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Bioprospecting in Antarctica

This report was written by

Dagmar Lohan and Sam Johnston.

The authors would like to thank the following individuals for their input:

Jill Barrett
Michael Danson, Bath University, UK
Roberta Farrell, University of Waikato, New ZealandSarah Laird
Lyle Glowka
Dominic Hodgson, British Antarctic Survey
Sarah Laird
Murray Munro, University of Canterbury, New Zealand
David Nichols, University of Tasmania, Australia
Glenys Parry
Tony Poole
Jim Raymond, Nevada University, USA
Mike Richardson
Nicholas Russell, Imperial College London
David Saul, University of Auckland, New Zealand
Martin Smith
Annick Wilmotte, Liege University, Belgium

For further information, contact:
United Nations University Institute of Advanced Studies (UNU-IAS)
6F, International Organizations Center
Pacifico-Yokohama, 1-1-1 Minato Mirai
Nishi-ku, Yokohama 220-0012, Japan
Tel: +81 45 221 2300, Fax: +81 45 221 2302
Email: unuias@ias.unu.edu
URL http://www.ias.unu.edu

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Foreword

Antarctica is a land of extremes. The continent is the coldest, highest, windiest, driest, wildest and most pristine. It is also a continent full of life. In addition to its well known inhabitants, such as penguins and seals, it also has a diverse and unique range of biodiversity that we are only just beginning to discover.

This unique biodiversity has begun to interest companies and bioprospectors. Their 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, which in many instances are of interest or use for commercial applications.

There is interest in Candida Antarctic, an alkali-tolerant yeast, found in the sediment of Lake Vanda. Two lipase variants from Candida antarctica, lipase A and B, have proven of particular interest to researchers (lipase being enzymes that break down fats). Higher organisms are also of interest including species of fish, sponges, lichen, moss along with micro-organisms.

There are many interesting ideas being explored now. The best-known work is on the antifreeze glycoproteins produced by various species of fish. For example, research into these proteins is looking for ways to:improve farm-fish production in cold climates; extend the shelf life of frozen food; and enhance the preservation of tissues to be transplanted.

There are many others examples of research that could lead to commercial products outlined in this report, such as new antibiotics, cold-active enzymes for better detergents and improved heat resistant dyes.

The growing commercial interest in Antarctic research raises key policy, ethical and moral questions. Some of the issues that need to be addressed include: Who owns these resources? How should they be used? And how should the benefits of this research be distributed?

Although some aspects of this type of use are adequately addressed by existing policies, there is uncertainty about the rules governing the use of Antarctic genetic resources outside of Antarctica. The specific arrangements examined in this report vary significantly, which is an indication of the lack of clarity in the rules.

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

How the international community responds to these questions is not only important for Antarctic, but will also set important precedents on how biotechnology is addressed in forums such as the United Nations Convention on Law of the Sea and the Convention on Biological Diversity. Thus, we see this issue as an important harbinger for one of the key policy questions of the next few decades.

The debate so far has indicated a strong need for more information and analysis. It is critical that this information and research be neutral, balanced and accurate.

The United Nations University Institute of Advanced Studies (UNU-IAS) was established in 1996 as a research and training centre of UNU to undertake research and post graduate education on emerging issues of strategic importance for the United Nations and its Member States. Pursuant to its Statute, UNU-IAS undertakes its work in an independent, neutral and objective manner. A key purpose of the Institute is to promote interaction between the UN System and other bodies. Development of this report is part of the wider programme on biodiversity at the Institute. The programme is also looking at bioprospecting in the deep seabed, certificates of origin for genetic resources and training for developing country officials. This report is the second UNU-IAS report we have prepared on bioprospecting in Antarctica. It not only updates our previous work, but also analyses the bioprospecting activities in more depth. I hope that our work in Antarctic will not only be of use to the governments involved in the Antarctic Treaty System but will also provide useful insights for our biodiversity programme as a whole.

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

1 Introduction

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

Commercially orientated scientific research raises many issues. Is such research contrary to any provisions of the Antarctic Treaty or the spirit of Antarctic research? Can anyone own the genetic resources of Antarctica? If so, how? How should the benefits of this activity be treated? Do the existing rules for biorprospecting apply in the Treaty Area?

Bioprospecting was first discussed within the Treaty System in 1999. Since then it has received regular attention at meetings of the Scientific Committee on Antarctic Research (SCAR), Committee for Environmental Protection (CEP) and the Antarctic Treaty Consultative Meeting (ATCM).

The debate so far has been hampered by a lack of detailed information about the level, type, nature and future of bioprospecting in Antarctica. This Report draws on a series of reports prepared by the authors for various meetings of the ATS to meet this need for detailed information. In particular, it draws on Information Paper 106 "Industry Involvement in Antarctic Bioprospecting" prepared for the XXVIIth ATCM and Information Paper 75 "Bioprospecting" prepared for the XXVIth ATCM.

The Report 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.

Biological prospecting as a term means different things to different people. Some see it as nothing more than the extension of everyday research, others as a distinct type of research aimed exclusively at commercial products. Still others consider the term to be too emotive and tainted by its association with "biopiracy" to be of any value. The need for clarity about the definition of biological prospecting has been highlighted in the various papers prepared on bioprospecting in Antarctica. For the purposes of this report we interpreted the term in a narrow way, focusing on those activities that all would agree are examples of biological prospecting. This has meant that many examples of activities that might normally be considered as biological prospecting were not included. Thus, for example, work examining various applications of krill, which many would describe as bioprospecting but some might consider simple use of krill, has not been included in this survey.

2 Review of Biological Prospecting Activities in Antarctica

This section considers the involvement of industry in Antarctic bioprospecting and reviews patents arising from such involvement. 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 and through interviews with industry representatives and researchers. It is evident from such an initial search that more bioprospecting than that documented here 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 complete records of the appropriate patent offices.

2.1 Industry Involvement

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 hypersaline lakes, and anti-freezes in sea-lakes.[1]

Amongst the many examples of commercially-useful compounds discovered, is a glycoprotein which functions as the 'anti-freeze' that circulates in some Antarctic fish, preventing them from freezing in their sub-zero environments.[2] The application of this glycoprotein in a range of processes is being considered, including to increase the freeze tolerance of commercial plants, improve farm-fish production in cold climates, extend the shelf-life of frozen food, improve surgery involving the freezing of tissues, and enhance the preservation of tissues to be transplanted.[3] 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. Attracted by such potentially useful discoveries, the private sector has started to include Antarctic flora and fauna in its product development programmes.

2.1.1 The case of *Micromat*

Perhaps the best known commercially orientated research is the Micromat Project. Micromat was a project funded by the European Commission under its Fourth EU Framework Programme and running from 1999 to 2001, involved the Universities of Liège (Belgium), Ghent (Belgium), Bordeaux (France) and Nottingham (UK), the DSMZ (Germany), the British Antarctic Survey (UK), Merck Sharp & Dohme (Spain), Genencor International, and Biosearch – now Vicuron – (Italy). Its aim was to improve knowledge of the biodiversity of bacteria, protists and fungi in Antarctic microbial mats and to test this biodiversity for novel compounds of potential biotechnological use.[4] In accordance with the consortium agreement, the research institutions conducted the microbiotic work, while the industrial partners screened the purified strains for commercially interesting activities. Logistic support had been provided by Australia and, indirectly, by the US.

According to Merck Sharp & Dohme (Spain), the strains were tested generally, rather than for specific purposes, and the work of the company was heavily restricted by its US lawyers on the grounds that they were not the owners of the strains. In contrast, Genencor focused its screening activities on bacterial enzymes in particular, which had been isolated by Ghent University and the DSMZ. The bacterial enzymes were not the property of the industry according to the consortium agreement, but remain the property of the laboratory which isolated the bacteria. In the case of commercialisation, a provision, which remains active despite the project's termination, stipulates that the industry would have to consult both with the original isolators, and with the government whose sector the sample was taken from. Since Micromat represented Genencor's first activity with regard to Antarctic microorganisms, Genencor did not expect the work to lead to product development, but rather considered it as a learning phase. The bacteria, which remain in Genencor's culture collections, have been re-examined in the summer of 2003 as part of a short screening project. Although no commercially-exploitable activities were identified, the microorganisms are likely to be examined again when screening for another characteristic will be undertaken.

In contrast to Merck Sharp & Dohme, Genencor International did not highlight the constraints of its

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[1] 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] http://www.nerc-bas.ac.uk/public/mlsd/micromat/

work imposed as a result of the lack of ownership of the genetic material, but instead underscored that the consortium provided it with a framework for obtaining interesting genetic samples in a legal manner. Another similar EU-funded project in China, which also involves collaboration with public and private partners, provides a similar opportunity to gain access to sample material. One problem identified with regard to working on Antarctic microorganisms is that they are difficult to grow and genetically very poorly characterised. The interviewee also pointed to the lag time between developing a sufficient knowledge base about an organism, and the commercial development on the basis of the organism. Thus, while Genencor is interested in Antarctic samples, it does not expect to conduct intense work on Antarctic microorganisms until the knowledge base on them is further developed. Moreover, given industry's result-driven character, the interviewee said that Genencor would "never" pay for researchers to "just" study Antarctic microbes, as this is considered a purely academic exercise too costly for the private sector. Finally, the company's involvement could in future be limited if it involves negotiating for months whether, or how, it will obtain samples.

The third industrial partner, Vicuron Pharmaceuticals (formerly Biosearch), explained that its focus in this project was on strains able to produce anti-freeze molecules or activities. In the search for anti-infective strains, some microorganisms were submitted to secondary tests. These showed, however, that the microorganisms had low activity-levels, known active molecules, or that they were toxic to mammalian cells. Such findings are usual, and illustrate the low success rate in screening. Like Genencor, Vicuron highlighted the advantage of collaboration agreements for the purposes of obtaining microbial strains, and noted that the company management would not fund employers to collect samples in Antarctica. The interviewee noted that although Vicuron has a general interest for setting up collaboration agreements to obtain Antarctic strains, currently this is not being pursued because the company has sufficient strains from other parts of the world to screen.

Micromat coordinator Annick Wilmotte from Liège University (Belgium) explained that the arrangement with Australia foresaw that data collected on the basis of the samples would be made available to all partners through a database. However, due to the fact that the database was insufficiently user-friendly, delays in this commitment occurred. She noted that the consortium agreement included one paragraph relating to intellectual property rights, which stipulates that in the case of an industrial application, negotiations would be held involving all Parties, including the relevant claimant State (in this case, Australia). However, it has not yet come to this. Her interpretation of industry's interest in Antarctic microorganisms is that it is high, but lack of funding prevents fully pursuing these interests. She also explained that under the 6th European Framework Programme little hope exists for similar projects as the guidelines foresee consortia with a significantly larger number of participants, an aspect that would make it more difficult to reach agreement on as difficult and complex an issue as intellectual property rights.

Dominic Hodgson, British Antarctic Survey, explained that under Micromat, industry screened 3,500 organisms, but that it would take some 8-10 years between research on these organisms and products entering the market because:

- the knowledge base remains to be fully developed
- present products have to be proven to be inadequate
- a "gap" in the market place must become available

Confirming statements made by industry, he noted that companies are generally interested in obtaining Antarctic microorganisms, but are not willing to make significant financial investments to this end. He explained that Antarctic microorganisms still have a relatively small profit margin, with no major results obtained yet. According to his interpretation, biological prospecting activities have not in fact been increasing, but rather the awareness of such activities and the drive under the Antarctic Treaty System to manage these activities have increased. He also noted that technological improvements are underway, with companies being able to screen larger amounts of samples in less time.

2.1.2 Other projects and activities

Nicholas Russell from Imperial College London (UK) outlined a European-funded project called "Coldzyme", whose main industrial partner was Unilever (The Netherlands) and whose aim was to identify and describe bacteria with cold-active enzymes. Under the project, cultures were collected, bacteria catalogued and preliminary research conducted on enzymes. Funding was discontinued when the project entered its second phase to investigate potential applications of the enzymes. The reasons for this remain unclear. He said industry's funding of Antarctic research has been low due to the fact that they cannot claim ownership of the Antarctic microorganisms, and mentioned that colleagues have discontinued cooperation with some industries as these had insisted on claiming ownership of the micro organism studied. He said that industry is waiting for more basic research before dealing with Antarctic microorganisms more intensively. He noted that while no Antarctic-based product or process has been commercialised to date, and it therefore remains to be seen how ownership issues will be solved, the fact that the microorganisms are usually genetically modified for this purpose may support the argument that the product or process is not "Antarctic-based" as

such. He questioned whether Antarctic bioprospecting activities themselves have increased over the past decade.

Reckitt-Benckiser (UK) said that extremophiles are of general interest to the industry, but must not necessarily originate from Antarctica. As such, Antarctic research is not at the forefront of its strategy, as opposed to in 2001 when it supported Michael Danson's work. No specific reason is attributable to this change in strategy, which changes frequently and rapidly due to the company's result-driven focus. The interviewee noted that the drawback of Antarctic projects include their long-term character, high risk and high cost; and explained that the agreement reached with the two other industrial partners and Danson are confidential and thus details of property ownership and commercialisation agreements cannot be disclosed.

Unilever (UK) said it had started working on Antarctic microorganisms in the 1980s with several universities in, amongst others, the UK, Norway, and the US. This effort has been discontinued, however, as the work remains largely pre-commercial and pre-exploitative.

According to a contract signed in 1995 between the Antarctic Cooperative Research Centre, University of Tasmania, Australia and AMRAD Natural Products, an Australian pharmaceutical company, 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.[5] 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.

David Nichols, formerly with the Antarctic CRC and now at the University of Tasmania, Australia, said the Antarctic CRC had had a commercial agreement between 1995 and 2002 with the Australian pharmaceutical company Cerylid Ltd concerning the isolation and provision of Antarctic bacteria isolated from, primarily, Antarctic soil samples. He said the commercial partner's screening of the isolates for human pharmaceuticals is ongoing, and might involve sharing the isolates with another company to further advance the screening process. The agreement contains a provision according to which royalties will flow back to the Antarctic CRC or its members. Regarding the isolates' ownership, the agreement provided that the pharmaceutical company did not own them, but that they were provided for a limited time period for a specific task, following which ownership would go back to the Antarctic CRC. He said such public-private partnerships for isolates screening are relatively rare. He noted that there is a slow shift in focus from thermophilic to cold-active enzymes.

Michael Danson from Bath University (UK) has conducted Antarctic bioprospecting activities that were funded to 50% by the British Research Council, and to 50% by Glaxo Smith Kline, Reckitt Benckiser, and Veridian Enviro Solutions. He said the companies expressed concern about legal issues surrounding this work, as they were reluctant to invest in developing enzymes if they were to find that they could not exploit them. The agreement reached was no more than a gentleman's agreement, according to which an agreement, involving royalties going back to Waikato University, the supplier of the organisms, would be reached before exploitation would start.

Jim Raymond from Nevada University (US), engaged in research on algal-based anti-freeze proteins, explained that the fish-based anti-freeze protein had a lot of promise but has so far failed to give rise to any specific products. He said much interest around this issue is present, but a lot of basic research remains to be done, and noted that fish anti-freezes can be obtained either by harvesting fish, which is wasteful, or by transposing the relevant genes into bacteria and cultivating them, which is relatively costly. He said that Unilever had expressed interest in these proteins (Unilever, however, did not confirm this). According to his knowledge, no product or process based on Antarctic microorganisms has been commercialised yet. He noted that Nevada University does not have any type of agreement with another institution/country regarding its anti-freeze research as the algae in question are not endemic to the Antarctic environment and could be collected from other parts of the world if restrictions were imposed on their collection in Antarctica.

David Saul from the University of Auckland (New Zealand) said that the thermophilic enzyme, isolated 15 years ago from an organism found in a volcanic vent in Mount Rebus, is expected to be commercialised for forensic work. The enzyme has unusually high levels of activity of extracting DNA from forensic material. Interest in the enzyme has been expressed by many forensic institutions scientists, the Australian Department of Justice and the Crown Prosecutor of the Northern Territory, Australia. He noted that the enzyme in question is very similar to others from extremely hot environments, and said that the difficulty with cold-loving organisms is that their genes, when transposed into a medium-temperature organism, often fail. Regarding potential restrictions on Antarctic bioprospecting activities, he said that given the vast microbial flora in any site around the world, researchers would simply go elsewhere. However, he noted that a restriction may not be necessary given that much bioprospecting is being

[5] See <http://www.antcrc.utas.edu.au/antcrc/research/commerce/humanpharm.html>.

undertaken as part of other research projects. Murray Munro from the University of Canterbury (New Zealand) explained that PharmaMar (Spain) started funding the University's Antarctic bioprospecting work some 12 years ago. The research led to the isolation of variolin from an Antarctic sponge, synthetic derivatives of variolin were developed and patented by PharmaMar, and are now being developed as an anti-cancer drug. Currently, the derivatives are being tested in vivo, which in terms of drug development means that about 50% of the work has been completed. The University of Canterbury's agreement with PharmaMar foresees that royalties of any commercial products will be paid, and also provides for milestone payment. Figures and further details are confidential. He noted that PharmaMar's current financial difficulties have led to the stalling of any further work.

2.2 Patents

In some cases research activities like those outlined above 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. A patent database search, which is not deemed exhaustive but indicative of existing patents, has revealed that companies applying for patents include: Bayer AG (Germany), Henkel KGAA (Germany), SmithKline Beecham, Astra, Novonordisk (Denmark), Du Pont (US), Chisso Corporation (Japan), Loders Croklaan (The Netherlands), Haarmann & Reimer GmbH (Germany), Unilever (UK), Lysi HF (Iceland), DSM NV (The Netherlands), Jujo Paper Co Ltd (Japan), Mitsubishi Gas Chemical Company Inc (Japan), Higashimaru Shoyu Company Ltd (Japan), Tokuyama Corporation (Japan), Lion Corporation (Japan), and Nippon Soda Company Ltd (Japan).

Of the 18 companies that have applied for Antarctic-based patents, most applicants are Japanese-based companies, followed by German ones (See Figure 1). The patents examined indicate a recent decrease in patents granted. Thus, between 2002 and 2003, 6 patents were issued, whereas 10 patents were granted between 1996 and 1997. Prior to this, fewer patents were granted, with one being issued between 1990 and 1991 (See Figure 2).

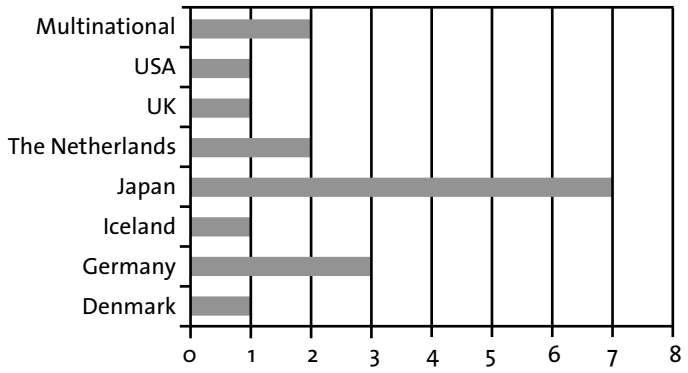

Figure 1: Number of patent applicants per country (1988-2003)

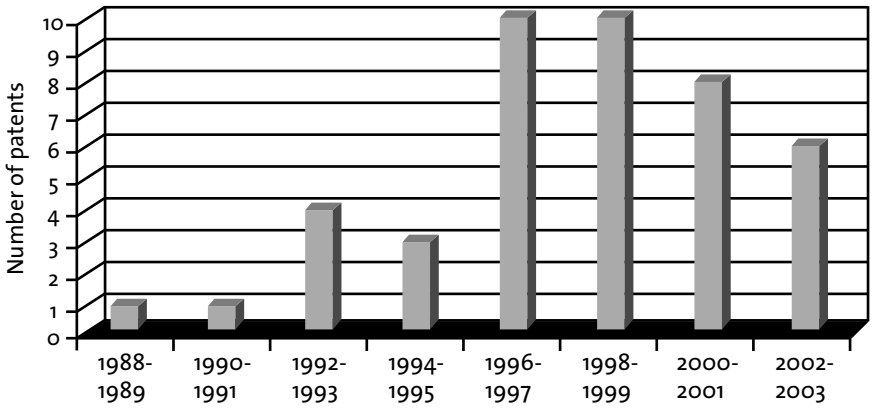

Figure 2: Number of patents granted (per biennium)

Candida antarctica
Candida antarctica, one of 154 species of the genus Candida, belongs to the Phylum Ascomycota and to the Class Ascomycetes. It is an alkali-tolerant yeast found in the sediment of Lake Vanda, Antarctica. Two lipase variants from Candida antarctica, lipase A and B, have proven of particular interest to researchers (Lipase being enzymes that break down fats.)

Most patents filed are process- rather than product-based, with many relating to the yeast Candida antarctica. The distinction between process- and product-based patents is determined by whether the invention relates to a product or to a process.

Examples of process-based patents relate to:

- the preparation of optically active amines, which are prepared in the presence of lipase from the Antarctic yeast Candida antarctica. The amines can be used as intermediates for preparing pharmaceuticals and crop protection agents (US6387692)
- the preparation of esters in the presence of Candida antarctica lipase A, or a variant thereof. The esters are useful as ingredients in fat blends such as margarine (WO0153511)
- the enzymatic synthesis of polyesters in the presence of a lipase derived from, amongst others, Candida antarctica. The polyesters are useful in formulating products such as skin cremes and cosmetics as they normally function as thickeners or softeners in such formulations (US5962624)
- the enzymatic resolution of certain esters, using Candida antarctica lipase fraction B as enzyme catalyst. The products of this invention are useful as precursors for chemicals of high value in the agricultural and pharmaceutical industry (US5928933)
- the preparation of a certain acid ethyl ester with lipase from Candida antarctica. The ester is the flavouring that is the character impact compound of William pears. Unlike according to the invented process, the old way of preparing the ester did not result in it being a natural substance in the context of food law and therefore could not ba called a natural aroma substance (US5753473)
- the preparation of a triglyceride in the presence of a mixture of lipase A and lipase B obtained from Candida antarctica. The triglycerides have beneficial medical effects (US5604119)
- the preparation of an optically active ester using an enzyme originating from Candida antarctica. The ester can be used for preparing pharmaceuticals such as benzothiazepines and benzazepines (US5407828)
- the immobilisation of thermostable microbial lipase, preferably from Candida antarctica. The immobilised lipase can be used for hydrolosis of fats (US5342768)
- the hydrolosis of water-insoluble ester in the presence of a lipase derived from a strain of Candida antarctica. The ester hydrolosis can be applied to hydrolosis of resin ester. This is useful as some types of pulp made from wood have high resin content, and the resin can create disturbances in the process of pulp manufacture and may have negative effects on the properties of the final pulp product (WO9218638)
- the production of optically active carboxylic acid in the presence of Candida antarctica or lipase originated therefrom. The carboxylic acid is useful as an intermediate for producing industrial chemicals, agrochemicals or medical agents (JP2003144190)
- the decomposing of soy sauce oil with the yeast Candida antarctica T-24 in order to generate soy sauce oil as a by-product in a soy sauce brewing method (JP2002101847)
- the production of a specific polymer not containing a metal atom in the presence of a lipase originating from Candida antarctica. The polymer can be useful for medical equipment (JP2000044658)
- the production of a particular furanone compound in the presence of a lipase from Candida antarctica. The compound has a sweet fruity frangrance and can be useful as food perfume (JP10084988)
- the production of an optically active compound in the presence of a hydrolase originating from fungi such as a lipase from Candida antarctica. The compound is useful as a synthetic intermediate for medicines and agrochemicals (JP7115992)
- the use of a glycoprotein produced by Pseudoalteromonas antarctica in the preparation of pharmaceutical, veterinary and cosmetic compositions for topical or mucosal application aimed at the treatment and re-epithelialisation of wounds (WO02102406)
- the use of an extract from the green alga Prasiola crispa spp. Antarctica for cosmetic skin treatment, care or protection, including as sun protector and after-sun cream (WO0238121)

Product-based patents relate to:

- the development of frozen confectionary products, such as ice cream, comprising one or more anti-freeze proteins derived from plants, including from the Antarctic-based Nothofagus antarctica, Deschampsia antarctica and Umbilicaria antarctica. The anti-freeze proteins inhibit ice recrystallisation and thus provide a good texture to frozen confectionary product (GB19970014412)
- the development of a Candida antarctica lipase A and a variant thereof, which can be be used as a detergent enzyme or digestive enzyme, or to avoid pitch trouble arising inter alia in processes for preparing mechanical pulp in paper-making processes using mechanical pulp (US6074863)

- a glycoprotein obtained by culture of the bacterial species Pseudoalteromonas antaractica CECT4664, which is useful for coating liposomes in order to improve their stability in relation to external factors such as surfactants (WO9842731)
- a thermally stable lipase native to Candida antarctica, to be used for processing high-melting substrates at 60°C for, inter alia, the randomisation of fat in the margarine industry (US5273898)
- the production of a particular stimulating agent containing the extract of an alga belonging to the genus Durvillea, including Durvillea antarctica. The stimulating agent prevents the development of skin wrinkles (JP9176036)

The above shows that sectors where patents have potential applications include the pharmaceutical, agriculture, food, cosmetics and chemistry sectors (See Figure 3).

"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

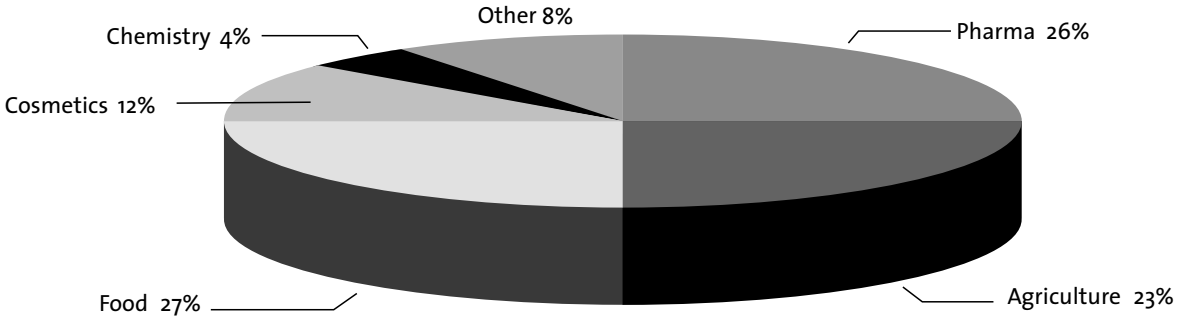

Figure 3: Patents applicable to different industry sectors (1988-2003)

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 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 is not clear from this research.

2.3 Conclusions

Despite these limitations, two key preliminary conclusions and observations can be drawn from this survey: bioprospecting is taking place and the potential for an increase in these activities exists; and the absence of clear rules is problematic for all stakeholders.

Regarding the first conclusion, it should be noted that commercial-orientated research on the genetic diversity of Antarctic has not yet directly produced a commercial product, although some research is relatively advanced in this regard. Thus, synthetic derivatives of an enzyme from an Antarctic sponge have been developed and patented by a Spanish company with a view to developing an anti-cancer drug. Currently, the derivatives are being tested in vivo, which in terms of the drug development means that the research is about half way through the necessary procedures to bringing a drug to the market. The best known and most widely examined genetic resource is the antifreeze glycoproteins produced by various species of fish. For example, research into these proteins is looking for ways to improve farm-fish production in cold climates, extend the shelf-life of frozen food, and enhance the preservation of tissues to be transplanted. There are many other examples of research that could lead to commercial products, such as new antibiotics, cold-active enzymes for better detergents and improved heat resistant dyes. Given that the largest part of inventions are of relevance to the pharmaceutical industry, a breakthrough commercialisation can be expected to attract a significant amount of publicity and thus, revived interest by companies.

Finally, there appears to be considerable interest in conducting further research into commercially useful genetic resources and biochemical processes in Antarctica. The future 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 also has significant potential for

commercial development. Two examples of such adaptation are the production of polyunsaturated fatty acids (PUFA) and of cold-active enzymes by bacteria inhabiting Antarctic ice.

Regarding the second conclusion on the uncertainty about the rules governing the use of Antarctic genetic resources, the specific arrangements outlined in this report varied significantly, which indicates the lack of clarity in the rules. The absence of clear rules governing the use of genetic resources from Antarctica restricts use of these resources, which significantly affects stakeholders. For industry, the uncertainty about the use and ownership of samples inhibits their support for Antarctic research. For scientists, the absence of clear protocols for exchanging information arising from commercial activities inhibits their ability to work with companies and adapt to the changing nature of basic research around the world. Finally, for governments it has proven difficult to negotiate the adequate sharing of benefits arising from commercially orientated research.

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, the pharmaceutical industry and cosmetics industry. 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 and Young publishes a 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 72 percent of the public company revenues were generated by companies in the U.S., 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.[6]

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;[7]
- 62% of cancer drugs approved by the US Food and Drug Administration are of natural origin or modelled on natural products.[8]

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. The most recent comprehensive survey of the private sector's use of naturally occurring genetic resources and biochemical processes was carried out by Kerry ten Kate and Sarah Laird[9] in 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.[10] 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.[11]

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[6] SM Nor & PN Avadhani 'Biotechnology for Developing Countries: Challenges and Opportunities', 11.
[7] S Laird 'Biodiversity and Traditional Knowledge' (Earthscan London 2002), 246.
[8] S Laird 'Biodiversity and Traditional Knowledge' (Earthscan London 2002), 250.
[9] 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.
[10] K Ten Kate & SA Laird, 55-57.
[11] K Ten Kate & SA Laird, 141 & 155.

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).[12]

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.[13] 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.[14]

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 10% hydrochloric acid and stands in contrast to the pH level of sea water, pH 8.[15]

The application of extremophiles in industrial processes ranges from their use in liposomes for drug delivery and cosmetics, waste treatment, molecular biology, to the food industry. A eukaryotic homologue of the myc oncogene product from halophilic archaea, for example, is being utilised to screen cancer patients' sera.[16] 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 30% 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.[17]

The best known example of the commercial applicability of extremophiles is the DNA polymerase of Thermus aquaticus called Taq polymerase.[18] This polymerase, which is central in the polymerase chain reaction (PCR) as it survives the reaction's successive heating cycles,[19] is widely used in medical diagnosis and forensics, and is at the basis of a US$ 300 million industry.[20] 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

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[12] 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).
[13] K ten Kate & SA Laird, 315-318.
[14] K ten Kate & SA Laird, 325.
[15] LJ Rothschild & RL Mancinelli 'Extremophilic organisms adapt to life in incredibly harsh environment' (2001) 409 Nature 1092-1101.
[16] R Cavicchioli & T Thomas 'Extremophiles' in J Lederberg (ed) Encyclopedia of Microbiology (2nd edn Academic Press San Diego 2000), 317-337.
[17] LJ Rothschild & RL Mancinelli 'Extremophilic organisms adapt to life in incredibly harsh environment' (2001) 409 Nature 1092-1101.
[18] 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' 26 Ecology Law Quarterly 1999, 402-405.
[19] PCR enables the to copy and amplify DNA.
[20] TD Brock Life at High Temperatures (Yellowstone Association for Natural Science, History & Education Wyoming 1994).

enzymes derived from extremophiles is forecast to grow at 15-20% per year'.[21]

Bioprospecting for these microbes continues to date, with current research focusing on extremophiles' ability to produce antibiotics, though research into other potential uses of extremophiles, (e.g. for the treatment of industrial effluents) is also being undertaken. Due to the fact that 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.[22] 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.[23] 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 3-year-long project on 'extremophiles as cell factories' with the contribution of some 7 million euros.[24]

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.[25] 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 in the near future.

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[21] 'Bioprospecting of Genetic Resources of the Deep Sea-Bed. Note by the Secretariat' (UNEP/CBD/SBSTTA/2/15), 13.
[22] Extremophile Biotechnology in the Chemical Engineering Department of the University of Bath (UK). See <http://www.bath.ac.uk/chem-eng/fundraising/biotechnology.htm>.
[23] R Cavicchioli & T Thomas 'Extremophiles' in J Lederberg (ed) Encyclopedia of Microbiology (2nd edn Academic Press San Diego 2000), 317-337.
[24] See <http://www.nf-2000.org/secure/Ec/S1077.htm>.
[25] S Maloney 'Extremophiles: Bioprospecting for Antimicrobials'. See <http://www.mediscover.net/Extremophiles.cfm>.

4 Bioprospecting and the Antarctic Treaty System

4.1 Legislative Background

The 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[26]. 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 comprehensively protect 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.[27]

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,[28] 'accord priority to scientific research and to preserve the value of Antarctica as an area for the conduct of such research'.[29] 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

[26] Arts I-III, Antarctic Treaty.
[27] Art 2 & 7, Madrid Protocol.
[28] Art 3(2)(a) & 3(2)(b)(iv), Madrid Protocol.
[29] Art 3(3), Madrid Protocol.

out.[30] 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, inter alia, examine whether the collection of material for bioprospecting would negatively impact 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.[31]

4.1.3 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,[32] 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'.[33] Pursuant to Article 2, any harvesting shall be regulated so as 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.[34] 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.[35]

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.[36]

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 CRAMRA

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 particular its provisions regulating mineral resource activities, its institutional structure, 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'.[37] 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.[38]

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.[39]

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.[40] The treaty provides that once the Commission

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[30] Art 8, Madrid Protocol.
[31] Article 8, Madrid Protocol & Article VII.5(a), Antarctic Treaty.
[32] Art 2(1), CCAMLR.
[33] Art 1(1), CCAMLR.
[34] Art 2(3), CCAMLR.
[35] Art 9(1)(f), CCAMLR.
[36] Art 20, CCAMLR.
[37] Art 5, CRAMRA.
[38] SK Chopra et al 'The Antarctic Minerals Agreement' 83 American Society of International Law Proceedings 1989, 216.
[39] Art 39(1) & 53(1), CRAMRA.
[40] Art 21(d), CRAMRA.

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.[41]

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.[42] 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,[43] as well as the power granted to the Commission.[44]

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)

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:

> 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(GOSEAC):

> 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

[41] Art 29(1), CRAMRA.
[42] Art 9, CRAMRA.
[43] Art 29(2), CRAMRA.
[44] Art 49, CRAMRA.

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....[45]

4.2.2 Committee for Environmental Protection(CEP)

The 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.

CEP considered the issue at its sixth session on the basis of two information papers (IP47 and 75) and an informal paper.

The main points recorded in the report of the CEP on bioprospecting 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.

4.2.3 ATCM

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

[45] 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).

> "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 also 'approved the draft preliminary agenda for CEP VI'.

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

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.[46]

5.1 UNCLOS

The 1982 United Nations Convention on the Law of the Sea, 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.[47]

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 sea-bed 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 mankind, 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.[48]

It establishes the International Sea-Bed Authority, which organises and controls activities in the Area concerned with sea-bed minerals, notably with a view to administering its resources.[49] To fulfil this objective, the Authority is composed of three organs, the decision-making Assembly, the Executive Council and its Secretariat.[50] The Authority's responsibilities include approving deep sea exploration and exploitation activities 'on behalf of mankind as a whole'.[51] Part XI envisages prospective miners to submit a plan of work for approval to the Council,[52] 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, so as to ensure the proportionate sharing of resources under a so-called 'parallel system'.[53]

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 sea-bed and ocean floor and subsoil thereof beyond the limits of national jurisdiction.[54]

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

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[46] In the interest of brevity many other international measures and instruments that deal with various aspects of bioprospecting, but are less relevant, are not considered here. These include: 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).

[47] Preamble, UNCLOS.

[48] Art 136-7, UNCLOS.

[49] Art 156-7, UNCLOS.

[50] Art 156-169, UNCLOS.

[51] Art 153(1), UNCLOS.

[52] Art 153(3), UNCLOS.

[53] K Dixon 'Law of the Sea – Deep Seabed Mining' 18 Georgia Journal of International and Comparative Law 1988, 500-501.

[54] Art 238, 245-6, 256-7 UNCLOS.

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.[55]

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.[56] 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.[57]

Article 274, which outlines the objectives of the International Sea-Bed Authority, provides that the International Sea-Bed 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 Sea-Bed 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.[58]

5.1.4 Regulations on Prospecting and Exploration for Polymetallic Nodules

Following three years of negotiations, the Assembly of the International Sea-Bed 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 prospector has been informed by the Secretary-General that

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[56] Art 266, UNCLOS.
[57] Art 269, UNCLOS.
[58] 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).

its notification has been recorded, and is not to be undertaken if substantial evidence indicates the risk of serious harm to the marine environment.[59] 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'.[60] 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.[61] 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.[62] 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.[63] 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.[64]

5.1.5 UNICPOLOS and bioprospecting

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 (UNICPOLOS). UNICPOLOS considered bioprospecting at its fifth and most recent meeting. At this meeting an expert outlined the types of bioprospecting that were being undertaken in the Oceans.[65]

In the ensuing discussions, delegates raised conflicting 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 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

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[59] Regulation 2(1) & (2), Regulations on Polymetallic Nodules Prospecting & Exploration.
[60] Regulation 2(4), Regulations on Polymetallic Nodules Prospecting & Exploration.
[61] 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.
[62] Regulation 35, Regulations on Polymetallic Nodules Prospecting & Exploration.
[63] Regulation 35 (2), Regulations on Polymetallic Nodules Prospecting & Exploration.
[64] ISBA/8/A/5.
[65] The current research into oceanic genetic resources could be divided into the following areas: (1) pharmaceutical – anti-viral, anti-inflammatory and anti-cancer agents; (2) bimolecular materials – such as the composition and production processes of the glue "threads" a mussel used to cling to rocks, which was already being commercially used as a water resistant glue; (3) the growth processes of the nanno spicules (millionths of an inch spikes) contained in the bodies of sponges that may have applications in the growing of nanno-level silicon microchips for the electronics industry; (4) proteins from an organism that made it special – Arctic/Antarctic fish had an "antifreeze" gene which could be implanted in tomatoes to make them frost resistant or the marsh minnow that was totally resistant to dioxin; and (5) materials used in biological/biomedical research – an enzyme used to identify DNA, genes that facilitate high temperature reactions or the "green" florescence of a jellyfish gene which, when attached to the gene being researched, allowed the site of the reactions to be pinpointed physically in a plant or animal.

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 Sea-Bed Authority 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 UNICPOLOS 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.

At its fifth meeting, UNICPOLOS came to no substantive conclusions about bioprospecting. It agreed to include it on the agenda of its next meeting. UNICPOLOS also welcomed a decision on bioprospecting on the use of deep seabed genetic resources taken by CBD (VII/5), considered below.

5.2 The Convention on Biological Diversity (CBD)

The Convention on Biological Diversity 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 utilization 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.[66] 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.

[66] 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.

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.[67] 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

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.[68] 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.[69] 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.[70] 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.[71] 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 bi-lateral or private system under which individual users and providers are left to determine the terms of access, use and benefit-sharing. At it most recent meeting, the COP launched new negotiations to further develop these rules. Even though it is unclear how rapidly these negotiations will conclude, they are a tangible manifestation that the issue of bioprospecting is still contentious and needs further policy clarity.

The issue of bioprospecting of marine genetic resources from the deep seabed has been raised by Parties to the CBD. A study submitted to the 8th 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 can only be effected if such resources are brought under a regime similar to the one governing the mineral resources of the Area under UNCLOS.[72] SBSTTA took note of the study and requested the Executive Secretary, in consultation with all organisations and Parties to

[67] Art 16(5), CBD.
[68] 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.
[69] 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'.
[70] Para 41, Bonn Guidelines.
[71] Para 51-61, Bonn Guidelines.

further work on the matter[73]. This recommendation was adopted by the COP. As a result, the matter will be considered further by SBSTTA at its next meeting. Some of the issues that SBSTTA will consider include: information on the methods for identification; assessment and monitoring of genetic resources of the seabed and ocean floor and subsoil; the status, trends and threats to such genetic resources; and the technical options for their protection.

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." [74]

Over 50 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, all Antarctic Treaty Consultative Parties are bound by the provisions of both treaties, being also Contracting Parties to the CBD.[75] 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 States, 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

The World Intellectual Property Organization (WIPO) administers 23 international treaties dealing with different aspects of intellectual property protection, including the Madrid Agreement Concerning the

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[72] 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).
[73] See Recommendation VIII/3/D, Document UNEP/CBD/COP/7/2.
[74] UNEP/CBD/SBSTTA/8/INF/3/Rev.1, para.68. The term is neither defined nor used in the Convention on Biological Diversity. The Encyclopaedia 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".
[75] Compare Handbook of the Antarctic Treaty System (US Department of State Washington 2002) 16-17, with <http://www.biodiv.org/world/parties.asp>.

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.[76] 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.[77]

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'.[78] 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.[79]

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.[80] 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.[81] 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.[82] This system provides a practical example of benefit sharing that may be useful for Antarctica.

5.6 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, entered into force on 29 June 2004 and has 55 Parties. 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.[83] 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 64 major crops and forages listed in Annex I of the treaty, it contains provisions for facilitating access to genetic resources and sharing benefits

76 '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.
77 Para 34, Contractual Practices.
78 Para 35, Contractual Practices.
79 Para 38, Contractual Practices.
80 Art 3(1), Budapest Treaty.
81 Art 7 & 6(2), Budapest Treaty.
82 Rules 6, 2, 9 & 11, Budapest Treaty Regulations.
83 Art 1(1), CGRFA.
84 Art 10(2), CGRFA.

arising from the use of these resources in an equitable and fair manner.[84]

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 under the CBD, may be regulated by a complementary system entered into in accordance with the International Treaty.

6 Conclusions

While products or processes based on Antarctic organisms have not yet been commercialised, the scope for such a development exists. Not only do some Antarctic extremophiles exhibit potentially exploitable characteristics, but industry has also displayed an interest in screening these organisms.

Restrained by the incomplete knowledge-base of Antarctic biodiversity and the current economic situation, companies have not made it a priority to focus their attention on Antarctic samples, as the cost, risk and time involved do not concur with the necessity to generate marketable products. In addition, lack of ownership of the samples, and uncertainty relating to intellectual property rights and commercial exploitation also appear to have acted as disincentives.

Given that the largest part of inventions are of relevance to the pharmaceutical industry, a breakthrough commercialisation can be expected to attract a significant amount of publicity and thus, revived interest by companies. Moreover, since rules regarding access, sample ownership, benefit-sharing and intellectual property rights would provide certainty to academic researchers, industries and governments, the timing seems more than suitable for the Antarctic Treaty Consultative Meeting to consider this issue carefully.

Factors that seem to influence a company's interest in Antarctic samples are not only its financial situation, but also its focus on research and development, as well as its existing expertise in working with extremophiles. If bioprospecting is to continue in a similar form as it has up to date, i.e. as part of wider research projects and with the sampling being undertaken by academic researchers, it should be in the interest of the international community as a whole to develop a framework under which the commitments of the Antarctic Treaty are honoured, and the opportunity for developing necessary products or processes maintained.

Regarding a possible legal framework, the use of Antarctic genetic resources needs to take account of the complex jurisdictional issues raised by Article IV and the different legal regimes applicable to the Southern Ocean. 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 in this regard.

A number of important issues that the ATS does not clearly address but that must be dealt with concern ownership of Antarctic genetic resources, legitimate acquisition of these resources by scientists working in the Antarctic Treaty area, measures scientists have to take to protect the resources, the feasibility and partners of any benefit-sharing arrangements, ownership of the commercial product resulting from the genetic resources, the relationship between the ATS and other international policies, and the consistency of bioprospecting with Article III of the Treaty.

Existing international policies governing bioprospecting activities elsewhere are of limited value in answering the above issues although they do provide some worthwhile elements. UNCLOS, for example, establishes a "public" model for prospecting, whereby resources are deemed the common heritage of mankind and a complex legal and institutional framework is established to manage the resources for the common good. While the CBD sets 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. Based on the concept that States have sovereignty over their genetic resources, 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. 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. Finally, 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 only, which are considered to be some of the most important in terms of world food security which are declared a "common concern of all countries".

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. Further analysis and research is necessary to promote detailed consideration of this complex subject. Key topics that require more information are:

- Information regarding existing and planned

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

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Institute of Advanced Studies

United Nations University
Institute of Advanced Studies
6F, International Organizations Center
Pacifico-Yokohama, 1-1-1 Minato Mirai
Nishi-ku, Yokohama 220-0012,
Japan

Tel: +81 45 221 2300
Fax: +81 45 221 2302
Email: unuias@ias.unu.edu
URL http://www.ias.unu.edu