its resources.[60] To fulfil this objective, the Authority is composed of three organs, the decision–making Assembly, the Executive Council, and its Secretariat.[61] The Authority's responsibilities include approving deep–sea exploration and exploitation activities "on behalf of mankind as a whole".[62] Part XI envisages prospective miners to submit a plan of work for approval to the Council,[63] indicating two sites. Upon approval of the work plan, the Authority's Enterprise has the right to mine one site and the miner the second, to ensure the proportionate sharing of resources under a so–called 'parallel system'.[64]

5.1.2 Part XIII: Marine Scientific Research

Subject to the rights and duties of other States as outlined in the Convention, Part XIII of UNCLOS sets out the right of all States, irrespective of their geographical location, and competent international organizations, to conduct marine scientific research in the territorial sea, within as well as beyond the exclusive economic zone (EEZ) and in the seabed and ocean floor and subsoil thereof beyond the limits of national jurisdiction.[65]

The publication and dissemination of information and knowledge is addressed in Article 244, which stipulates that information on proposed programmes, their objectives, and resulting knowledge are to be made available through publication and dissemination. Article 244 moreover emphasises that States and competent international organizations shall actively promote the flow of data and information, and the transfer of knowledge, to developing States in particular. Also of relevance in the context of information sharing is Article 242, according to which States shall provide other States, as appropriate, "with a reasonable opportunity to obtain from it, or with its co–operation, information necessary to prevent and control damage to the health and safety of persons and to the marine environment". Finally, Article 250 stipulates that communications on marine scientific research projects are to be made through appropriate official channels, unless otherwise agreed.

Part XIII specifically addresses the rights of neighbouring land–locked and geographically disadvantaged States, which include receiving upon request and when appropriate relevant information on proposed marine scientific research projects, and being given the opportunity upon request and whenever feasible, to participate in the proposed research project through qualified experts appointed and not objected to by the coastal State.[66]

5.1.3 Part XIV: Development and Transfer of Marine Technology

According to the general provisions of Part XIV, States shall "co–operate in accordance with their capabilities to promote the development and transfer of marine science and marine technology on fair and

reasonable terms and conditions". In addition, States 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, including land–locked and geographically disadvantaged States". Finally, States are to promote favourable economic and legal conditions for technology transfer on an equitable basis.[67] Notwithstanding these provisions, Article 267 binds States to have due regard to "all legitimate interests including, *inter alia*, the rights and duties of holders, suppliers and recipients of marine technology".

In order to achieve the basic objectives of Part XIV, a number of measures are outlined, including that Parties shall endeavour to establish programmes of technical co–operation for the effective transfer of marine technology to States which may need and request such technical assistance, promote the exchange of scientists and of technological and other experts, and promote favourable conditions for concluding agreements and contracts under equitable and reasonable conditions.[68]

Article 274, which outlines the objectives of the International Seabed Authority, provides that the International Seabed Authority shall ensure that:

- Nationals of developing States, whether coastal, land–locked or geographically disadvantaged, shall be taken on for the purposes of training as members of the Authority's staff
- The technical documentation is made available to all States, in particular developing States
- Adequate provision is made by the Authority to facilitate the acquisition of technical assistance in the field of marine technology by States which may need and request it, in particular developing States
- States which may need and request technical assistance in this field, in particular developing States, are assisted in the acquisition of necessary equipment, processes, plant and other technical know–how through any financial arrangements provided for in this Convention.

The International Seabed Authority continues to fail to be self–supporting from seabed mineral revenues since the provisions on deep seabed mining were negotiated on mistaken assumptions and predictions that deep seabed mining would be a commercial reality soon after the treaty's adoption.[69]

5.1.4 Regulations on Prospecting and Exploration for Polymetallic Nodules

Following three years of negotiations, the Assembly of the International Seabed Authority approved in July 2000 regulations on prospecting and exploration for polymetallic nodules, which complement the legislative regime for the international seabed laid out in Part XI of UNCLOS. The Regulations are divided into nine parts, including provisions on prospecting, applications for approval of plans of work for exploration in the form of contracts, contracts for exploration, the protection and preservation of the marine environment, and confidentiality. As noted in Regulation 1, the Regulations "shall not in any way affect the freedom of scientific research... or the right to conduct marine scientific research in the Area... Nothing in these Regulations shall be construed in such a way as to restrict the exercise by States of the freedom of the high seas..."

Prospecting can only commence after the Secretary–General has informed the prospector that its notification has been recorded, and is not to be undertaken if substantial evidence indicates the risk of serious harm to the marine environment.[70] Regulation 2 provides that prospecting does not confer on the prospector rights with respect to resources, but that the prospector may "recover a reasonable quantity for minerals, being the quantity necessary for testing and not for commercial use".[71] As suggested by Lodge, the incentive for prospectors to notify the Authority of their activities is small as most of these can be carried out under the cover of marine scientific research, and because no rights to the resource are granted.[72] In contrast, entering into contracts for exploration do confer such rights, and are dealt with in later parts of the Regulations.

The rules governing confidentiality provide that, with the exception of a few cases, data and information submitted or transferred to the Authority pursuant to the Regulations, and designated by the contractor in consultation with the Secretary–General as confidential, shall be treated as such.[73] Regulation 35 further provides that confidential data and information may only be used by the Secretary–General, Secretariat staff, and members of the Legal and Technical Commission as necessary to effectively exercise their powers and functions.[74] On the timing of the information's confidentiality, Regulation 35(3) provides the following:

> Ten years after the date of submission of confidential data and information to the Authority or the expiration of the contract for exploration, whichever is the later, and every five years thereafter, the Secretary–General and the contractor shall review such data and information to determine whether they should remain confidential. Such data and information shall remain confidential if the contractor establishes that there would be a substantial risk of serious and unfair economic prejudice if the data and information were to be released. No such data and information shall be released until the contractor has been accorded a reasonable opportunity to exhaust the judicial remedies available to it pursuant to Part XI, section 5, of the Convention.

Procedures ensuring confidentiality are set out in Regulation 36, which places limitations on the access and use of confidential data, and outlines procedures to be followed by the Secretary–General to this end.

In August 2002, the International Seabed Authority agreed to develop a system for regulating the prospecting and exploration of polymetallic sulphides and cobalt–rich crust.[75]

5.2 The Convention on Biological Diversity (CBD)

The Convention on Biological Diversity (CBD) was adopted in June 1992 at UNCED, and entered into force in December 1993. The CBD is the principal international legal framework concerning the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits arising from the utilisation of genetic resources. It is the first international treaty to take a holistic, ecosystem–based approach to the conservation and sustainable use of biological diversity. The CBD is a framework instrument laying down broad goals, key objectives, and general principles, which are to be implemented by Contracting Parties through measures at the national level on the basis, *inter alia*, of guidance provided by the Conference of the Parties. The CBD sets out two types of measures aimed at fulfilling these objectives, relating to the conservation and sustainable use of biodiversity, and to technology transfer and benefit–sharing.

The CBD is relevant because it contains the pre–eminent international standards for bioprospecting and may apply to some extent to bioprospecting activities in Antarctica. The CBD establishes provisions relating to access to genetic resources, transfer of technologies, and funding, contained in Articles 15 to 21.[76] Article 15(1) provides:

> Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.

Each State shall endeavour to facilitate access to genetic resources for environmentally sound uses by other Parties, and it is specified that access shall be provided on mutually agreed terms. Parties shall moreover endeavour to undertake scientific research based on resources provided by other Parties with their full participation, and Parties shall take measures with the aim of sharing benefits with Parties providing the resources.

Pursuant to Article 16, Parties are to provide and/or facilitate access for and transfer to developing countries of technologies under "fair and most favourable terms", and shall co–operate to ensure that intellectual property rights are supportive of the CBD's objectives.[77] Article 19, which addresses the handling of biotechnology and distribution of its benefits, stipulates 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 to results and benefits arising from biotechnology.

Based on the provision contained in Articles 8(j), 10(c), 15, 16 and 19, Parties to the CBD have developed guidelines regulating access and benefit–sharing of genetic resources, considered below.

5.2.1 The Bonn Guidelines on Access and Benefit–Sharing (ABS)

The Bonn Guidelines, adopted in April 2002 and which provide voluntary guidance for policy–makers and persons using and providing genetic resources, apply to all genetic resources covered by the CBD, with the exception of those covered by the International Treaty on Plant Genetic Resources for Food and Agriculture once it comes into effect, and benefits arising from the commercial and other utilisation of such resources.[78] They recognise the need for flexibility of application, that each country is a provider and user of genetic resources, and may be used in the development of national access and benefit–sharing (ABS) strategies.

Section 2 of the Guidelines lays out the roles and responsibilities in access and benefit–sharing pursuant to Article 15 of the CBD, notably for National Focal Points, Competent National Authorities, Providers and Users. The following Section considers the participation of stakeholders, and Section 4 identifies steps in the access and benefit–sharing process. Accordingly, access to genetic resources is to be subject to prior informed consent of the Party providing the resources, unless otherwise determined by that Party.[79] Paragraph 27 provides that elements of a prior informed consent system may include identification of the competent authority granting or providing evidence of prior informed consent, timing and deadlines, specification of use, procedures for obtaining prior informed consent, and mechanisms for consultation of stakeholders. The second step proposed to form part of the access and benefit–sharing process is the adoption of mutually agreed terms (MATs) to ensure the fair and equitable sharing of benefits.[80] The Bonn Guidelines also provide guidance on incentives, accountability in implementing access and benefit–sharing arrangements, national monitoring and reporting, means for verification, settlement of disputes, and remedies.[81] Finally, Appendix I outlines suggested elements for Material Transfer Agreements, and Appendix II addresses monetary and non–monetary benefits.

Although the CBD and the Bonn Guidelines allow for great flexibility on how countries should develop their national legislation, it promotes a bilateral or private system under which individual users and providers are left to determine the terms of access, use, and benefit–sharing.

Developments relevant to the Bonn Guidelines include the World Summit on Sustainable Development's stipulation that an international regime promoting and safeguarding the fair and equitable sharing of benefits arising out of the utilisation of genetic resources be negotiated within the framework of the CBD and bearing in mind the Bonn Guidelines.[82] Responding to this statement, the CBD process considered this issue in a preliminary manner at its Meeting on the Multi–Year Programme of Work up to 2010 and agreed that Parties submit views on the process, nature, scope, elements and modalities of such an international regime. Parties also recommended that the Working Group on Access and Benefit–Sharing consider this matter further in its ongoing work and provide advice to COP–7 on how it may wish to address this issue.[83]

Parties to the CBD have raised the issue of bioprospecting of marine genetic resources from the deep seabed. Most recently, a study submitted to the eighth meeting of SBSTTA considered the relationship between the CBD and UNCLOS with regard to the conservation and sustainable use of genetic resources on the deep seabed. It noted that benefit–sharing arising from the exploitation of these resources beyond the limits of national jurisdiction could only be effected if such resources are brought under a regime similar to the one governing the mineral resources of the Area under UNCLOS.[84] SBSTTA took note of the study and requested the Executive Secretary, in consultation with all organisations and Parties to further work on the matter.[85]

Bioprospecting as such is not defined in the CBD's provisions or in the COP's decisions. Nevertheless, it has been identified with "the exploration of biodiversity for commercially valuable genetic and biochemical resources" and further defined as "the process of gathering information from the biosphere on the molecular composition of genetic resources for the development of new commercial products." [86]

Over fifty Parties have reported efforts to develop national legislation, or policies to implement the provisions of the CBD relating to the 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.

5.2.2 The CBD's Applicability to Antarctica

In examining the possible applicability of the CBD to Antarctica, it is worthwhile noting that with the exception of the US, the provisions of both treaties bind all Antarctic Treaty Consultative Parties, being also Contracting Parties to the CBD.[87] The difficulty in determining the applicability of the CBD to Antarctica arises from the differing views about whether Antarctica lies outside of the scope of national territories and thus national jurisdiction.

Article 4 of the CBD on jurisdictional scope reads as follows:

> Subject to the rights of other Sates, and except as otherwise expressly provided in this Convention, the provisions of this Convention apply, in relation to each Contracting Party:
> (a) In the case of components of biological diversity, in areas within the limits of its national jurisdiction; and
> (b) In the case of processes and activities, regardless of where their effects occur, carried out under its jurisdictional control, within the area of its national jurisdiction or beyond the limits of national jurisdiction.

The arguments about whether these provisions cover bioprospecting in Antarctica are complex and perhaps irresolvable due to the sovereignty issues surrounding Antarctica. Whether or not the provisions of the CBD apply is also perhaps moot. This is because Article 5 of the CBD stipulates that each Contracting Party shall, as far as possible and as appropriate, cooperate with other Contracting Parties, directly or, where appropriate, through competent international organizations, in respect of areas beyond national jurisdiction and on other matters of mutual interest, for the conservation and sustainable use of biological diversity. Article 5 has been used to develop regional efforts to apply the provisions of the CBD and has been used as the basis for considering how the CBD applies to regulating the use of marine genetic resources from the high seas and deep seabed. Moreover, another factor that needs to be borne in mind is that the basic approach of the CBD—based on sovereignty being exercised over the genetic resources and bilateral agreement between user and provider of the genetic resources—is not readily applicable to regulating bioprospecting in Antarctica.

5.3 World Intellectual Property Organization (WIPO)

The World Intellectual Property Organization (WIPO) administers 23 international treaties dealing with different aspects of intellectual property protection, including the Madrid Agreement Concerning the International Registration of Marks, the Strasbourg Agreement Concerning the International Patent Classification, and the Berne Convention for the

Protection of Literary and Artistic Works. WIPO's mandate being to promote the protection of intellectual property worldwide, it engages in standardising intellectual property systems around the world. Intellectual Property Rights convey a monopolistic right of the intellectual property in questions to his/her owner, in exchange for publication of information thereon.

Of relevance in considering access and benefit–sharing of genetic resources generally is the work of WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) with respect to intellectual property aspects of contracts and licenses concerning genetic resource. At its fourth session in 2002, the IGC agreed to develop a pilot database of contractual practices and clauses relating to IP, access and benefit–sharing which would serve as a practical tool to providing information in this area. A document prepared by the Secretariat for the IGC's fifth session in July 2003 provides amongst others an overview of IP aspects of contracts relating to biological materials and associated traditional knowledge.[88] On confidentiality, the document notes that due to its central role 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.[89]

It is noted in particular that "scientific institutions... may ... allow limited time restrictions on publications to allow an industrial partner to review research results and to arrange for protection of any resulting IP rights. Such a time restriction would need to be clearly stated in the accompanying confidentiality agreement".[90] Other elements proposed for inclusion in a contractual arrangement when considering IP and confidentiality 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 IP rights and monitoring and reporting on the use of confidential information.[91]

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. According to the treaty, Contracting Parties recognise a deposit made in the specified culture collections, or 'International Depositary Authorities', as adequate for the purposes of their patent procedure.[92] In order to designate a culture collection an International Depositary Authority (IDA), the Contracting Party must assure that the IDA will comply with the treaty's requirements, including that it will be available to other 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.[93] The Treaty contains procedures governing the behaviour of depositors and IDAs, the duration of microorganism storage and the mechanism for providing samples. Accordingly, samples are to be furnished at any time to the depositor, a person having the depositor's written authorisation, and any industrial property office. Provisions guarding against the loss of deposited microorganisms stipulate that the IDA must have the necessary expertise and facilities to keep microorganisms viable and uncontaminated during the prescribed storage period.[94] This system provides a practical example of benefit–sharing that may be useful for Antarctica.

5.4 International Treaty on Plant Genetic Resources for Food and Agriculture

The International Treaty on Plant Genetic Resources for Food and Agriculture was adopted in November 2001 and will enter into force ninety days following the ratification of the fortieth government. Its objectives are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of benefits arising out of their use for sustainable agriculture and food security.[95] Part 4 of the treaty establishes a Multilateral System of Access and Benefit–Sharing, which could be drawn upon as an example by ATCPs in considering a benefit–sharing measure for Antarctic bioprospecting. Applying to sixty–four major crops and forages listed in Annex I of the treaty, it contains provisions for facilitating access to genetic resources and sharing benefits arising from the use of these resources in an equitable and fair manner.[96]

The International Treaty is not only noteworthy because it includes a model for a multi–lateral benefit–sharing system, but also because it provides an example in which natural resources regulated for under the CBD, may be regulated by a complementary system entered into in accordance with the International Treaty.

5.5 The World Summit on Sustainable Development

No direct mention of Antarctica or the ATS was made in the principal instruments adopted at the World Summit on Sustainable Development. As mentioned in paragraph 44 the Plan of Implementation did, however, call upon states to negotiate an international regime promoting and safeguarding the fair and equitable sharing of benefits arising out of the utilisation of genetic resources within the framework of the CBD and bearing in mind the Bonn Guidelines.[97]

6 Conclusion

In summary, main points coming from this survey include:

i. Biological prospecting activities, though currently modest in scope, are taking place in Antarctica and the Southern Oceans.
ii. The commercial use of Antarctic biota has been recognised, with industrial applications being developed and patents filed.
iii. Further biological prospecting is planned.
iv. The prospecting activities in Antarctica appear to be confined to sampling, with no indication of plans to harvest material.
v. Collection of material is generally carried out for many purposes and by consortiums (i.e. this survey found no evidence of purely commercially orientated collecting.
vi. It is difficult to clearly distinguish between commercial and scientific activity.
vii. Questions that have arisen in the development of products include:
    1. How can ownership be properly acquired?
    2. What procedures need to be followed to ensure that the use is legitimate?
    3. What if any approvals are necessary to ensure that the patent application is valid?
    4. Is benefit sharing required and if so with whom?
viii. No comprehensive or adequate study of Antarctic bioprospecting exists.
ix. The use of biotechnology in a variety of sectors is generally increasing.
x. Natural products development is experiencing a decline in part due to complex regulatory measures being developed to govern bioprospecting.
xi. Commercialisation takes a long time and requires a considerable investment of resources.
xii. The ATS does not directly address bioprospecting, this lacunae may increase the likelihood of bioprospecting.
xiii. Existing provisions of relevance to bioprospecting include: Articles II, III, IV, VI and VIII.1 of the Antarctic Treaty, Annex I (EIA) to the Madrid Protocol, and Article 20 of CCAMLR.
xiv. The EIA procedures outlined in the Madrid Protocol and the harvesting requirements of CCAMLR address the physical effects of bioprospecting.
xv. The use of the genetic resources in Antarctica needs to take account of the complex jurisdictional issues raised by Article IV and the different legal regimes applicable to the Southern Ocean.
xvi. Features of CRAMRA's provisions regulating mineral resource activities and its treatment of data and information that have potential commercial value may be of particular relevance.
xvii. ATS and other bodies that have considered Antarctic bioprospecting include SCAR, CEP and the ATCM.
xviii. A number of important issues that the ATS does not clearly address have been identified. These include:
    1. Who owns the Antarctic genetic resources?
    2. How can scientists working in the Antarctic Treaty area legitimately acquire these resources?
    3. What measures do scientists have to take to protect these resources?
    4. Is benefit sharing feasible and if so with whom?
    5. Who owns the commercial products resulting from these resources?
    6. The relationship between the ATS and other international policies.
    7. Is bioprospecting contrary to Article III of the Treaty?
xix. Existing international policies governing bioprospecting activities elsewhere are of limited value in answering the above issues although they do provide some worthwhile elements.
xx. UNCLOS establishes a 'public' model for prospecting, whereby resources are deemed the common heritage of humanity and a complex legal and institutional framework is established to manage the resources for the common good.
xxi. The CBD set out basic principles for access to genetic resources and the fair and equitable sharing of benefits. The Bonn Guidelines give more detailed guidance to governments, users and providers of genetic resources. It is for users and providers to determine what is equitable and how benefits should be managed.
xxii. The CBD establishes a model for achieving these basic aims, whereby providers of genetic resources are given the means to come to equitable arrangements with users. Such a model is based on the concept that States have sovereignty over their genetic resources.
xxiii. The Budapest Treaty establishes a system that potentially provides a practical example of benefit sharing that may be useful for Antarctica but does not address underlying problems associated with the activity of bioprospecting in Antarctica.
xxiv. The International Treaty on Plant Genetic Resources for Food and Agriculture provides an interesting model for multilateral benefit–sharing but covers a specific set of genetic resources considered to be some of the most important in terms of world food security which are declared a "common concern of all countries".

In conclusion, although the physical impact of bioprospecting is currently addressed by the ATS regime, establishing the legal and policy basis that controls the commercialisation of genetic resources, in line with the basic principles of the ATS as well as equity and fairness, is a more complex matter. Indeed, developing measures on bioprospecting in Antarctica would require some basic conceptual agreement

about the overall aims of any regulation and the type of management system that is desirable, feasible, practical, and equitable. The key issues that have been identified in the consideration of the matter by the ATS provide a good structure for developing the fundament concepts that need further clarity before practical policies can be developed.

Before practical measures can be developed In light of the above, it is recommended that further analysis and research is necessary to begin addressing this complex issue. To this end, Parties may consider focusing in particular on:

i. Information regarding existing and planned bioprospecting activities in Antarctica.
ii. Information regarding current and planned commercially orientated research involving Antarctic biota.
iii. A working definition of bioprospecting.
iv. What are the legal issues relating to the ownership and protection of these resources.
v. Who owns the commercial products resulting from the resources?
vi. Is benefit sharing feasible and if so with whom?
vii. The relationship between the ATS and other international policies.
viii. Is bioprospecting contrary to Article III of the Treaty?
ix. Preliminary views about the need for regulation or guidelines.

7 Epilogue

This Paper was presented to the ATCM XXVI as Information Paper 75 by the UK and Norway. The CEP considered the relevant item on its agenda and the Paper on 10 June 2003. A paper submitted by New Zealand entitled " 'Bioprospecting in Antarctica' An Academic Workshop" (Information Paper 47) was also considered by the CEP at the same time.

The main points recorded in the report of the CEP on this issue were:

(174) Chile stressed the value of the precautionary approach to issues raised by bioprospecting in Antarctic marine areas and recalled that CCAMLR encompassed all living organisms in the Southern Ocean.

(175) Several members of the Committee thought that current environmental impact of bioprospecting in Antarctica was small. One Member noted that the EIA procedures of the Madrid Protocol could be used to assess bioprospecting proposals.

(176) Several Members said it was important to differentiate between fundamental scientific and commercial bioprospecting activities. Others noted that a definition of what is meant by bioprospecting might be useful in further considering the issue.

(177) SCAR noted that bioprospecting could raise important issues of freedom of scientific information if confidentiality required by commercial developments limited opportunities for scientific publication. SCAR also noted their concern that in marine realm there could also be potential for harvesting of slow growing species containing compounds of pharmaceutical interest.

The ATCM accepted the CEP recommendation that the draft agenda for CEP VII be the same as that for CEP VI, which means that biological prospecting is on the draft agenda for CEP. The ATCM also decided to include the issue on the agenda of its next meeting (item 17 of the preliminary agenda for ATCM XXVII).

Although the outcome of the ATCM XXVI may seem trite, it is in fact a significant step in the development of policies regulating bioprospecting in Antarctica. The fact that the matter is now on the agenda of the governing body itself indicates that the Parties to the ATS have recognised that the issue requires action. Unravelling the complex issues that the matter raise will, however, be a long and slow process. Nevertheless, as the resources become more and more valuable, Parties will feel more and more need to act. Moreover, it is likely that legal and policy measures the ATS does develop to regulate this activity will be an important ground breaking example of international access and benefit–sharing policy.

Endnotes

1 MICROMAT has undertaken a study of the biodiversity of mat communities from various freshwater and saline lakes. JP Bowman 'Antarctica a Global "Hot Spot": Biodiversity and Biotechnology'. See <http://www.atse.org.au/publications/symposia/proc-2001p9.htm>.
2 CC Cheng & L Cheng 'Evolution of an Antifreeze Glycoprotein' (1999) 401 *Nature*, 443-444. See also 'Antifreeze Proteins – Secrets for Mankind?' at <http://www.nsf.gov/od/lpa/nsf50/nsfoutreach/htm/n50_z2/pages_z3/04_pg.htm>.
3 'Antifreeze Proteins – Secrets for Mankind?' at <http://www.nsf.gov/od/lpa/nsf50/nsfoutreach/htm/n50_z2/pages_z3/04_pg.htm >.
4 M Fenice *et al* 'Production of extracellular enzymes by Antarctic fungal strains' (1997) 17 *Polar Biology* 3, 275-280.
5 See <http://www.antcrc.utas.edu.au/antcrc/research/commerce/humanpharm.html>.
6 Approximately 8 per cent of the library's samples have been collected in Antarctica. See <http://www.biomedoz.com.au/Organisation/profile.asp?CompanyID=1088>.
7 Personal communication with Professor Roberta Farrell, University of Waikato.
8 Patent number ES2181592.
9 Patent number DE10055558.
10 Patent number RU2069696.
11 MJ Berry *et al* 'Processes and organisms for the production of anti-freeze proteins' US Patent Application 20020072108, 13 June 2002.
12 United States Patent Application 20030044864.
13 Personal communication with Professor Roberta Farrell, University of Waikato.
14 Several species of fish are harvested in the Southern Ocean. For the purposes of this Information Paper these harvesting activities are understood to be a different type of activity to bioprospecting.
15 E.g. Correspondence between MICROMAT to SCBD. See Paragraph 9 (Personal communication with Roberta Farrell, University of Waikato). See Paragraph 9 (Personal communication with Roberta Farrell, University of Waikato).
16 SM Nor & PN Avadhani 'Biotechnology for Developing Countries: Challenges and Opportunities', 11.
17 S Laird *Biodiversity and Traditional Knowledge* (Earthscan London 2002), 246.
18 Laird *Biodiversity and Traditional Knowledge*, 250.
19 K ten Kate & SA Laird *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing* (Earthscan London 1999). This publication is the most recent work on this issue.
20 Ten Kate & SA Laird, 55-57.
21 K Ten Kate & SA Laird, 141 & 155.
22 See 'Report of the Panel of Experts on Access and Benefit-Sharing' (UNEP/CBD/COP/5/8), and 'Report of the Panel of Experts on Access and Benefit-Sharing on the Work of its Second Meeting (UNEP/CBD/WG-ABS/1/2).
23 K ten Kate & SA Laird, 315-318.
24 K ten Kate & SA Laird, 325.
25 LJ Rothschild & RL Mancinelli 'Extremophilic organisms adapt to life in incredibly harsh environment' (2001) 409 *Nature* 1092-1101.
26 R Cavicchioli & T Thomas 'Extremophiles' in J Lederberg (ed) *Encyclopedia of Microbiology* (2nd edn Academic Press San Diego 2000), 317-337.
27 LJ Rothschild & RL Mancinelli 'Extremophilic organisms adapt to life in incredibly harsh environment' (2001) 409 Nature 1092-1101.
28 *Thermus aquaticus* was discovered in 1960s in the Yellowstone National Park's hot springs (H Doremus 'Nature, Knowledge and Profit: the Yellowstone's Bioprospecting Controversy and the Core Purposes of America's National Parks'
29 Ecology Law Quarterly 1999, 402-405.
30 PCR enables the to copy and amplify DNA.
31 TD Brock *Life at High Temperatures* (Yellowstone Association for Natural Science, History & Education Wyoming 1994).
32 'Bioprospecting of Genetic Resources of the Deep Sea-Bed. Note by the Secretariat' (UNEP/CBD/SBSTTA/2/15), 13.
33 Extremophile Biotechnology in the Chemical Engineering Department of the University of Bath (UK). See <http://www.bath.ac.uk/chem-eng/fundraising/biotechnology.htm>.
34 R Cavicchioli & T Thomas 'Extremophiles' in J Lederberg (ed) *Encyclopedia of Microbiology* (2nd edn Academic Press San Diego 2000), 317-337.
35 See <http://www.nf-2000.org/secure/Ec/S1077.htm>.
36 S Maloney 'Extremophiles: Bioprospecting for Antimicrobials'. See <http://www.mediscover.net/Extremophiles.cfm>.
37 Arts II.
38 Art. 2 & 7, Madrid Protocol.
39 Art 3(2)(a) & 3(2)(b)(iv), Madrid Protocol.
40 Art 3(3), Madrid Protocol.
41 Art 8, Madrid Protocol.
42 Article 8, Madrid Protocol & Article VII.5(a), Antarctic Treaty.
43 Art 2(1), CCAMLR.
44 Art 1(1), CCAMLR.
45 Art 2(3), CCAMLR.
46 Art 9(1)(f), CCAMLR.
47 Art 20, CCAMLR.
48 Art 5, CRAMRA.
49 SK Chopra *et al* 'The Antarctic Minerals Agreement' 83 *American Society of International Law Proceedings* 1989, 216.
50 Art 39(1) & 53(1), CRAMRA.
51 Art 21(d), CRAMRA.
52 Art 29(1), CRAMRA.
53 Art 9, CRAMRA.
54 Art 29(2), CRAMRA.
55 Art 49, CRAMRA.
56 Although not adopted, it is worth referring to Recommendation XXVII – Biol 3 concerning the Convention on Biological Diversity proposed by SCAR's Working Group on the Convention on Biodiversity. The Recommendation, *inter alia*, suggests that SCAR draft a Working Paper for the ATCM outlining the importance of adoption of the principles of the Convention on Biological Diversity by the ATCM so as to ensure that Antarctic biological resources are treated on an equal basis to those of the rest of the World (A copy of SCAR's relevant report was not obtained).
57 WTO Agreement on Trade related Aspects of Intellectual Property Rights (TRIPs), SPS Agreement, UN Convention to Combat Desertification, The FAO Code of Conduct for Plant Collecting and Transfer of Germplasm, Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct, International Convention on the Harmonized Commodity Description and Coding System, International Maritime Dangerous Goods Code (IMDG Code), the ICAO Technical Instructions, the IATA Dangerous Goods Regulations, the International Plant Protection Convention (IPPC) and its various codes of conduct (e.g., the Code of Conduct for the Import and Release of Exotic Biological Control Agents) and the United Nations Recommendations on the Transport of Dangerous Goods developed by the United Nations, which are popularly known as the "Orange Book" (document ST/SG/AC.10/11/Rev.3) and the Universal International Postal Union's rules and standards for the shipment of goods by post (see, for example, the 1995 *Manual of the Universal Postal Convention*).
58 Preamble, UNCLOS.
59 Art 136-7, UNCLOS.
60 Art 156-7, UNCLOS.
61 Art 156-169, UNCLOS.
62 Art 153(1), UNCLOS.
63 Art 153(3), UNCLOS.
64 K Dixon 'Law of the Sea – Deep Seabed Mining' 18 *Georgia Journal of International and Comparative Law* 1988, 500-501.
65 Art 238, 245-6, 256-7 UNCLOS.
66 Art 254 (2) & (3), UNCLOS.
67 Art 266, UNCLOS.
68 Art 269, UNCLOS.
69 See 'Proposed budget for the International Seabed Authority for the financial period 2003-2004' which sets contributions of members, noting that administrative costs of the Authority are to be met by member contributions until the Authority has sufficient funds from other sources (ISBA/8/A/6-ISBA/8/C/2).
70 Regulation 2(1) & (2), Regulations on Polymetallic Nodules

Prospecting & Exploration.
71 Regulation 2(4), Regulations on Polymetallic Nodules Prospecting & Exploration.
72 MW Lodge 'The International Seabed Authority's Regulations on Prospecting and Exploration for Polymetallic Nodules in the Area' *Centre for Energy Petroleum and Mineral Law and Policy Internet Journal*.
73 Regulation 35, Regulations on Polymetallic Nodules Prospecting & Exploration.
74 Regulation 35 (2), Regulations on Polymetallic Nodules Prospecting & Exploration.
75 ISBA/8/A/5.
76 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.
77 Art 16(5), CBD.
78 Human genetic resources and ex-situ genetic resources collected before the entry into force of the CBD are excluded from the scope of the CBD.
79 Para 24, 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', UNEP/CBD/COP/6/20). Hereafter referred to as 'Bonn Guidelines'.
80 Para 41, Bonn Guidelines.
81 Para 51-61, Bonn Guidelines.
82 Para 44 (0), WSSD Plan of Implementation. Available at <http://www.johannesburgsummit.org/html/documents/summit_docs/2309_planfinal.htm>.
83 Para 2 & 4, Recommendation 5 'International regime on access and benefit-sharing' (UNEP/CBD/COP/7/5).
84 Para 10, 'Marine and Coastal Biodiversity: Review, Further Elaboration and Refinement of the Programme of Work. Revised Note by the Executive Secretary' (UNEP/CBD/SBSTTA/8/INF/3/Rev.1).
85 See Recommendation VIII/3/D, Document UNEP/CBD/COP/7/2.
86 UNEP/CBD/SBSTTA/8/INF/3/Rev.1, para.68. The term is neither defined nor used in the Convention on Biological Diversity. The Encyclopedia of Biodiversity (Academic Press, 2001, p.471) 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". Fiji's draft sustainable development bill restricts bioprospecting to "any activity undertaken to harvest or exploit biological resources for commercial purposes...[including] investigative research and sampling" (emphasis added). The Philippines' Executive Order 247 is broader in defining bioprospecting as the "collection and utilization of biological and genetic resources for purposes of applying the knowledge derived therefrom to scientific and/or commercial purposes".
87 Compare Handbook of the Antarctic Treaty System (US Department of State Washington 2002) 16-17, with <http://www.biodiv.org/world/parties.asp>.
88 '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). Referred to hereafter as Contractual Practices.
89 Para 34, Contractual Practices.
90 Para 35, Contractual Practices.
91 Para 38, Contractual Practices.
92 Art 3(1), Budapest Treaty.
93 Art 7 & 6(2), Budapest Treaty.
94 Rules 6, 2, 9 & 11, Budapest Treaty Regulations.
95 Art 1(1), CGRFA.
96 Art 10(2), CGRFA.
97 Para 44 (0), WSSD Plan of Implementation. Available at <http://www.johannesburgsummit.org/html/documents/summit_docs/2309_planfinal.htm>.

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