# BIOPROSPECTING IN AREAS OUTSIDE NATIONAL JURISDICTION: ANTARCTICA AND THE SOUTHERN OCEAN

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*[This article examines the issues surrounding bioprospecting for potential resources from areas outside national jurisdiction. Bioprospecting is attracting attention in international law because there is a lack of clarity in the interplay between sovereign rights over biological resources and intellectual property rights in inventions developed from those resources. The situation is even more complex where sovereign rights are disputed or absent. This article focuses on the Antarctic and the Southern Ocean because, although this region is in the administrative custody of 45 state parties to the* Antarctic Treaty*, the status of Antarctic resources is legally unclear. While there may not be direct conflict between the Antarctic legal regime and other international regimes, including the* Agreement on Trade-Related Aspects of Intellectual Property*, the* Convention on Biological Diversity *and the* United Nations Convention on the Law of the Sea*, neither does the legal regime provide adequate guidance in the treatment of resources from global commons areas. An examination of the issues has led the authors to conclude that at the very least the* Antarctic Treaty *consultative parties should make clear their collective policy on bioprospecting before the industry takes hold.]*

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## I INTRODUCTION

> At the start of the 21st century, the industrial world stands on the edge of a new revolution. The industries of the future will tap increasingly into the materials and processes in plants, animals and microorganisms. They will draw on the chemicals and genetic material of the world's biological resources to provide new feedstocks and new modes of manufacture.[1]

The process of tapping into the world's biological resources is known as bioprospecting and its economic importance is widely recognised.[2] For example, in Australia, it has been noted that 'the world's biota represents a source of raw materials that has the potential to replace petrochemicals as an industrial feedstock and to provide novel chemicals for use in drugs and other products'.[3] One of the significant features of the bioprospecting industry is that research into and development of new products often involves collaborative contractual arrangements between public institutes and the private sector, providing for access to collections of samples in exchange for financial support.

Access to microbial collections is particularly important to the industry, because these species are recognised as sources of potential pharmaceutical and therapeutic compounds. Large collections of species are being created. One example is the Australian Collection of Antarctic Micro-Organisms ('ACAM'),

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1 Standing Committee on Primary Industries and Regional Services, House of Representatives Parliament of Australia, *Bioprospecting: Discoveries Changing the Future* (2001) [vi].

2 See generally ibid; John Bowman, 'Antarctica a Global "Hot Spot": Biotechnology and Biodiversity' (Paper presented at the Australian Academy of Technological Sciences and Engineering Symposium, 'Looking South: Managing Technology, Opportunities and the Global Environment', Hobart, Australia, 20–21 November 2001) <http://www.atse.org.au/publications/symposia/proc-2001.htm> at 1 May 2003.

3 See Standing Committee on Primary Industries and Regional Services, above n 1, [2.2].

which houses around 300 species collected from the Antarctic.[4] A further private collection of around 7400 species is held by the Cooperative Research Centre for the Antarctic and Southern Ocean in collaboration with Cerylid Biosciences.[5] Similar Antarctic bioprospecting activity is being undertaken by public institutes, in partnership with commercial enterprises, from a number of other states. In order to protect their investment, it is likely that commercial enterprises will claim intellectual property rights in the form of patents over biological resources sourced from Antarctica and the Southern Ocean, or at least over the downstream[6] products resulting from further research and development.

The process of bioprospecting can be divided into a number of phases, which are described in detail below. The first phase — sample collection — is likely to be benign from an environmental perspective because sample sizes are small. However, if products derived from bioprospecting activity cannot be synthetically produced but must be extracted from harvested biological resources, there will be environmental consequences. The primary focus of this article is not so much on the regulation of harvesting of Antarctic resources for bioprospecting purposes, but on the impact of bioprospecting on scientific activity and access to its resources by others. It is accepted that bioprospecting is progressive, innovative, and offers great promise for the development of new products that are beneficial to humankind. Therefore, it should be encouraged. Moreover, commercial enterprises should be rewarded for their investment in such activity in the form of patent rights over the end products. However, these claims to patent rights should not be at the cost of freedom of scientific research on the resources in their natural environment, nor should they be allowed without some sharing of the benefits that come from the use of those resources. It may be necessary to regulate bioprospecting, both in the Antarctic and elsewhere, in order to balance these conflicting interests.

The legal regime established by the *Antarctic Treaty*[7] is premised on freedom of scientific research and the exchange of observations and results for the benefit of humankind.[8] These scientific philosophies are also widely held by the international community. For example, the fundamental principles in the *United Nations Convention on the Law of the Sea*[9] include freedom of scientific research in the high seas.[10] In both legal regimes, however, these principles were enunciated long before the full potential of the bioprospecting industry was acknowledged. Exactly how these principles might be protected within the new commercial era of science is unclear.

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4 Wendy Pyper, 'Biotech Bugs' (2002) 14(3) *Today's Life Science* 12. Note that the authors use the terminology 'the Antarctic' to refer to the continent of Antarctica and the Southern Ocean surrounding it, unless reproducing a direct quote which is inconsistent with this usage.

5 Ibid.

6 The term 'downstream' is used to denote the subsequent products from subsequent research and development. 'Upstream' is used to denote the initial products of research and development.

7 Opened for signature 1 December 1959, 402 UNTS 71 (entered into force 23 June 1961).

8 See ibid, arts II–III.

9 Opened for signature 10 December 1982, 1833 UNTS 3 (entered into force 16 November 1994) ('*LOSC*').

10 Ibid art 87(1)(f).

With regard to benefit sharing, the Antarctic and the high seas are most commonly referred to as global commons areas where resources are available to all. The finest example of this is the deep-sea bed, where mineral resources are deemed to be the 'common heritage of mankind'.[11] Access, ownership and sharing of the benefits of resource exploitation are regulated by *LOSC*.[12] Neither the *Antarctic Treaty* nor *LOSC* provides specific guidance for regulating bioprospecting, other than by linking together some of the fundamental principles contained within these instruments, such as conservation and rational management. Other international legal regimes offer little assistance. The *Convention on Biological Diversity*[13] deals with issues of conservation, sustainable use, and fair and equitable sharing of benefits arising from the use of genetic resources. Although not inconsistent with either the *Antarctic Treaty* or *LOSC* provisions in this regard, the *CBD* covers only material subject to national jurisdiction.[14] As such, material sourced from the Antarctic and the high seas are not subject to the same level of legal protection as state-owned resources.

In regards to the high seas, there has been some academic commentary and more formal international discussions on the question of how the exploitation of these resources might be regulated.[15] In the context of the Antarctic, the need to consider this question has also been recognised.[16] These issues are not new. However, to date, the *Antarctic Treaty* parties have not accorded discussion of bioprospecting a high priority. It is the opinion of the authors that at the very least, the *Antarctic Treaty* parties should be proactive in formulating a policy for regulation of bioprospecting in the Antarctic to uphold the fundamental principles of freedom of scientific research and cooperation, and to provide added protection from unregulated resource use.

Bioprospecting in global commons areas like the Antarctic and the high seas is likely to become increasingly controversial. Issues of ownership, access, sovereignty and jurisdiction are complicated and will need to be further elaborated as the industry develops.[17] Three of the critical questions that will need to be addressed are examined in this article:

1 Does the commercialisation of publicly funded science have the potential to place inappropriate limits on freedom of scientific investigation fundamental in both Antarctic and high seas law?

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11 Ibid art 136.

12 Ibid art 136. See generally ibid pts 11, 13.

13 Opened for signature 5 June 1992, 1760 UNTS 79 (entered into force 29 December 1993) ('*CBD*').

14 Ibid art 4.

15 See, eg, Lyle Glowka 'Biopropspecting, Alien Invasive Species, and Hydrothermal Vents: Three Emerging Legal Issues in the Conservation and Sustainable Use of Diversity' (2000) 13 *Environmental Law Journal* 329. See also *CBD* Subsidiary Body on Scientific, Technical and Technological Advice, *Marine and Coastal Biodiversity: Review, Further Elaboration and Refinement of the Programme of Work*, United Nations Environmental Program, [11]–[12], UN Doc UNEP/CBD/SBSTTA/8/9 (25 November 2002).

16 See, eg, Committee for Environmental Protection, *Final Report of the Committee for Environmental Protection* (10–20 September 2002) [58]–[61] <http://www.cep.aq/default.asp?casid=5305> at 1 May 2003 ('*CEP V*').

17 Lee Kimball, *International Ocean Governance: Using International Law and Organisations to Manage Marine Resources Sustainably* (2001) 57–8.

2 Should there be limitations on ownership rights over biological resources from global commons areas to ensure that benefits are shared equitably among humankind?
3 If the answer to the above questions is yes, how should bioprospecting in areas outside national jurisdiction be regulated?

This article aims to address these questions specifically within the context of the *Antarctic Treaty* and the instruments emanating from the *Antarctic Treaty*, given the lack of attention that bioprospecting in the region has received to date. We will also discuss some of the provisions of *LOSC*, but only in so far as they relate to the Southern Ocean.[18] We consider the current Antarctic legal regime and how it has dealt with resource management issues in the past, particularly in the context of unproven legal sovereignty over the resources. We illustrate, with examples, some bioprospecting activity in the Antarctic, the phases of research and development that lead to product development from such activity, and the subsequent claim to intellectual property rights. The extent to which these rights can be asserted and protected is examined within the context of the international legal framework for patenting, provided by the *Agreement on Trade-Related Aspects of Intellectual Property*[19] and the legal framework for access and benefit sharing, provided by the *CBD*. The impact of intellectual property rights on freedom of scientific research, the sharing of common resources, and the equitable distribution of benefits flowing from their utilisation is described and analysed in order to establish why specific regulation may be necessary in the Antarctic context. Finally, we develop some options for regulation that the *Antarctic Treaty* parties may wish to consider.

## II THE ANTARCTIC LEGAL REGIME AND RESOURCE MANAGEMENT

### A *The* Antarctic Treaty

The 12 original signatories to the *Antarctic Treaty*[20] agreed that the freedom of scientific research and international cooperation with respect to the Antarctic was paramount for the good of all humanity.[21] Subsequent instruments emanating from the *Antarctic Treaty* — the *Convention for the Conservation of Antarctic Seals*,[22] the *Convention on the Conservation of Antarctic Marine Living Resources*,[23] the *Convention on the Regulation of Antarctic Mineral*

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18 See *Antarctic Treaty*, above n 7, art VI. The *Antarctic Treaty*'s area of application is south of 60°S latitude, pursuant to art VI, which also reads: 'nothing in the present *Treaty* shall prejudice or in any way affect the rights, or the exercise of the rights, of any State under international law with regard to the high seas within that area', leading the authors to treat the maritime zone south of 60°S as 'high seas' for the purpose of this article.

19 Opened for signature 15 April 1994, 1869 UNTS 299 (entered into force 1 January 1995) ('*TRIPS*').

20 Argentina, Australia, Belgium, Chile, France, Japan, New Zealand, Norway, Russian Federation (formerly USSR), South Africa, the UK and the US.

21 See *Antarctic Treaty*, above n 7, especially the language contained in the preamble, arts II, III and the liberal inspection and observation provisions of art VII.

22 Opened for signature 1 June 1972, 1080 UNTS 175 (entered into force 11 March 1978) ('*CCAS*').

23 Opened for signature 20 May 1980, 1329 UNTS 47 (entered into force 7 April 1982) ('*CCAMLR*').

*Resource Activities*,[24] and the *Protocol on Environmental Protection to the Antarctic Treaty*[25] (collectively known as the '*Antarctic Treaty* System')[26] — have all served to reinforce this founding philosophy. More than 40 years on, however, this altruistic tenor is likely to be challenged by, for instance, the potential for compromise between publicly funded, common-good scientific research and the results of commercialisation of that research effort through the assertion of patent rights over what many see as global commons resources.

The *Antarctic Treaty* parties have traditionally reacted to challenges by establishing legal instruments to regulate specific activities — commercial sealing is regulated by the *CCAS*, marine living resources harvesting by the *CCAMLR*, and mineral resources activities by the *Madrid Protocol*. In fact, attempts are being made to regulate all authorised human activity[27] in the Antarctic through the *Antarctic Treaty* System's latest addition, the *Madrid Protocol.* This instrument requires that environmental impact assessment be a critical pre-planning exercise for all activities, including scientific research.[28]

The interaction between publicly funded, common-good research and its commercial application, including claims to patent rights, has not yet been specifically addressed by the *Antarctic Treaty* parties as a group,[29] although as individual states they may have regulated the use and conservation of biological resources through their own national laws to meet their international obligations under *LOSC* and the *CBD*. In the Antarctic context, it will not be simple, primarily because of the intractable nature of sovereignty during the life of the *Antarctic Treaty.* There is no consensus about the legal status of the Antarctic, ergo who owns or can exercise jurisdiction over its resources.[30] Seven of the 12 original signatories (including Australia) claim portions of the Antarctic continent as legal territory.[31] The area between 90˚ and 150˚ west remains the

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24 Opened for signature 25 November 1988, 27 ILM 868 ('*CRAMRA*'). The 12-month time period for signature expired on 25 November 1989, therefore *CRAMA* never entered into force.

25 Opened for signature 4 October 1991, 30 ILM 1461, art 7 (entered into force 14 January 1998) ('*Madrid Protocol*').

26 The System also includes a range of internal regulations that are the products of annual *Antarctic Treaty* Consultative Meetings ('ATCMs').

27 Authorised human activity is that which the *Antarctic Treaty* parties must give advanced notice of, such as for 'all expeditions to and within Antarctica', pursuant to the *Antarctic Treaty*, above n 7, art VII(5)(a).

28 See generally *Madrid Protocol,* above n 25, annex 1 (Environmental Impact Assessment).

29 Within the group, 27 of the 45 *Antarctic Treaty* parties have earned the right to become consultative parties (ie decision-makers) on the basis of their continued investment in scientific research activity. Their decisions are made by consensus. They are the original signatories (see above n 20), Brazil, Bulgaria, China, Ecuador, Finland, Germany, India, Italy, the Netherlands, Peru, Poland, South Korea, Spain, Sweden and Uruguay.

30 For a comprehensive overview of the conundrum faced by the *Antarctic Treaty* parties with regard to sovereignty, see Keith Brennan, 'Criteria for Access to the Resources of Antarctica: Alternatives, Procedure and Experience Applicable' in Fransisco Orrego Vicuña (ed), *Antarctic Resources Policy: Scientific, Legal and Political Issues* (1983) 217. Although this work is now 20 years old, its basic arguments are still relevant.

31 Gillian Triggs (ed), *The* Antarctic Treaty *Regime: Law, Environment and Resources* (1987) 51. Antarctic territorial claimants are: Argentina, Chile and the UK (whose claims overlap in the Peninsula region); Australia, France, New Zealand and Norway. In Australia's case, this also includes an Exclusive Economic Zone proclaimed in 1994 by the *Maritime Legislation Amendment Act 1994* (Cth).

largest single portion of territory on earth as yet unclaimed. Two other *Antarctic Treaty* parties, the United States and the Russian Federation, reserve their rights to a basis of claim but the claims and reservations are suspended status quo ante (as they existed in 1959) by art 5 of the *Antarctic Treaty*.[32] The application of sovereign jurisdiction is, therefore, the prerogative of the claimant states; those *Antarctic Treaty* parties that do not claim have a reciprocal prerogative not to recognise the claims of others. In other words, sovereignty (and therefore jurisdiction) is unproven in law.

The *Antarctic Treaty* parties have had some prior experience with the difficulties this raises in the management of resource use. It was a key factor during the *CRAMRA* negotiations in the 1980s. The decision to develop an instrument such as the *CRAMRA* was based on the premise that if mining were to be conducted in the Antarctic, it would be prudent to have in place a means of regulating it. It was acknowledged at the time that any agreement to regulate mining would need to incorporate inter alia an explicit means of allocating property rights because commercial investors would demand such assurances.[33] This was one of the sticking points that stalled the negotiations for six years.[34] The *Antarctic Treaty* parties did eventually agree on legal regulation of mineral resource activities through the *CRAMRA*, which arguably contained some of the most thoughtful and wide-ranging environmental provisions of its time. However, for a number of the *Antarctic Treaty* parties — including two of the claimants, Australia and France — the final instrument was far from acceptable, resulting in their refusal to sign.[35] The *Antarctic Treaty* parties went back to the negotiating table with the discord over the *CRAMRA*'s failure ringing in their ears. Then in just two years they turned the issue around completely by prohibiting absolutely any activity (other than scientific research) related to mining through the mechanism of the *Madrid Protocol*, and more specifically art 7. There is no doubt that this decision to turn the Antarctic 'green' was a compromise. There seemed to be no chance of reconciling the incongruities that unproven sovereignty raised, such as who should profit from commercial mining

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[32] *Antarctic Treaty*, above n 7, art IV reads:

> 1. Nothing contained in the present *Treaty* shall be interpreted as:
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> (a) a renunciation by any Contracting Party of previously asserted rights of or claims to territorial sovereignty in Antarctica;
>
> (b) a renunciation or diminution by any Contracting Party of any basis of claim to territorial sovereignty in Antarctica which it may have whether as a result of its activities or those of its nationals in Antarctica, or otherwise;
>
> (c) prejudicing the position of any Contracting Party as regards its recognition or non-recognition of any other State's right of or claim or basis of claim to territorial sovereignty in Antarctica.
>
> 2. No 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. No new claim, or enlargement of an existing claim, to territorial sovereignty in Antarctica shall be asserted while the present *Treaty* is in force.

[33] See Brennan, above n 30, 224.

[34] Ibid.

[35] Sam Blay and Martin Tsamenyi, 'Australia and the *Convention for the Regulation of Antarctic Mineral Resource Activities* (*CRAMRA*)' (1990) 26 *Polar Record* 195, 195–202.

in a commons area, providing protection from subsidised (unprofitable) mining, payment of licence fees and royalties to claimants without overtly acknowledging their sovereign rights to such monies, and allocation of compensation for environmental damage. The notion that the Antarctic was a global commons, the resources of which were not open to property rights, was paramount.[36]

Currently, the *Antarctic Treaty* System prescribes limits on resource use to the extent that only regulated marine living resources harvesting shall be carried out,[37] and mineral resource activity is banned.[38] As bioprospecting is an activity with potentially both environmental and resource implications, the *Antarctic Treaty* parties need to determine a more comprehensive policy position, if not a regulatory framework. The *Antarctic Treaty* System is, by design, dynamic, allowing the *Antarctic Treaty* parties the flexibility to incorporate new regulations as the need arises. At their annual meetings they make recommendations for action to be taken by all of the individual state governments. As these are made by consensus, agreement may take some time, particularly if the action is a meeting measure.[39] When discussing the issue of bioprospecting, which is on the agenda of the next ATCM in Madrid in June 2003, one critical question the *Antarctic Treaty* parties face is where to draw the line between the 'jurisdiction' of the *Antarctic Treaty* parties over common property resources (resources originating from areas outside national jurisdiction) and the right (or even obligation) of researchers and their partners to commercialise. The following sections attempt to partially answer this question.

### B *Bioprospecting Interest in the Antarctic*

Bioprospectors have been drawn to the Antarctic because its extreme environment has led to the evolution of a range of interesting physiological adaptations. Antarctic biological resources, particularly the large numbers of indigenous Antarctic micro-organisms, are seen as potentially rich sources of raw materials for pharmaceutical and other industries.[40] There is particular interest in the ability of Antarctic micro-organisms to produce polyunsaturated fatty acids and cold-active enzymes.[41] Because of their biodiversity and their relationship with other species that have already been found to produce pharmaceutically active compounds, some Antarctic bacteria are the focus of a

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36 Keith Suter, *Antarctic Private Property or Public Heritage?* (1991) 46.

37 *CCAS*, above n 22, art 2(1); *CCAMLR*, above n 23, art 3.

38 *Madrid Protocol*, above n 25, art 7.

39 The ATCM determinations include 'measures' (text containing legally binding obligations), 'decisions' (text regarding international organisational matters) and 'resolutions' (for example, hortatory text encouraging compliance).

40 See generally Richard Laws, 'Scientific Opportunities in the Antarctic' in Gillian Triggs (ed), *The Antarctic Treaty Regime: Law, Environment and Resources* (1987) 28.

41 David Nichols, 'Case Studies of Biotechnology Opportunities in Antarctica' (Paper presented at the Australian Academy of Technological Sciences and Engineering Symposium — Looking South: Managing Technology, Opportunities and the Global Environment, November 2001) <http://www.atse.org.au/publications/symposia/proc-2001.htm> at 1 May 2003. See also Committee on Primary Industries and Regional Services, above n 1, [3.2].

bioprospecting research program being undertaken by a group of Australian scientists.[42]

Antarctic yeast are another source of potentially beneficial pharmaceuticals. For example, a Russian patent claims a unique multifunctional agent derived from a strain of Antarctic black yeast.[43] The agent is claimed to be useful in the treatment of

> a plurality of functional, organic, structural and sexual pathological and pre-pathological conditions such as osteochondrosis, arthritis/osteoarthritis, radiculitis, various pain syndromes, cardiac and gastroenterological pathologies, gynaecological affections, stress, immune problems, psycho-emotional disorders, etc.[44]

A range of potentially important pharmaceutical compounds are also being isolated from Antarctic krill and fish. For example, a US patent[45] describes a multifunctional enzyme derived from krill and fish that is

> useful for treating viral infections such as herpes outbreaks, fungal, bacterial or parasitic infections, including the primary and secondary infections of leprosy, colitis, ulcers, haemorrhoids [sic], corneal scarring, dental plaque, acne, cystic fibrosis, blood clots, wounds, immune disorders including autoimmune disease and cancer.[46]

Other patents claim families of antifreeze polypeptides derived from fish and other organisms.[47]

These examples demonstrate the potential value of Antarctic biological resources in the development of products with a range of applications, including the alleviation of human suffering caused by ill health and disease. Fulfilling this potential will inevitably require investment by the private sector, who will in turn seek patent protection to secure a return for their investment. The underlying rationale of the patent system, which is examined in the next section, is that the grant of a patent gives the holder exclusive rights to the patented invention. As such, the holder is granted the right to restrict access to the invention. Increasingly, patents are being granted for 'inventions' derived from naturally occurring material. Confidentiality requirements in the terms of agreements between researchers and commercial partners are likely to further restrict access to research results. This will be problematic in the Antarctic context for a number of reasons, including the obligations of freedom of

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42 See Nichols, above n 41.

43 Details of this patent can be accessed from the European Patent Office, Patent Database <http://ep.espacenet.com> at 1 May 2003. The patent number is WO0020012 and it was filed in 1998.

44 European Patent Office, *WO0020012: Agent Called 'Astromelanin'/'Astronella' for Treating Pathological Conditions* (2000) <http://ep.espacenet.com> at 1 May 2003.

45 Details of this patent can be accessed from the US Patent and Trademark Office, Patent Database <http://www.uspto.gov/main/patents.htm> at 1 May 2003. The patent number is 5945102 and it was filed in 1995.

46 US Patent and Trademark Office, *5945102: Crustacean and Fish Derived Multifunctional Enzyme* (1999) <http://www.uspto.gov/main/patents.htm> at 1 May 2003.

47 See, eg, US Patent 6307020, claiming intracellular antifreeze polypeptides and nucleic acids, the details for which can be found at US Patent and Trademark Office, Patent Database.

scientific research and the free exchange of scientific observations and results.[48] The process of bioprospecting for Antarctic micro-organisms for the purpose of drug discovery thus provides a useful platform for analysis of the complexity and controversial nature of bioprospecting in the Antarctic.

### C *The Process of Bioprospecting for Antarctic Biological Resources*

The process of bioprospecting can be subdivided into a number of discrete phases.[49] The phases described here relate specifically to the isolation and culture of samples of terrestrial and marine micro-organisms in a laboratory for the purpose of drug discovery. It is likely that bioprospecting for other biological resources, including terrestrial and marine plants and animals, and for other purposes, will follow a similar pattern. However, it is acknowledged that some of those resources will be difficult to maintain in the laboratory for successive generations, and in some instances, it will be impossible to synthetically produce the end product. In such cases, it will be necessary to harvest the resource and extract the end product.

#### 1 *Phase 1: Sample Collection*

The collection of samples from the Antarctic is the first phase in the search for pharmaceutically active compounds. Collections of sample material are presently being gathered from the Antarctic terrestrial and marine environments for the purposes of isolating and culturing micro-organisms for potential pharmaceutical use, in addition to a range of other uses.

At the outset it must be acknowledged that sample collection is unlikely to have a significant environmental impact and is not inconsistent with conservation. Therefore sample collection would not be excluded by the instruments dealing with environmental impact such as the *Madrid Protocol* or the *CCAMLR*. The *Madrid Protocol* certainly imposes environmental impact assessment obligations on researchers collecting samples.[50] However, in the case of micro-organism samples, only very small quantities are taken (in some cases teaspoonfuls) and the activity of collection is almost certain to cause 'less than a minor or transitory impact' on the environment.[51] The same cannot be said for harvesting of biological resources for the purpose of extracting target compounds. This may well have a significant impact on the environment and will therefore be subject to a higher level of environmental impact assessment.

National legislation may also require permits to be issued for the collection of material from protected areas. Australian legislation, for example, requires compliance with environmental impact assessment requirements under the *Antarctic Treaty (Environment Protection) Act 1980* (Cth) and the issuing of permits to import quarantine material into Australia under the *Quarantine Act 1908* (Cth).

It is likely that the samples will be collected by scientific researchers employed by governments or universities. These scientists use their skill and

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48 *Antarctic Treaty*, above n 7, arts II–III.

49 See Committee on Primary Industries and Regional Services, above n 1, 4.

50 *Madrid Protocol*, above n 25, art 8.

51 Ibid art 8(1)(a).

knowledge in choosing appropriate samples for collection. Where the collection of samples is funded by the public sector, it is likely that access to the samples will be available to any researcher worldwide.[52] On the other hand, where collection is funded by the private sector, it will be regulated by contractual provisions, which may prohibit free access.[53] This basically provides participants with a head start in the second phase of the bioprospecting process.

### 2 *Phase 2: Isolation, Characterisation and Culture*

In the laboratory, researchers attempt to isolate and characterise micro-organisms from the collected samples. If this is achieved, an attempt may be made to culture the micro-organisms and, in some cases, sequence their DNA.[54] Where this research is funded by the public sector, results will be published through normal scientific channels and it is likely that specimens will be made available to other researchers on request.[55]

Where this research is funded by the private sector, researchers report discoveries and provide extracts cultured from micro-organisms to their commercial partner. During this phase, the researcher's institution and/or the commercial partner may choose to take out patents on the gene sequences and proteins derived from the micro-organisms, and in some instances, even the micro-organisms themselves.[56] However, this is not always the case — the commercial partner may delay patenting until pharmaceutically active products are isolated (see phase 3). Irrespective of whether or not patents are taken out, the parties may be bound by confidentiality requirements to keep their discoveries secret. Patents and contractual confidentiality requirements may limit access by other researchers to basic research results.

It is likely that the contractual arrangements will require that ownership of any intellectual property created from the processes of isolating and extracting will be assigned to the commercial partner. However, researchers and their employers may be entitled to a share in the royalties from future products and are likely to retain the background intellectual property. Contractual terms will also dictate these matters. It is still open to other researchers to independently access the original material and isolate the same micro-organisms. However, this requires duplication of research effort and carries the risk of legal liability for patent infringement.

### 3 *Phase 3: Screening for Pharmaceutical Activity*

Screening for pharmaceutical activity will generally be carried out by the commercial partner using samples from the original material. Screening will identify the potential for a 'product' to be developed from the organism samples.[57] Samples are grown under a range of different conditions and cellular

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52 One example is the ACAM collection in the Department of Agricultural Science at the University of Tasmania.

53 However, samples may become publicly accessible upon termination of a specific contract.

54 See Committee on Primary Industries and Regional Services, above n 1, [1.10].

55 See ibid [3.15]–[3.17].

56 The legitimacy of patenting these biological resources is discussed further below at part III.

57 See Committee on Primary Industries and Regional Services, above n 1, 4.

extracts are removed and screened for biological activity. Thousands of extracts are assessed in this way, perhaps resulting in the identification of only one potentially pharmaceutically active compound.[58]

The screening phase is costly and risky and, unless it is fully automated, it is also labour-intensive. It is during this phase that a patent may be sought in relation to the pharmaceutically active product. This is also the point at which the results of the research effort take on a much more commercial flavour. The guarantee of intellectual property rights at this stage provides sufficient incentive to continue investing in the research necessary to progress to phase 4 and beyond.

#### 4 *Phase 4: Development of Product, Patenting, Trials, Sales and Marketing*

Once activity has been detected, the active compound must be isolated and ideally synthetically produced, although this is not always possible.[59] If resources must be harvested to extract the active compound, the environmental impact would need to be assessed. A successful trial product is then subjected to a range of procedures to test its safety and efficacy.[60] One or more patents, and other exclusive intellectual property rights, such as certification trade marks using the 'Antarctic' brand, would protect this innovative phase, ensuring a return on the investment.

In order to understand the implications of bioprospecting in the Antarctic, it is essential to have a basic understanding of how the patent system works, what is patentable and how patents can be used. The protection provided by patenting is likely to attract criticism because of its potential to curtail freedom of access, freedom of scientific research, and benefit sharing.

## III THE INTERNATIONAL LEGAL REGIME FOR THE PROTECTION OF INTELLECTUAL PROPERTY RIGHTS

Most states in the world (including all of the *Antarctic Treaty* parties) are obliged to have intellectual property laws that comply with *TRIPS.* Amongst other matters, *TRIPS* sets out the essential requirements for obtaining a patent, the allowable exclusions from patenting, and the allowable restrictions on the use of patents.[61]

Patents are generally justified on the basis that they encourage innovation by granting the inventor a period of market exclusivity in which to commercialise their invention. Patenting is particularly necessary in the pharmaceutical industry for a number of reasons, including the high costs of the research and commercialisation phases, and the time lag between invention and marketing that arises out of regulatory requirements for drug approvals (generally estimated as

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58 Ibid [3.59].

59 For example, proteins from krill have been found to be particularly difficult to synthetically produce: see Stephen Nicol and Yoshinari Endo, 'Krill Fisheries of the World' (Fisheries Technical Paper 367, Food and Agriculture Organisation of the UN, 1997) [5.2.8].

60 See Committee on Primary Industries and Regional Services, above n 1, 4.

61 *TRIPS,* above n 19, arts 27–34.

around 14 years).[62] Patents allow for recovery of the costs of research and development through monopoly pricing, licence fees and royalty payments. As such, it is difficult to find convincing arguments against patenting of pharmaceuticals that are derived from biological resources through bioprospecting. Similar arguments can also be raised in support of patenting of other downstream products of bioprospecting.

Patenting of living organisms, genes and other like products is more controversial, in part because of the perception that this amounts to ownership of life.[63] Contrary to this popular misconception, the patent system does not grant ownership in the traditional sense. The owner of patent number US5945102 does not own each and every multifunctional krill enzyme that is naturally produced. Nor does the owner of patent number WO0020012 own every naturally produced multifunctional yeast agent. Simply put, a krill cannot be accused of infringing patent 5945102 by manufacturing its own enzyme. The patent system gives patent holders the right to prevent others from exploiting their inventions without permission for a limited period, generally 20 years.[64] Nevertheless, patents can, and often are, drafted in such a way as to foreclose the use of naturally occurring materials by anyone except the patent holder.

### A *Essential Requirements*

Article 27(1) of *TRIPS* requires that member states must make patents available for any inventions in all fields of technology, bar the exclusions listed further in the article.[65] To be patentable, inventions must satisfy the following criteria:

1 Industrial applicability or utility: this requires that the invention have a commercially useful purpose;
2 Novelty: one of the most obvious requirements for a patentable invention is that it must be new or novel; and
3 Inventive step: this requires an analysis of the prior art, what has gone on before in the field including what is generally known and what is written. The question that the inventive step requirement seeks to address is whether the teachings from the prior art make the invention obvious to an ordinary person skilled in the field.

Each of these requirements has been subjected to extensive judicial interpretation in all states with well established patent systems. Article 29 of *TRIPS* further requires the inventor to fully describe the nature of the invention and its scope. For example, depositing a micro-organism in an internationally recognised depository fulfils these requirements. With respect to gene sequences,

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62 Pharmaceutical Research and Manufacturers of America, *PhRMA Pharmaceutical Industry Primer 2001* (2001) 4 <http://www.phrma.org/publications/publications/10.08.2001.528.cfm> at 1 May 2003.

63 See Daniel Kevles and Ari Berkowitz, 'The Gene Patenting Controversy: A Convergence of Law, Economic Interests and Ethics' (2001) 67 *Brooklyn Law Review* 233, 240–1; Dan Burk, 'Patenting Transgenic Human Embryos: A Nonuse Cost Perspective' (1993) 30 *Houston Law Review* 1597, 1599.

64 *Patents Act 1990* (Cth) ss 13, 67.

65 These exclusions are discussed further below at part III(B).

generally the entire sequence must be filed with the patent application. This requirement to disclose the invention to the public is one of the main justifications for the patent system in that it provides a trade-off of temporary exclusivity to the inventor in return for disclosure. It is supposed to provide sufficient information for others to make and use the invention once the patent has expired.

### B *Allowable Exclusions under* TRIPS

#### 1 *Exclusions Based on Ethical Concerns*

Article 27(3)(a) of *TRIPS* allows states to exclude inventions when it is necessary to prevent the commercial exploitation of the invention to protect public order or morality, including protection of human, animal or plant life or health and avoidance of serious prejudice to the environment. Some states, including Australia and the US, do not include this provision in their patent legislation. A number of states in Europe do have an equivalent provision[66] but the way that it has been interpreted by the European Patent Office precludes ethical considerations in all but the most exceptional circumstances. As such, patents claiming animals, plants and gene sequences are not generally excluded on this basis.[67]

Nevertheless, it must be acknowledged that the ethics of patenting naturally occurring materials is highly contentious. In 1995, for example, representatives of over 80 different faiths and denominations in the US declared their opposition to patenting of genetically engineered animals and human genes, cells and organs, on the basis 'that humans and animals are creations of God, not humans, and as such should not be patented as human inventions.'[68] Subsequently, a group of scientists, clergy and activists met in the Blue Mountains in the US and proposed that:

> The humans, animals, microorganisms and plants comprising life on earth are part of the natural world in which we are born. The conversion of these life forms, their molecules or parts into corporate property through patent monopolies is counter to the interests of the peoples of the world.
>
> No individual, institution, or corporation should be able to claim ownership over species or varieties of living organisms. Nor should they be able to hold patents on organs, cells, genes or proteins, whether naturally occurring, genetically altered or otherwise modified.[69]

The opposition to patenting of biological inventions on ethical grounds is growing and becoming more broadly based. A number of international

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66 See, eg, *Patents Act 1977* (UK) s 1(3).

67 See, eg, *Oncomouse T19/90* [1990] Official Journal of the European Patent Office 476 (genetically engineered animals); *Plant Genetic Systems T356/93* [1995] Official Journal of the European Patent Office 545 (genetically engineered plants); and *Relaxin* [1995] Official Journal of the European Patent Office 388 (human genes).

68 Richard Stone, 'Religious Leaders Oppose Patenting Genes and Animals' (1995) 268 *Science* 1126, 1126.

69 This quote is extracted from the *Blue Mountains Declaration*, cited in Philip Bereano, 'Genetic Patents' (1996) 271 *Science* 14, 14.

organisations are turning their attention to this issue (most notably the United Nations Educational, Scientific and Cultural Organisation, the World Intellectual Property Organisation and the World Trade Organisation).[70] Nevertheless, unless there are significant changes to existing patent practices throughout the world, it seems most unlikely that patents claiming products of nature would generally be refused on ethical grounds.

#### 2 *Exclusion of Plants and Animals*

Article 27(3)(b) of *TRIPS* allows for the exclusion from patenting of plants and animals and biological processes for their generation. However, micro-organisms and microbiological processes for the generation of plants and animals cannot be excluded.[71] On this basis, Antarctic micro-organisms cannot be excluded from patenting. Most industrialised states do not expressly exclude plants and animals either, although a number of European states exclude plant and animal varieties.[72]

### C *Patentability of Naturally Occurring Organisms and Substances*

Although micro-organisms cannot be expressly excluded from patenting and most states do not exclude plants and animals, there is an ongoing debate about whether naturally occurring organisms and substances isolated from their natural surroundings are inventions or discoveries.[73] It is important to recall here that art 27(1) of *TRIPS* requires that patents are made available only for inventions.

Patent protection for inventions derived from biological resources has become available only relatively recently.[74] Patenting of living organisms was first allowed in the US in 1980 in the case of *Diamond v Chakrabarty*.[75] In that case, Dr Ananda Chakrabarty filed patent claims for a human-made, genetically engineered bacterium that was capable of breaking down multiple components of crude oil. The invention involved the transfer of four different plasmids capable of degrading four different components of oil into a *Pseudomonas* bacterium. The patent application included a number of claims including one to the bacterium itself. This claim was rejected by the patent examiner on two bases:

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70 UN Educational, Scientific and Cultural Organisation, *International Symposium: Ethics, Intellectual Property and Genomics*, UN Doc SHS/HPE/2001/CONF-804/3 (19 December 2002).

71 *TRIPS*, above n 19, art 27(3)(b).

72 The question of what constitutes a 'variety' has been considered in a number of cases. See, eg, *Oncomouse T19/90* [1990] Official Journal of the European Patent Office 476, *Plant Genetic Systems T356/93* [1995] Official Journal of the European Patent Office 545, *Transgenic Plant/Novartis* T1054/96 [1998] Official Journal of the European Patent Office 511. *Transgenic Plant/Novartis II G1/98–EBA* (Unreported, European Patent Office, 20 December 1999) <http://www.european-patent-office.org/dg3/g_dec/pdf/g980001.pdf> at 1 May 2003. In *Transgenic Plant/Novartis,* the term 'variety' was given a narrow interpretation.

73 Burk, above n 63, 1625–6.

74 See generally Klaus Bosselman, 'Plants and Politics: The International Legal Regime Concerning Biotechnology and Biodiversity (1996) 7 *Colorado Journal of International Environmental Law and Policy* 111; Stephen Bent et al, *Intellectual Property Rights in Biotechnology Worldwide* (1987) ch 3; Friedrich-Karl Beier et al, *Biotechnology and Patent Protection: An International Review* (1985).

75 447 US 303 (1980) ('*Chakrabarty*').

1 That micro-organisms are products of nature; and
2 That as living things they are not patentable subject matter.[76]

A number of appeals were made and the case eventually reached the Supreme Court. The majority judgment was delivered by Burger CJ, with whom four of the other judges on the bench agreed. Burger CJ decided that the task for the Court was a narrow one of statutory construction of the US *Patent Act*, which provides that:

> Whoever invents or discovers *any* new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent thereof, subject to the conditions and requirements of this title.[77]

Burger CJ noted that there are limits on what is patentable. For example, laws of nature, physical phenomena and abstract ideas are not patentable.[78] After considering these factors, his Honour decided that Chakrabarty's micro-organism plainly qualified for a patent on the basis that

> the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork but his own, accordingly it is patentable subject matter under §101.[79]

*Chakrabarty* has been widely accepted as correctly stating the law both in the US and other jurisdictions.[80] It has set the benchmark for the patentability of inventions derived from living resources. Patent protection is now available in many states for a wide range of inventions involving biological resources.[81] In Australia, for example, the list includes bacteria and other prokaryotes, processes involving bacteria and other living organisms, genotypically and phenotypically modified living organisms (excluding humans), synthetically manufactured DNA and gene sequences with a definite industrial use, and products of living matter, provided that the patent application satisfies the normal patent criteria.[82]

As mentioned previously, the requirements for patentability of biological resources are that the resource (whether it is an organism, a gene sequence or some other substance) must have been identified for the first time and it must have a commercially useful purpose. This means that micro-organisms and higher organisms are likely to be patentable if they have undergone some modification from their natural state and if they fulfil all of the patenting criteria.[83] In the case of gene sequences and proteins, and in some instances,

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76 Ibid 306.
77 35 USC §101 (1952) (emphasis added).
78 *Chakrabarty*, 447 US 303, 309 (1980).
79 Ibid 310.
80 See generally Jeffrey Ihnen, 'Patenting Biotech: A Practical Approach' (1985) 11 *Rutgers Computer and Technology Law Journal* 407.
81 See, eg, *Patents Act 1977* (UK), sch 2A, s 76A; *Patents Act 1990* (Cth) s 18.
82 Intellectual Property Australia, *Australian Patents For: Microorganisms; Cell Lines; Hybridomas; Related Biological Materials and Their Use; and Genetically Manipulated Organisms* (1998) 1–2.
83 *Chakrabarty*, 447 US 303, 309 (1980).

even micro-organisms themselves,[84] the mere isolation and characterisation may be enough for them to be patentable. However, for gene sequences, the requirement that a commercially useful purpose is identified generally means that the function of the gene must be disclosed and consequently, in general, raw gene sequences are not patentable.[85]

It is important to acknowledge that although these matters appear settled legally, they remain the subject of extensive debate in the policy arena both at the national and international levels.[86] These debates may, eventually, lead to law reform, as a result of which some biological resources may be more broadly excluded from patenting.

### D *Patent Rights and the Experimental Use Exemption*

As previously stated, a patent provides its owner with the exclusive right to exploit the invention claimed in the patent for a limited period.[87] The owner can also permit or licence others to use the invention, usually on payment of upfront licence fees or royalties or a combination of both.[88] Patents are granted on a national basis. As such, an Australian patent can only be enforced in Australia. For this reason, most applicants file for patents in all states in which there is likely to be a market for their invention. If a person uses a patented invention in a particular state without the permission of the patent owner, the owner can institute infringement proceedings in that state and, if successful, recover damages or enforce other remedies.

Importantly in the context of this article, the freedom to carry out research is recognised in patent law in some states.[89] This means that even if a micro-organism or a gene sequence is the subject of a patent, other scientists can carry out research using the micro-organism or the gene sequence provided that the research is of a non-commercial nature. This protection from infringement — known as the 'experimental use exemption' — varies between states. The difficulty that this creates for individual Antarctic researchers is that they do not have any certainty of protection by way of this exemption.

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84 Isolated micro-organisms may be patentable if significant inventive ingenuity is required to isolate and characterise them. Perhaps the best example is the Hepatitis C virus. See, eg, European Patent Office, *GB2212511: Hepatitis C Virus* (1989) <http://ep.espacenet.com> at 1 May 2003. This UK patent is entitled Hepatitis C virus and includes in its claim ten purified Hepatitis C viruses. See also, John Conley and Roberte Makowski, 'Back to the Future: Rethinking the Product of Nature Doctrine as a Barrier to Biotechnology Patents (Part 1)' (2003) 85 *Journal of the Patent and Trademark Office Society* 301, 318–19.

85 In the US, this limitation is found in the utility requirement: see US and Patent Trademark Office, *Manual of Patent Examining Procedure* (8th ed, 1st rev, 2003) § 2107 <http://www.uspto.gov/web/offices/pac/mpep/index.html> at 1 May 2003. In Europe, it is found in European Parliament and Council, *Directive 98/44/EC of the European Parliament and of the Council and on the Legal Protection of Biotechnological Inventions* [1998] OJ L 213/13. In Australia, see Intellectual Property Australia, above n 82, 2.

86 The Australian Law Reform Commission is currently undertaking an inquiry into gene patenting: Australian Law Reform Commission, *Gene Patenting* <http://www.alrc.gov.au/inquiries/current/patenting/index.htm> at 1 May 2003.

87 See, eg, *TRIPS*, above n 19, art 33, where the prescribed time period is stated as 20 years.

88 Ibid art 28(2).

89 John Golden, 'Biotechnology, Technology Policy, and Patentability: Natural Products and Inventions in the American System' (2001) 50 *Emory Law Journal* 101.

For example, in Europe, the *European Patent Convention* expressly states that there is exemption from patent infringement for experimental purposes.[90] In the US, the patent legislation does not expressly refer to such exemption.[91] However, a case law defence of experimental exemption from liability has been developed against patent infringement.[92] From the outset, the US exemption has been narrowly interpreted by the courts.[93] Although there was some indication in subsequent cases of a willingness to extend its ambit,[94] the US Court of Appeals for the Federal Circuit recently confirmed that the defence is very narrow and strictly limited.[95] The Court followed a line of precedent limiting the defence to actions performed for 'amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.'[96] This does not include use that is in any way commercial in nature or conduct that is 'in keeping with the alleged infringer's legitimate business, regardless of commercial implications.'[97] Consequently, a public research institution could not rely on the defence when a researcher uses a patented invention in a research project because it furthers that institution's legitimate business objectives.[98] In Australia, there is no statutory experimental use exemption and there has been no judicial consideration of whether or not a common law exemption exists.

Presently there is little indication that patent holders are generally enforcing their patent rights against researchers of public institutions.[99] If they were to systematically do so, much of the research conducted in the public research arena (including Antarctic research) could at the very least become more expensive through the payment of licence fees and also more time consuming through licence applications. At the worst, some research may actually be prevented if licensing were refused by the patentee. For these reasons, a more explicit research exemption in patent legislation is justified in order to ensure that research having no commercial implications is not impeded.

### E *Patentability of Antarctic Biological Resources*

On current interpretations of patent law in most states, genetically modified Antarctic micro-organisms and higher organisms are likely to be patentable provided that they fulfil the essential patenting criteria,[100] and in some cases,

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90 *European Patent Convention*, opened for signature 5 October 1973, 1065 UNTS 199, art 53 (entered into force 7 October 1977) art 64(2). See also *Patents Act 1977* (UK) c 37, s 60(5)(b).

91 *Patents Act*, 35 USC §§ 272, 282 (1952).

92 *Whittemore v Cutter*, 29 F Cas 1120 (CCD Mass, 1813) (No 17 600).

93 For example in *Roche Products Inc v Bolar Pharmaceutical Co*, 733 F 2d 858, 863 (ED NY, 1984), the court characterised the exemption as being 'truly narrow'.

94 Rebecca Eisenberg 'Patents and the Progress of Science: Exclusive Rights and Experimental Use' (1989) 56 *University of Chicago Law Review* 1017, 1018–19.

95 *Madey v Duke University*, 307 F 3d 1351, 1360–1 (Fed Cir, 2002) ('*Madey*').

96 Ibid 1362.

97 Ibid.

98 Ibid.

99 See John Walsh, Ashish Arora and Wesley Cohen, 'Working Through the Patent Problem' (2003) 299 *Science* 1021.

100 In Canada, following *Oncomouse*, even if higher organisms are genetically modified they will not be patentable.

isolated and characterised Antarctic micro-organisms may be patentable even if they have not been modified from their natural state. Gene sequences from Antarctic organisms may be patentable if they have a known function and fulfil the usual requirements. Downstream products and processes derived from Antarctic biological resources will generally be patentable if they fulfil these requirements. Opposition to the patenting of inventions originating from Antarctic biological resources based solely on ethical grounds is unlikely to succeed. The extent to which Antarctic researchers in public institutions could rely on the experimental use exemption is uncertain, particularly in Australia and the US.

## IV THE INTERNATIONAL LEGAL REGIME FOR SHARING OF COMMON RESOURCES AND EQUITABLE DISTRIBUTION OF BENEFITS

What are the consequences of ownership rights, in the form of patents, being asserted over biological resources derived from global commons areas? The questions are first, whether the assertion of such rights precludes equitable sharing of benefits stemming from utilisation of these common resources and secondly, whether this is appropriate or not.

International organisations, non-governmental organisations, academics and the media have all focused considerable attention on bioprospecting for resources found in a number of developing and least-developed states because of the combination of rich genetic diversity and broadly based traditional knowledge in agricultural and pharmaceutical practices in those countries.[101] Many people believe that this is a form of biopiracy[102] and not legitimate bioprospecting.[103] In particular, they object to the assertion of patent rights over inventions derived from biological resources that have been used as traditional medicines for centuries.[104] Inventions derived from biological resources in global commons areas have not, as yet, come under the spotlight.

### A *The Role of the* CBD

Concerns about biopiracy have been alleviated to a certain extent by the *CBD*. The *CBD* establishes the principal international legal regime for regulating access to biological resources. It was opened for signature at the Rio Conference on Environment and Development in 1992. The *CBD* imposes limitations on access to biological resources by requiring, inter alia, consent and fair and equitable sharing of benefits. The *CBD* incorporates in its objectives the conservation of biological diversity and equitable sharing of the benefits from use of genetic resources, including access to and transfer of technology.[105] The

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101 Charles McManis, 'Re-Engineering Patent Law: The Challenge of New Technologies' (2000) 2 *Washington University Journal of Law and Policy* 1, 7.

102 Biopiracy is a term used to denote the exploitation of genetic resources endemic to particular states without the permission of the host government or the local community.

103 See McManis, above n 101, 7; David Downes, 'How Intellectual Property Could Be a Tool to Protect Traditional Knowledge' (2000) 25 *Columbia Journal of Environmental Law* 258; Emily Marden, 'The Neem Tree Patent: International Conflict over the Commodification of Life' (1999) 22 *Boston College International and Comparative Law Review* 279.

104 Downes, above n 103, 277.

105 *CBD*, above n 13, art 1.

ongoing relevance of these objectives was affirmed at the 2002 World Summit on Sustainable Development in Johannesburg, South Africa.[106] Questions of access to genetic resources and benefit sharing are seen by the parties to the *CBD* as being critical aspects of the *Convention.*[107]

The provisions relating to access to genetic resources are included in arts 15, 16 and 19 of the *CBD*. The focus is primarily on protecting the sovereign rights of states over their genetic resources. In particular, art 15 of the *CBD* declares that it is for the state that is the provider of genetic material to determine access to that material, but that restrictions on access should not run counter to the *CBD*. This article also requires that financial mechanisms should be established with the aim of providing for fair and equitable sharing of research and development and the benefits of commercialisation. Article 16 of the *CBD* requires the transfer of technology to developing states on fair and favourable terms. It further provides that intellectual property rights should be supportive of and not run counter to the objectives of the *CBD*. Article 19 of the *CBD* encourages the participation of provider states of genetic materials in their subsequent development.[108] In summary, the *CBD* requires that the provider state be consulted with respect to acquisition of genetic material and shares in the profits of patenting.

The Conference of the Parties to the *CBD* recommended at its meeting in October 2001 that guidelines should be prepared to assist parties in developing access and benefit sharing strategies. The *Bonn Guidelines on Access to Genetic Resources and Benefit-Sharing* were drafted by the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing and adopted at the 6th Conference of the Parties to the *CBD* in April 2002.[109] The *Bonn Guidelines* include the objectives of contributing to the conservation and sustainable use of biological diversity and developing transparent frameworks to facilitate access to genetic resources and equitable sharing of benefits.[110] Paragraph 13 of the *Bonn Guidelines* calls for each party to designate a national focal point for access and benefit-sharing and to make such information available through a clearing-house mechanism. The focus is on informed consent and also on access and benefit-sharing arrangements.

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106 United Nations World Summit on Sustainable Development, *Report of the World Summit on Sustainable Development*, [44], UN Doc A/CONF.199/20* (26 August – 4 September 2002).

107 Conference of the Parties to the *Convention on Biodiversity*, *Report of the Inter-Sessional Meeting on the Operations of the* Convention, [6], UN Doc UNEP/CBD/COP/5/4 (15–26 May 2000).

108 These articles are discussed in more detail in Michele Powers, 'The United Nations *Framework Convention on Biological Diversity*: Will Biodiversity Preservation Be Enhanced through Its Provisions concerning Biotechnology Intellectual Property Rights?' (1994) 12 *Wisconsin International Law Journal* 103.

109 Conference of the Parties to the *CBD*, *Decision VI/24: Access and Benefit-Sharing as Related to Genetic Resources*, annex 1 ('*Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of Their Utilization*') <http://www.biodiv.org/decisions/default.asp?m=cop-06&d=24> at 1 May 2003 ('*Bonn Guidelines*').

110 Ibid [11(a)–(b)].

### B *Applicability of the* CBD *and the* Bonn Guidelines *in the Antarctic*

Because the focus of the *CBD* and the *Bonn Guidelines* is on state-owned resources, biodiversity issues in global commons areas such as the Antarctic and the high seas are not dealt with. Article 4 of the *CBD* assigns jurisdiction to parties over their national biological diversity and over processes and activities carried out by their citizens beyond the limits of their national jurisdiction. While citizens carrying out bioprospecting activities in the high seas, for example, could be subject to state regulation, this would represent only an ad hoc and possibly inconsistent approach to global commons biodiversity issues, unless such state regulation was based on a global regulatory framework.[111]

Our concern is that open access areas like the Antarctic and the high seas may be vulnerable to exploitation because of increased levels of interest in freely available biological resources. For example, it could be argued that *Antarctic Treaty* parties may be entering into contracts to provide biological resources when they are not, in fact, entitled to do so — an action discouraged in para 16(c)(i) of the *Bonn Guidelines.* Our concerns are shared by other commentators, and international organisations responsible for these areas are similarly turning their attention to bioprospecting.[112] The Committee for Environmental Protection ('CEP') established under the *Madrid Protocol* has stated that '[t]he complexities and rapid developments in this field were strong reasons for the Antarctic community to be preemptive on this issue.'[113]

Recognising that it was not in a position to 'address all the problems', the CEP recommended that *Antarctic Treaty* parties further consider the issue of bioprospecting at their next meeting in 2003.[114] With regard to the high seas, the *Report of the Secretary-General* on Oceans and Law of the Sea flags deep-sea biodiversity and genetic resources of the deep-sea bed beyond national jurisdiction and of the high seas as raising important questions.[115] Relevant considerations include the duties of conservation and sustainable use of marine biodiversity. The *Report* goes on to state that there has been a surge in interest and research effort in genetic resources and marine biodiversity.[116]

The *Bonn Guidelines* strive to promote strategies of regional level (as well as state level) access and benefit sharing for the conservation and sustainable use of biological diversity,[117] based primarily on the process of prior 'informed consent'.[118] This notion cannot be directly applied to states with unproven ownership over resources. However, many of the guidelines may be able to be

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111 *CBD* Subsidiary Body on Scientific, Technical and Technological Advice, *Marine and Coastal Biodiversity: Review, Further Elaboration and Refinement of the Programme of Work*, UN Doc UNEP/CBD/SBSTTA/8/INF/3/Rev.1 (22 February 2003).

112 *Bonn Guidelines*, above n 109, [16(b)(i)].

113 *CEP V*, above n 16, [61].

114 Ibid.

115 *Ocean and the Law of the Sea: Report of the Secretary-General*, 55th Sess, Agenda Item 34, [136], UN Doc A/55/61 (20 March 2000). For a comparative study on the *LOSC* and the *CBD* in this regard see *CBD* Subsidiary Body on Scientific, Technical and Technological Advice, *Marine and Coastal Biodiversity 2003*, above n 111.

116 Ibid [226].

117 *Bonn Guidelines*, above n109, [16(b)(i)].

118 Ibid [16(b)(i)].

translated into a guiding framework for regulation of common property resources. It is timely, therefore, to propose answers to the three questions raised in the introduction.

## V DOES THE COMMERCIALISATION OF PUBLICLY FUNDED SCIENCE HAVE THE POTENTIAL TO PLACE INAPPROPRIATE LIMITS ON FREEDOM OF SCIENTIFIC INVESTIGATION FUNDAMENTAL IN BOTH ANTARCTIC AND HIGH SEAS LAW?

Three features emerge from the above accounts of Antarctic bioprospecting and international patent law. First, there is likely to be commercial involvement in bioprospecting in the Antarctic. Secondly, patents are the usual means whereby commercial organisations recoup their investment in research. Thirdly, Antarctic biological resources can be patented. It is necessary to consider whether these factors together have the potential to place inappropriate limits on freedom of scientific investigation fundamental in both Antarctic and high seas law. As a starting point, the general trend towards commercialisation of scientific research will be examined.

The interplay between public science and private commercialisation is a matter of ongoing debate in many areas of biological research, and the influence of commercialisation on scientific research cannot be ignored. The pharmaceutical and agricultural industries have always been commercial ventures, and each sector has conducted its own applied technological research. As a result of new developments in biotechnology, both pharmaceutical and agricultural companies, together with core biotechnology companies, are becoming interested in the earlier basic research phase, perhaps because of the perceived need to stake their claims to particular DNA sequences at the outset. The other change that is occurring in public research institutions is that many of the scientists who are involved in basic research, and for whom academic kudos has in the past been sufficient reward, are now required to consider the best ways to transfer their technology to industry. Consequently, technology-driven science is favoured by funding agencies, institutions and scientists themselves. For example, the Australian *National Principles of Intellectual Property Management for Publicly Funded Research* state that '[r]esearch institutions, and where appropriate, individual researchers, *are expected* to consider the most appropriate way of exploiting the IP generated from publicly funded research'.[119]

### A *Commercialisation and the Norms of Science*

The growing imperative to commercialise and patent the products of scientific research is radically altering the culture of research, based as it is on what have been referred to as the norms and rewards of science, namely, universalism,

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[119] Working party comprising the Australian Research Council; the Australian Tertiary Institutions Commercial Companies Association; the Australian Vice-Chancellors' Committee; the Department of Education, Training and Youth Affairs; the Department of Industry, Science and Resources; IP Australia; and the National Health and Medical Research Council, *National Principles of Intellectual Property Management for Publicly Funded Research* (2001) 6 <http://www.arc.gov.au/pdf/01_01.pdf> at 1 May 2003 (emphasis added).

communism, disinterestedness and organised scepticism.[120] The tradition of rapid publication of results in widely circulated journals is not only the primary reward for academic scientists, but is also the dominant measure of academic excellence. However, there may now be valid commercial reasons, including the possibility of patenting, why the early disclosure of results is not always forthcoming. At the same time, it must be acknowledged that commercialisation per se need not ultimately cause a decrease in publication rate. On the contrary, evidence shows that researchers from government institutes in the US that have formal partnerships with industry tend to have higher publication rates than those from non-industry aligned institutes.[121]

One of the requirements of patenting is that data is kept secret until the patent is filed.[122] Once the patent has been filed, research data can be published, provided that it does not compromise future intellectual property rights. Patent law itself also requires disclosure of the nature of the invention.[123] However, where patents are involved there may be a longer time lag between research and publication than would otherwise be the case. Furthermore, scientists may be required to enter into confidentiality agreements and obtain approval from commercial sponsors before publishing their research results. The norms and rewards of science require disclosure of information to allow for its subsequent use by others. Confidentiality is premised on the fact that there is no disclosure. For this reason the use of confidentiality as a means of retaining control over information could create a 'destructive, anti-intellectual climate',[124] particularly if the duration of the obligation of confidence is lengthy.

### B *Commercialisation of Antarctic Bioprospecting*

The above patent analysis has shown that patents can be claimed over biological resources themselves as well as the downstream products of research using those resources. The extent to which researchers in the public sector are protected from infringement proceedings for use of patented products and processes is unclear. The situation may become more problematic when confidentiality obligations require that preliminary research results are kept secret. This new closed research culture based on economic imperatives poses problems that are fundamentally different from those normally associated with research conducted in the public sector.[125]

Antarctic scientists have, to some extent in the past, been relieved of the need to justify their research on economic grounds because the policy of various governments was to use scientific research as a means of maintaining a presence

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120 Robert Merton, *The Sociology of Science: Theoretical and Empirical Investigations* (1973) 267. See also Peter Drahos, 'Intellectual Property Law and Basic Science: Extinguishing Prometheus?' (1992) 10 *Science, Law and Society: A Special Issue of Law in Context* 56.

121 Office of Technology Assessment, US Congress, *Federal Technology Transfer and the Human Genome Project, OTA–BP–HER–162* (1995) 35.

122 *TRIPS*, above n 19, art 39.

123 Ibid art 27(3)(b).

124 George Poste, 'The Case for Genomic Patenting' (1995) 378 *Nature* 534, 535.

125 It has been argued that this results in the tragedy of the anticommons, in that product development will be impeded: see Michael Heller and Rebecca Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698, 700.

in the Antarctic for sovereignty purposes. The situation is now somewhat different. In Australia, for example, one of the four government goals for the Australian Antarctic Program is to 'undertake scientific work of practical, economic and national significance'.[126] Bioprospecting is clearly a commercial venture and patents are likely to play a vital role in encouraging investment in innovative Antarctic bioprospecting research and development by ensuring return for investment. If there is support for this type of activity in the Antarctic, there is strong justification for continuing to allow patents for downstream products. However, patents *may* have a detrimental effect on other scientific research in the Antarctic if they are claimed over pre-commercial or upstream research products, particularly micro-organisms and gene sequences. This detrimental effect is likely to be exacerbated if associated research results are protected by confidentiality agreements.

Even if patents are limited to the downstream products of commercial research and development, there may still be detrimental effects if the products of upstream research are protected by confidentiality agreements. The concern is that while an upstream research product (for example, a particular gene or protein isolated from an Antarctic micro-organism) may have value in a specific line of pharmaceutical investigation, it may have other important applications, both scientific and commercial. Because access is restricted, the full potential of the upstream product may not be realised. Restrictions of this kind may be contrary to both the general spirit and, more specifically, arts II and III of the *Antarctic Treaty*.

### C *The Role of Articles II and III of the* Antarctic Treaty

The *Antarctic Treaty* parties have a longstanding philosophy regarding the free exchange of scientific observations and results.[127] This is reflected in the *Antarctic Treaty* itself, specifically in the wording of arts II and III:

> Article II
>
> Freedom of scientific investigation in Antarctica and cooperation toward that end, as applied during the International Geophysical Year, shall continue, subject to the provisions of the present *Treaty*.
>
> Article III
>
> 1. In order to promote international cooperation in scientific investigation in Antarctica, as provided for in Article II of the present *Treaty*, the

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126 Antarctic Science Advisory Committee, Report to the Parliamentary Secretary for the Antarctic, *Australia's Antarctic Program beyond 2000: A Framework for the Future* (October 1997) recommendation 1 <http://www-new.aad.gov.au/default.asp?casid=3354> at 1 May 2003.

127 The World Ocean Circulation Experiment ('WOCE') is a contemporary example of this philosophy that originated in the 1957–58 International Geophysical Year — the oft-quoted premise upon which the *Antarctic Treaty* was built. WOCE, which incorporated the Southern Ocean as one of three core projects, utilised scientific researchers from 30 countries to collect global oceanographic data for the World Climate Research Program. Collective data gathering, data sharing, analysis and storage are strong features of its success and shows WOCE to be an exemplar of international cooperation as envisaged by the *Antarctic Treaty*. For further details about the WOCE, see the WOCE Global Data Resource <http://www.wocediu.org> at 1 May 2003.

> 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*.[128]

It is possible that the scientific commons that underlies the *Antarctic Treaty* (at least in so far as the *Antarctic Treaty* parties are concerned) could be undermined if access to scientific observations and results from the Antarctic is restricted through patent and confidentiality requirements. The terminology 'to the greatest extent feasible and practicable' allows the *Antarctic Treaty* parties some discretion in the way in which they 'exchange and make freely available' scientific observations and results from the Antarctic. Is bioprospecting, as described here, 'Antarctic science'? If so, to what extent does commercially driven bioprospecting contravene the spirit and intent of the *Antarctic Treaty*, particularly when restrictions are placed on access to Antarctic observations and results?

In order to determine whether or not commercial Antarctic bioprospecting could offend against the express provision in art III(1)(c) of the *Antarctic Treaty*, it is necessary to examine whether:

1 Antarctic bioprospecting falls within the concept of 'scientific observations and results';
2 Bioprospecting activity, most of which is carried out in the laboratory, is 'from Antarctica';
3 Delays in the release of results and observations until patents are filed and/or confidentiality obligations come to an end offend the requirement that observations and results are freely available, or are protected by the provision 'to the greatest extent feasible and practicable'.

### 1 *Scientific Observations and Results*

Does bioprospecting fit within the category of activities that could be considered to be 'scientific observations and results' — or should it more properly be considered as data collection for the purposes of resource exploration and exploitation? As noted above, art II of the *Antarctic Treaty* articulates as a priority the fundamental freedom of scientific investigation, but fails to explicitly define what is meant by this phrase. A clue to the intention of the original *Antarctic Treaty* parties is contained in the text of art II, which states that scientific investigation and cooperation should be strived for 'as applied during the International Geophysical Year' (of 1957–58). Eminent Antarctic scientist William Budd has noted that International Geophysical Year investigations included meteorology, geomagnetism, aurora and airglow, ionospherics, solar activity and other physical sciences, as well as

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128 *Antarctic Treaty,* above n 7, arts II–III (emphasis added).

oceanography.[129] Budd refers specifically to biology and geology as scientific disciplines that have expanded since the International Geophysical Year.[130] Significantly, both have the capacity for commercial application and William Bush has cautioned that the Antarctic could become attractive to large corporations, over which states have only limited control, as a consequence of this capacity.[131] He therefore forecasts the possibility of an awkward connection between early Antarctic investigations such as those mentioned above, which were traditionally 'non-controversial', and the more contemporary trend of conducting research of 'economic relevance'.[132]

Scientific activity in the Antarctic has undergone a series of transitions from the early days of exploration, discovery and description. Five broad categories of scientific activity can be defined:

1 Inquisitive or knowledge-driven Antarctic science, involving much the same sort of analysis as in the early days of scientific endeavour. This scientific activity is driven by the quest for knowledge for knowledge's sake. The goal is to understand more about the Antarctic, its history, its living and non-living resources and the way in which they interact. Examples include many of the terrestrial Antarctic programs involving living and non-living resources. Technology both underpins and imposes limits on the activities undertaken under this banner.

2 Exploitation-driven Antarctic science, involving scientific activities which provide data to assist in developing downstream technologies. Examples include surveying for new fish stocks and geological surveys.

3 Management-driven science, focusing on setting appropriate limits on the development of commercial opportunities. This aspect of Antarctic science centres on management of Antarctic resources and the environment. It includes research to provide data for fisheries stock assessment, ecosystem management and environmental impact assessment. The emphasis is on the common-good objective of setting appropriate limits on exploitation.

4 Global science, conducted in the Antarctic as well as other locations. Examples include weather forecasting, climate change and ocean circulation. In this situation, the Antarctic is the 'location' rather than the object of the research.

5 Technological research, which is an essential component in the development of commercial opportunities, as distinct from exploitation-driven science, which is a precursor to that development. There is some doubt as to whether technological research is 'science' as such. Research of this nature may well fall outside the concept of scientific investigation

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129 William Budd, 'The Scientific Imperative for Antarctic Research' in Julia Jabour-Green and Marcus Haward (eds), *The Antarctic: Past, Present and Future* (2002) 41 <http://www.vias.studies.aq/publications/40th/Budd.pdf> at 1 May 2003.

130 Ibid.

131 William Bush, 'The Next 40 Years: the Challenge of Economic Globalisation and 21st Century Security Threats' in Julia Jabour-Green and Marcus Haward (eds), *The Antarctic: Past, Present and Future* (2002) 125 <http://www.vias.studies.aq/publications/40th/Bush.pdf> at 1 May 2003.

132 Ibid 137–8.

> in art II of the *Antarctic Treaty*. Science is a systematic activity that adds to the body of knowledge, whereas technological research seeks to provide solutions to an immediate problem so that exploitation can proceed. Much of the early work on Antarctic krill falls into this latter category. The difficulties in processing huge catches for distant markets required extensive technological research, which is demonstrated by the large number of patents filed in the late 1970s and 1980s claiming methods for shelling krill and extracting meat from krill.[133]

It is difficult to put bioprospecting into any single one of these categories. Certainly it does not fall within the traditional notion of hypothesis-driven science. Nevertheless, it could conceivably fall within a number of the categories of science outlined above. Bioprospecting can be seen as inquisitive science because the research undertaken in phase 2 adds to the stock of knowledge about the Antarctic and the species that make up the living Antarctic world. There is also no doubt that bioprospecting is exploitation-driven, because the primary purpose of the bioprospecting effort in the Antarctic is for use in downstream drug and related technologies. At the same time, bioprospecting could be seen as pure technology research, because it seeks to provide a solution to the immediate problem of drug discovery.

This difficulty has been highlighted with respect to the distinction between marine scientific research and commercially oriented investigations of marine biological resources in the deep-sea bed.[134] Article 87(1)(f) of *LOSC* enshrines marine scientific research as a fundamental freedom. It further elaborates the rules in part 13, with art 257 specifically referring to uninhibited research in 'the water column beyond the exclusive economic zone', that is, the high seas. As with scientific investigation under the *Antarctic Treaty*, *LOSC* does not explicitly define 'marine scientific research' and therefore offers no legal demarcation between scientific and technological research in the context of bioprospecting.

Alfred Soons proposes a narrow definition of marine scientific research. He says it 'can be defined as any scientific investigation having as object the marine environment (water column and atmosphere above it, seabed and subsoil).'[135] He specifically excludes 'resource exploration (including prospecting for mineral resources) and fisheries, research involving fishing' and 'hydrographic surveys'.[136] These exclusions seem to be based on what we have called 'exploitation-driven science'. Following from these exclusions, bioprospecting could be placed in the same category as prospecting for mineral resources. However, these activities that Soons excludes would produce data with multiple applications. For example, fisheries science could not only lead to identification of commercial stocks but also add to the body of scientific knowledge about the

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133 See US Patent and Trademark Office, Patent Database, above n 45. These include, amongst many others, patent numbers 4133077, 4158249, 4251902, 4307492, 4387485. See also Stephen Nicol and Jacqueline Foster, 'Recent Trends in the Fishery for Antarctic Krill' (2003) 16 *Aquatic Living Resources* 42.

134 See Glowka, above n 15, 352–69.

135 Alfred Soons, 'Regulation of Marine Scientific Research by the European Community and Its Member States' (1992) 23 *Ocean Development and International Law* 259, 260.

136 Ibid.

species. How relevant Soons' definition and his exclusions are in the context of bioprospecting, is yet to be determined.

A broad approach to interpretation of art III(1)(c) would suggest that phases 1 and 2 of bioprospecting, as outlined above, are scientific investigation, but this is more unlikely for phases 3 and 4. On Soons' interpretation, none of the phases would be included (at least for marine bioprospecting). The question of whether or not bioprospecting is scientific investigation is important, because if it is, then there is an obligation on *Antarctic Treaty* parties to make observations and results freely available. However, this is not an easy question to answer. Based on the broad interpretation, art III(1)(c) would impose reporting obligations on researchers from *Antarctic Treaty* parties for phases 1 and 2 of bioprospecting, but not for phases 3 and 4. Researchers from non-*Antarctic Treaty* parties would not have these obligations. On Soons' interpretation, there would be no reporting obligations for marine bioprospecting in the Southern Ocean.

### 2 *From Antarctica*

Even if bioprospecting, or at least phase 2 of bioprospecting, is considered to be scientific investigation, in order for it to come within the ambit of art III(1)(c) of the *Antarctic Treaty*, it must also be categorised as 'scientific observations and results from Antarctica.' Micro-organisms and other Antarctic samples that are isolated and cultured in phase 2, as described above, may have passed through many generations during their transit from the Antarctic to the researcher's home laboratory. The question that must be addressed is whether this means that any of the observations and results from this phase of research are still 'from the Antarctic' or not.

Much of the science conducted under the banner of 'Antarctic science' is not in fact conducted in the Antarctic. Samples, data and other information collected in the Antarctic will generally be taken back to home laboratories for analysis. Samples will be physically transported by ship or air, and satellite or other remote means may send data. Does the fact that the observations and results of these scientific endeavours originate in home laboratories mean that they are not 'from the Antarctic'? We doubt that this is the case. Whilst research conducted on Antarctic penguins that have been bred in captivity in Edinburgh Zoo for a number of generations could hardly be said to be 'from the Antarctic', the same could not be said for samples collected in the Antarctic and transported directly to a researcher's home laboratory.

### 3 *Freely Available, to the Greatest Extent Feasible and Practicable*

Article III(1)(c) of the *Antarctic Treaty* requires that *Treaty* parties exchange and make freely available scientific observations and results from the Antarctic, 'to the greatest extent feasible and practicable'. Commercial bioprospecting agreements will generally require confidentiality and non-disclosure obligations to protect downstream intellectual property and to ensure that the commercial partner retains their head start in assessing the commercial potential of the specimens supplied to it. However, generally once any relevant patent applications have been filed and the bioprospecting contract has come to an end, the research partner will be free to publish research results and share materials

with other researchers. The question that must be asked here is whether the delay in exchange of observations and results for the contract period is objectionable or whether the caveat mentioned above legitimises such delay.

Article III(1)(c) imposes no time limits on the requirement that observations and results are exchanged. During the *CRAMRA* negotiations in the 1980s, one commentator made the following observation about geological information collected by *Antarctic Treaty* parties:

> Although the laboratory processing of much of this data may require a considerable length of time, and some measurements may perhaps never be made public, their overall value is available for purposes of scientific research and dialogue.[137]

On the contrary, private fishing interests are not expected to report data such as precise location of target fish stocks that is considered to be commercial-in-confidence despite the reporting requirements under the *CCAMLR*. Similarly, the *CRAMRA* would have had confidentiality provisions in its reporting requirements for minerals prospecting.[138]

There may be circumstances when scientific observations and results are of such fundamental importance that delay in their release would be contrary to the spirit of arts II and III.[139] The question is whether this situation is likely to arise in relation to the sample collection phase of bioprospecting, any more so than it would for other, non-commercial science. At present, it is apparent that a major source of interest in bioprospecting is coming from pharmaceutical companies in their quest to discover new pharmaceutical products.[140] Delay in release of observations and results may be justified on the basis that it enables a company investing in bioprospecting in the Antarctic to protect its investment from competing companies. However, this should not be at the cost of free access to microbial cultures, sequence information and the like for the purpose of legitimate scientific research.[141] If free access were denied, this would most likely be considered a breach of the spirit, if not the letter, of art III(1)(c) of the *Antarctic Treaty*.

### 4 *Conclusions on the Interpretation of Article III(1)(c)*

This analysis has shown that it is difficult to unequivocally characterise bioprospecting as science or technology and as Antarctic or non-Antarctic science. The precise nature of the disclosure requirements imposed on *Antarctic Treaty* parties by art III(1)(c) is also uncertain. Consequently, it is difficult to reach any final conclusion on the issue of whether bioprospecting contracts imposing limitations on the disclosure of research findings are contrary to the

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137 Oscar González-Ferrán, 'Geologic data and its impact on the Discussion on a Regime for Mineral Resources' in Fransisco Orrego Vicuña (ed), *Antarctic Resources Policy: Scientific, Legal and Political Issues* (1983) 159, 161.

138 See, eg, *CRAMRA*, above n 24, arts 16, 37, regarding the availability and confidentiality of data and information.

139 The discovery of the thinning of the ozone layer is perhaps the best example of such a circumstance.

140 Missouri Botanical Garden, *Bioprospecting* (2003) <http://www.mobot.org/MOBOT/research/applied_research/bioprospecting.html> at 1 May 2003.

141 See, eg, Committee on Primary Industries and Regional Services, above n 1, [3.17], [3.23].

obligation in art III(1)(c) to exchange and make freely available scientific observations and results from the Antarctic. Resolution of these issues will require extensive debate and analysis of the core ideologies of science, the underlying philosophy of the *Antarctic Treaty* and the background to the drafting of arts II and III.

Irrespective of whether or not bioprospecting offends against the strict wording of arts II and III of the *Antarctic Treaty*, if claims to intellectual property rights over Antarctic resources offend the way that *Antarctic Treaty* parties view the underlying philosophy of the *Antarctic Treaty*, then they should act now to clarify this issue. The *Antarctic Treaty* parties will need to address the fundamental question of whether it is appropriate to allow commercial use of Antarctic biological resources, particularly where that use has the potential to benefit humanity, and if so, how this might be achieved. Is it anachronistic to expect Antarctic science to continue in a vacuum? Considerable work is still required to clarify the issues and make recommendations on how to treat bioprospecting in the high seas. A conference planned for December 2003, 'Deep Sea 2003', has an opportunity to examine some of the issues surrounding this activity and to make recommendations for future action.[142]

### D *Other Laws*

The assistance to be gained from analysing extant international law is limited primarily because although these agreements promote freedom of scientific investigation, such investigation is not limited to investigating resources that are owned by sovereign states. The *CBD*, based as it is on sovereign ownership, and the *Bonn Guidelines*, are silent on the issue of access to genetic resources when no ownership rights exist. As such, they do not provide guidance in areas like the Antarctic or the high seas, except in so far as principles within both can be incorporated into any regulatory framework in the future.

## VI SHOULD THERE BE LIMITATIONS ON OWNERSHIP RIGHTS OVER BIOLOGICAL RESOURCES FROM GLOBAL COMMONS AREAS TO ENSURE THAT BENEFITS ARE SHARED EQUITABLY AMONG HUMANKIND?

Having established that the Antarctic and the high seas are global commons areas, largely insulated from expansive resource use by a variety of legal instruments, is it appropriate to further restrict resource use by imposing limits on ownership rights? As discussed earlier, Antarctic sovereignty is not proven in international law, although it is a fact within the national legislation of claimant states. Antarctic sovereign neutrality is, therefore an imposing hurdle. To illustrate this point, during the *CRAMRA* negotiations, it was suggested that one way forward in appeasing the concerns of outsiders about the *Antarctic Treaty* parties' rights over Antarctic mineral resources was that 'sovereignty will have to find an alias'.[143]

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142 Deep Sea 2003 Conference <http://www.deepsea.govt.nz> at 1 May 2003.

143 Brennan, above n 30, 226.

Furthermore, provisions within *LOSC* mean that no state may claim sovereignty over any part of the high seas[144] or claim any part of the marine environment or its resources by virtue of marine scientific research activities conducted there.[145] Commercial harvesting is another fundamental freedom of the seas[146] that is qualified only to the extent that other treaty obligations and conservation and management strategies are concurrently fulfilled by harvesters. It may be decided that other biological resources from the high seas, such as those targeted by bioprospecting activity, should be treated as open access, common property resources like fish. If this occurs, these resources need limitations on ownership rights just like fish have acquired through the various regional management agreements applicable to some of the world's oceans. Greater protection could therefore be gained by giving marine biological resources, other than commercially harvested species, the same special status granted to the mineral resources of the deep-sea bed — 'the Area' — that is, resources to be the common heritage of humankind.[147]

There is a major difference between bioprospecting for resources in commons areas and in areas of national jurisdiction. Where resources are found in the territory of a particular state they could be said to be owned by that state, and bioprospecting without permission could be seen as theft. For this reason, the requirement of informed consent is a central tenet of the regime created by the *CBD* as elaborated in its *Bonn Guidelines*. Where resources are found in a global commons area, they could be said to be owned by no-one and hence there is no-one to steal them from. The counterargument is that they are owned by everyone and hence they should not be used at all. Alternatively, if they are used, the benefits arising out of that use should be shared equitably and they should still be available for others to use.

Clearly, then, there are layers of legal uncertainty where claims are made over biological resources sourced from areas where there is no legally proven ownership of the resource. In this sense, issues surrounding acquisition of biological resources from the Antarctic and the high seas are analogous. Questions arise as to whether any biological resources from these areas should be:

1 Open for use by anyone to the extent that the resource becomes depleted — the tragedy of the commons;
2 Open for use and ownership by anyone to the extent that access by others is restricted — the new commercial era;
3 Not open for use or ownership — closed commons; or
4 Available to all without depletion but with only limited ownership rights, ensuring on-going access by others and benefit sharing opportunities — the true global commons.

Currently, the situation in both the Antarctic and the high seas could be construed as being tenuously consistent with the first example above. That is, that material is open for use by anyone, who may then gain financial benefit

144 *LOSC*, above n 9, art 89.
145 Ibid art 241.
146 Ibid art 87(1)(e).
147 Ibid pt 11.

from value-adding. The case of high seas fishing illustrates this point. The fundamental freedom to fish embodied in *LOSC* is modified by instruments of international law such as the *CCAMLR*, which set limits on the concept of global commons access — in this case in order to conserve Antarctic marine living resources. However, the *CCAMLR* Commission's jurisdiction over Antarctic waters is simply not universally recognised — these waters are deemed 'high seas' by those conducting illegal, unreported and unregulated ('IUU') fishing.[148] IUU is suspected of reaping harvests in greater quantities than legal or authorised activities, thereby undermining the authority of the Commission. Of significant concern is the fact that vessel origin is often disguised through flags and companies of convenience.[149] When IUU activities occur in the territorial waters of sovereign states (the sub-Antarctic island territories of Australia or France, for example), jurisdiction is exercised and the operators of the vessels, if caught, are prosecuted through national laws. However, where IUU fishing occurs within the *CCAMLR* area of application, the Commission can exercise limited authority over states parties to the *CCAMLR* only. In other words, compliance is voluntary, and non-*CCAMLR* states essentially have unrestricted access. There has been no better illustration of the tragedy of the commons than the state of the world's fisheries resources.

In considering how to move forward over bioprospecting in areas outside national jurisdiction, if the imposition of limitations on ownership rights is considered essential to controlling resource use, then a regime for management is indicated.

## VII SHOULD BIOPROSPECTING IN AREAS OUTSIDE NATIONAL JURISDICTION BE REGULATED AND IF SO, HOW?

Bioprospecting in the Antarctic and the high seas is likely to be a focus of public debate for two main reasons. First, there is a perception in some sectors of society that bioprospecting is inextricably linked to biopiracy, and therefore, bioprospecting in any guise will cause concern.[150] Second, the perception of the Antarctic and the high seas as being global commons protected from harmful, exploitative activities and dedicated to unrestricted scientific research does not marry well with commercial involvement in bioprospecting. Do these concerns have any foundation?

In some respects, bioprospecting for the purposes of product development in the laboratory could be considered to be an ideal industry for the Antarctic and the high seas. In general, the sample collection and laboratory phases are not likely to pose problems relating to over-exploitation and thus, have an impact on biodiversity. Commercial involvement may actually enhance the opportunity for scientific observation if it provides much needed additional funding. Furthermore, in combination, the patent disclosure requirements and

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148 See Commission for the Conservation of Antarctic Marine Living Resources, *Illegal, Unregulated and Unreported (IUU) Fishing* <http://www.ccamlr.org/pu/E/sc/fish-monit/iuu-intro.htm> at 1 May 2003.

149 See Greenpeace Australia Pacific, *Pirates Plunder Our Ocean* <http://www.greenpeaceusa.org/media/publications/ccamlrtext.htm> at 1 May 2003.

150 See, eg, Vandana Shiva, *Stopping Biopiracy* (1999) Z Net <http://www.zmag.org/sustainers/content/1999-09/6shiva.htm> at 1 May 2003.

experimental use exemption (if clarified) potentially allow for exchange of and access to research results.

On the other hand, companies involved in bioprospecting are primarily concerned about profits. Decisions regarding whether or not to pursue particular lines of inquiry will be made on commercial grounds and consequently information that may have great scientific value could be buried for many years as a result of strict confidentiality requirements. Bioprospecting may not always be benign. As we have established, in some circumstances it may be more economically sound to harvest resources and extract pharmaceutically active compounds than to make them synthetically (for example, krill enzymes are notoriously difficult to produce in the laboratory, as previously mentioned). There is also the issue that companies are profiting from publicly funded research, whether it is through the use of public research facilities, the expertise of researchers in public institutions, or the use of facilities at Antarctic bases or on board Antarctic ships. Finally, broad patent claims over upstream research products and confidentiality requirements are perhaps the most contentious aspects of private sector involvement in research involving naturally occurring materials. Should bioprospecting in commons areas be regulated? The authors think that the answer to this is unequivocally yes, although the *Antarctic Treaty* parties, for example, may have a different view.

The *Antarctic Treaty* parties are attempting to regulate fishing, mining and other human activities and are, in effect, endeavouring to establish a true global commons. However, because current bioprospecting activities (sample collections) are environmentally innocuous, they are largely unregulated and this situation ignores the potential for industry expansion or diversion into resource harvesting. Currently, the *Antarctic Treaty* parties need comply with only minimal Environmental Impact Assessment and other regulatory requirements in satisfying their legal obligations with regard to sample collection. As for non-parties, until proven otherwise under customary international law, they owe no allegiance to the *Antarctic Treaty* System and are therefore not regulated (except to the extent that their own national laws impose restrictions on citizens). If one holds the view that the Antarctic is a true global commons, resources should not be appropriated by anyone, but rather, should be available to all with only limited ownership rights, ensuring ongoing access by others and benefit sharing opportunities. This, in our opinion, is the intent of the *Antarctic Treaty*. Intellectual property and confidentiality requirements have the effect of creating de facto ownership rights. If material is to remain available to all, when, how, under what conditions and under whose authority could this occur?

The *Antarctic Treaty* parties have a range of mechanisms at their disposal with which to achieve regulation of bioprospecting. For example, it is possible to amend the *Madrid Protocol* by the addition of annexes. An annex on bioprospecting would require extensive debate leading to consensus on its need, form and function.[151] A more simple solution in the short term would be for the *Antarctic Treaty* parties to agree on the wording of a 'measure' — a legally

[151] However, the *Antarctic Treaty* parties do not have a good track record in this regard. An annex on liability for environmental damage, which began its life in the *CRAMRA* and was transferred to art 16 of the *Madrid Protocol*, has been on the drawing board since 1991 and no resolution is in immediate sight.

binding text with less content but no less obligation than a *Protocol* annex. In the Antarctic marine context it may be much easier to harness an existing regime like the *CCAMLR* to regulate the sample collection phase of bioprospecting than to get international agreement on a new regime. The *CCAMLR*, as it exists now, could regulate the collection of Antarctic marine micro-organisms because its scope is 'the populations of finfish, molluscs, crustaceans and all other species of living organisms, including birds'.[152] Sample collections per se would not contravene any existing *CCAMLR* provisions. Furthermore, if bulk harvesting of micro-organisms from the *CCAMLR* area were carried out by *CCAMLR* members, it would come directly under *CCAMLR* regulation in the same way that Southern Ocean fishing does now. This is convenient, but not without its problems; if the activity were conducted by parties outside the *CCAMLR*, the same issues that the *CCAMLR* faces with regard to IUU fishing would arise.

## VIII RECOMMENDATIONS FOR THE WAY FORWARD

Bioprospecting and downstream product development are not new; for decades, the commercialisation of science has occurred through these processes. However there has been scant debate about these issues in the Antarctic and high seas contexts. Collections of Antarctic micro-organisms are being used for the purpose of bioprospecting, and yet the *Antarctic Treaty* parties have not fully canvassed the issues surrounding the utilisation of these kinds of Antarctic living resources.

Bioprospectors have found the Antarctic to hold potentially rich sources of raw materials for the pharmaceutical and other industries and their value is inestimable. The *Antarctic Treaty* was built on a solid foundation of cooperative science first encountered during the International Geophysical Year, and this spirit has generally been maintained for the 42 years of the *Antarctic Treaty*'s existence. The spirit is not only philosophical; there is a legal obligation as well.

The way that the *Antarctic Treaty* parties deal with emerging challenges is for the most part commendable. In the past they have framed agreements to deal with new issues in a more or less precautionary manner. Although the *CCAS* was reactive management to the exploitation of seals, it envisaged a return to commercial seal harvesting and sought regulation of such an event. The *CRAMRA* was established before any mining was envisaged and failed largely on rights allocation issues. The *CCAMLR* anticipated a krill harvest potentially damaging to the virtually unknown Antarctic marine ecosystem and sought a more holistic approach to resources management. The *Madrid Protocol* envisaged the Antarctic as 'a natural reserve, devoted to peace and science'[153] and has the objective of the 'comprehensive protection of the Antarctic environment and dependent and associated ecosystems'.[154] Bioprospecting has not yet touched a serious nerve among the Antarctic custodians. This article suggests, however, that maybe now is the time for them to consider at the very least a policy position, if not a more overarching regulatory framework, in order to fulfil the obligations they have set for themselves. A dedicated regulatory

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152 *CCAMLR*, above n 23, art 1(2).
153 *Madrid Protocol*, above n 25, art 2.
154 Ibid.

regime will clarify rights and duties; it will also benefit stakeholders by 'instilling confidence in the current and potential investors in such commercially-oriented activities in that it could promote legal certainty and predictability, an important element in any commercial venture.'[155]

The patent process and the generalised terms of agreements between researchers and commercial partners described in this article impose restrictions and confidentiality requirements that limit access by other researchers. There are compelling reasons to conclude that Antarctic inventions, particularly proteins and gene sequences, will generally fulfil all patent requirements and will therefore not be excluded from patenting. Indeed, as this article has illustrated, patents already exist. Confidentiality agreements almost certainly exist as well, as they are a common term of agreement. This means that there may be a conflict brewing between the notion of Antarctica and the Southern Ocean (or high seas) as a global commons and the imperative many researchers face to commercialise aspects of their work. Whilst other researchers may be free to continue their own independent studies, they may not necessarily be able to rely on the 'experimental use exemption' to avoid patent infringement. Moreover, confidentiality requirements may hinder free access to original material, or even equitable and affordable access.

The legal and policy issues are likely to become more troublesome as the bioprospecting industry develops. Consequently, it would be in the best interests of the *Antarctic Treaty* parties to prioritise the development of a policy position on bioprospecting with a view to developing a legal regime in the future. It is acknowledged that such an outcome will only be arrived at by consensus. However, consensus may be difficult to achieve without further research examining in greater detail the issues raised here. There are a number of ways to achieve a satisfactory regulatory outcome:

1 Commercial developers could be required to pay a fee for access to Antarctic material and this fee could be deposited into a common fund administered by the *Antarctic Treaty* Secretariat. Perhaps the successful development of downstream products should attract royalty payments, also deposited into a common fund. In this regard, there are a number of precedents that may provide guidance on how a multinational regime could be set up for ensuring facilitated access to Antarctic resources and benefit sharing. In particular, three components in the appendices to the *Bonn Guidelines* relating to material transfer agreements, monetary and non-monetary benefits and capacity building would seem relevant. The purpose of the fund would be to sponsor ongoing scientific cooperation.

2 All Antarctic samples could be deposited in a common receptacle, to which any researcher, anywhere in the world, could have access for non-commercial research. The clearing house mechanism in paragraph 13 of the *Bonn Guidelines* could provide a framework for this.

3 Individual *Antarctic Treaty* parties could create their own regimes for depositing Antarctic samples and making them available to commercial and non-commercial researchers in accordance with standardised terms.

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155 *CBD* Subsidiary Body on Scientific, Technical and Technological Advice, *Marine and Coastal Biodiversity 2003*, above n 111, [103].

This arrangement would be similar to that envisaged by the *Bonn Guidelines* in its advice on national focal points.

4 Individual institutions could enter into their own negotiations with commercial partners, which is the current position. If this option is chosen, institutions should be educated on the value of the resources that they are bargaining with and the nature of the restrictions that are being imposed on their own research and research undertaken by others.

5 Some mechanism for licensing 'brand Antarctic' should be considered, for example through the certification trade mark process in the Australian *Trade Marks Act 1995* (Cth). There is growing recognition internationally of the intrinsic value of traditional knowledge and the therapeutic use of natural resources by indigenous communities, now formally acknowledged through the *CBD* and the *Bonn Guidelines*. In our view, material originating in the Antarctic should be similarly acknowledged as being unique and beneficial to humankind. Accordingly it should have a value attached to it as a means of securing sustainable development of Antarctic resources into the future.

6 For the *Antarctic Treaty* parties to retain control over access, use and benefit sharing of the resource, there would need to be some requirement in the patent application process to confirm the origin of the biological material and arrangements for access and benefit sharing.

In formulating a policy and legal framework, it is essential to find an appropriate balance between supporting the potential of the emerging industry to develop products for the good of humankind and maintaining the integrity of the global commons. In the case of the Antarctic (and the high seas to the extent of *CCAMLR* jurisdiction), the *Antarctic Treaty* parties have the right, and indeed the obligation, to take these matters into their own hands with due regard to other international obligations. They could, for instance, revisit the *CRAMRA* for insight into specific questions on the definitions of terms such as prospecting, commercialisation, operators, sponsoring states, joint ventures, effective control, reporting and other obligations. Although the *CRAMRA* did not enter into force, and was replaced by the *Madrid Protocol*, it was a consensus document and perhaps it still has relevance.