ENVIRONMENT AUSTRALIA

SUBMISSION

INQUIRY INTO DEVELOPMENT OF HIGH TECHNOLOGY INDUSTRIES IN REGIONAL AUSTRALIA BASED ON BIOPROSPECTING

THE HOUSE OF REPRESENTATIVES STANDING COMMITTEE ON PRIMARY INDUSTRIES AND REGIONAL SERVICES

February 2001

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INTRODUCTION

To date, progress in Australia towards the development of policies and/or legislation on bioprospecting has been very slow. However, in the last two years, there has been renewed activity as a result of Australia's National Biotechnology Strategy, the Voumard Inquiry into Access to Biological Resources in Commonwealth Areas and developments in some States, particularly Queensland, South Australia and Western Australia, which are keen to promote local biotechnology industries.

The importance of policies and/or legislation to regulate access to biological and genetic resources and to capture benefits arising from their use is widely recognised. By now, debate centres on 'what' and 'how' (that is, developing the details of access and benefit-sharing schemes) rather than 'why?'. Accordingly, Environment Australia is developing draft regulations on access and benefit sharing in Commonwealth areas under s 301 of the *Environment Protection and Biodiversity Conservation Act* 1999 (the EPBC Act) and will be seeking public comment on them shortly.

In promoting local and international interest in access to its biological resources, Australia has several advantages:

- mega-diversity in which there is evidence of both local and international interest (Australia is classified as one of about a dozen megadiverse countries in the world, with a high percentage of organisms occurring only in Australia);[1]
- a stable political system;
- efficient administrative systems;
- a well-developed legal system, and
- local biotechnology industries, as well as research organisations such as the Australian Institute of Marine Science (AIMS) and CSIRO which have considerable experience and expertise in bioprospecting and related activities.

However, Australia is not alone in possessing these advantages. Other countries possess high levels of biodiversity and are developing policy/legislative instruments to capture benefits arising from its use. It is currently estimated that over 40 countries (including some states of those countries) are in the process of developing access and benefit sharing schemes.[2]

The terms of reference of the Inquiry into Development of High Technology Industries in Regional Australia based on Bioprospecting are as follows:

The House of Representatives Standing Committee on Primary Industries and Regional Services will inquire into and report on the following areas, with particular emphasis on the opportunities in rural and regional Australia:

- *The contribution towards the development of high technology knowledge industries based on bioprospecting, bioprocessing and related biotechnologies;*

[1] Commonwealth of Australia (1998: 10), *Australia's National Report to the Fourth Conference of the Parties to the Convention on Biological Diversity*
[2] Ten Kate and Laird (1999: 16)

- *Impediments to growth of these new industries;*
- *The capacity to maximise benefit through intellectual property rights and other mechanisms to support development of these industries in Australia; and*
- *The impacts on and benefits to the environment.*

Environment Australia's submission focuses on the second, third and fourth of the Inquiry's terms of reference.

SUMMARY

Term of reference 2

With respect to the second term of reference, impediments to growth of new industries, this submission addresses the policy background to the development of legislation on access and benefit sharing, the scheme for access to biological resources in Commonwealth areas proposed in the Voumard Report (and since then to be expressed in draft regulations under s 301 of the EPBC Act) and the need to develop a nationally consistent approach.

Environment Australia submits that if bioprospecting is to be facilitated in Australia, with the aim of developing high technology knowledge industries based on it, there is an urgent need for a nationally consistent approach to access and benefit sharing at the Commonwealth, State and Territory levels. The need for clear rules regarding access to Australia's biological resources is widely recognised:

The National Biotechnology Strategy states that

> Future development of Australia's interests in biotechnology, particularly in the environmental management, pharmaceutical, forestry, fisheries, aquaculture and agriculture sectors, will be facilitated by clear and transparent terms of access and conditions for the use of Australia's marine and terrestrial biological resource.[3]
>
> Box 1

Similarly, the submission of Agriculture, Fisheries, Forestry – Australia (AFFA) to the Voumard Inquiry stated that

> In establishing clear rules for accessing in situ biological resources in Commonwealth areas … the Commonwealth can add certainty. In doing so Commonwealth intervention can provide incentives to invest in Australian industry sectors based on biological resource use.
>
> Box 2

The Commonwealth-State Working Group on Access to Australia's Biological Resources identified similar 'significant' benefits to industry development from 'the effective and efficient management of access to Australia's indigenous biological resources':

[3] Commonwealth of Australia (2000: 26)

- Socio-economic benefits from the development of (for example) new pharmaceuticals and foodstuffs from native biota, from the licensing of intellectual property rights, and from the development of new value-adding resource based industries
- Scientific benefits including enhancement of knowledge and of Australia's research capacity, and training of scientists[4]

Box 3

Term of reference 3

With respect to the third term of reference, the capacity to maximise benefits to support the development of high technology knowledge industries in Australia, this submission addresses ways in which the proposed access scheme would ensure that the Australian community, including local or locally-based research and industry, benefits from bioprospecting agreements.

Terms of reference 4

The fourth term of reference, the impacts on and benefits to the environment, was a major aspect of the terms of reference of the Voumard Inquiry which made several recommendations in relation to environmental issues. These issues are discussed below under 'Impacts on and benefits to the environment'.

[4] Commonwealth State Working Group (October 1996: 7)

TERM OF REFERENCE 2: IMPEDIMENTS TO GROWTH OF NEW INDUSTRIES BASED ON BIOPROSPECTING

The importance of facilitating – and thereby promoting - bioprospecting has been recognised for many years.

Policy Background

The Convention on Biological Diversity, the Coalition Government's 1998 election policy statement on the environment, *Our Living Heritage*, and Australia's National Biotechnology Strategy are the key policy bases for addressing access to biological and genetic resources in Commonwealth areas in Australia.[5]

The Convention on Biological Diversity

The Convention on Biological Diversity was opened for signature on 5 June 1992 and entered into force on 29 December 1993 after the necessary 30 countries ratified it. Australia signed the Convention on 5 June 1992 and ratified it on 18 June 1993.

The Convention provides the international law framework in which national policies and/or legislation on access and benefit sharing are being developed.

Australia's obligation to facilitate access to, and benefit sharing arising from the use of our genetic resources, is based on the following Articles of the Convention.

Article 1 Objectives

The objectives of this Convention … are … the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.

Article 15 Access to Genetic Resources

2. Each contracting party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties …

3. For the purposes of this Convention, the genetic resources being provided by a Contracting Party .. are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this convention.

4: Access, where granted, shall be on mutually agreed terms …

5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources …

[5] A more detailed account of Australia's international and domestic obligations to facilitate access to, and benefit sharing arising from the use of our genetic resources, as well as developments to date, can be found at Chapter 3 of the Voumard Report (2000). Some international examples of access and benefit sharing schemes are at Appendix 9 of the Report.

7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, … with the aim of sharing in a fair and equitable way the results of the research and development and the benefits arising from the commercial and other utilization of genetic resources of the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

Box 4

The conceptual shift from the common heritage of mankind to the principles of common concern and national sovereignty

Before the negotiation of the Convention, the prevailing view had been that genetic resources constitute the 'common heritage of mankind'. From the late 1970s, this view was subject to increasing debate as plant breeders and biotechnology rights were developed. Early in the negotiations for the Convention, the common heritage conceptualisation of genetic resources was rejected in favour of the notion that 'the conservation of biological diversity is a common concern of mankind' (CBD Preamble paragraph 3). A consequence of the shift from common heritage to common concern was the need to affirm national sovereignty over genetic resources.[6]

The reasons for these shifts were a rejection by developing countries of the notion of unrestrained free access to their resources while faced with increasing restrictions and intellectual property rights from developed countries on the products produced from their resources. The fact that developed countries wanted these resources conserved for environmental and economic reasons provided developing countries with a powerful negotiating tool. The result can be seen in two key articles that link biodiversity protection, biotechnology and intellectual property rights and that adopt the basic element of national sovereignty. Article 3 sets out the basic principle of national sovereignty found in principle 21 of the Stockholm Declaration on the Human Environment as a principle of the Convention, and Article 15 (1) establishes sovereignty as the basis for the authority to determine access to genetic resources.[7]

[6] This is in keeping with the normal conceptualisation in international law of national jurisdiction over all the resources found within a state's territory which is found, for example, in Principle 21 of the 1972 Stockholm Declaration, updated in Principle 2 of the Rio Declaration on Environment and Development.

[7] Mann, 1996, 23-26

Article 3 Principle

States have, in accordance with the charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their own jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

Article 15 Access to Genetic Resources

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

Box 5

Our Living Heritage

Before the 1998 federal election, the Coalition Government made a commitment in its environment policy document, *Our Living Heritage*, "within two years, [to] introduce regulations to regulate access to genetic resources in Commonwealth areas".

S 301 of the *Environment Protection and Biodiversity Conservation Act* 1999 provides the mechanism to implement Australia's international and domestic obligations for the control of access to biological resources in Commonwealth areas.[8]

[8] The Convention on Biological Diversity does not use the term 'bioprospecting', referring instead to 'access to genetic resources'. The Convention defines genetic resources as 'genetic material of actual or potential value' and 'biological resources' as including 'genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity'. This terminology is reflected in the heading of s 301 of the EPBC Act: 'Access to biological resources', and in the definitions of biological and genetic resources and native species in the Act. Issues of coverage and definitions are discussed in more detail in appendix 2.

Section 301 Control of access to biological resources

(1) The regulations may provide for the control of access to biological resources in Commonwealth areas.

(2) Without limiting subsection (1), the regulations may contain provisions about all or any of the following:

  (a) the equitable sharing of the benefits arising from the use of biological resources in Commonwealth areas;

  (b) the facilitation of access to such resources;

  (c) the right to deny access to such resources; and

  (d) the granting of access to such resources and the terms and conditions of such access.

Box 6

Australia's National Biotechnology Strategy

On 3 July 2000 the Minister for Industry, Science and Resources, Senator Nick Minchin, announced the National Biotechnology Strategy at the Australian Biotechnology Association conference in Brisbane. The objective and strategies relating to access to biological and genetic resources are set out in the Strategy as follows:

Objective

The development of measures to enhance access to Australian biological resources

Future development of Australia's interests in biotechnology, particularly in the environmental management, pharmaceutical, forestry, fisheries, aquaculture and agriculture sectors, will be facilitated by clear and transparent terms of access and conditions for the use of Australia's marine and terrestrial biological resources.

Strategies

- Resolve legal issues on the ownership of Australian biological resources.
- Work with sectoral interests to identify their resource needs in biotechnology, including in the utilisation of Australian indigenous and exotic biological resources.
- Work with the States to achieve nationally consistent regimes on access.
- Develop appropriate documentation, management and access protocols.
- Address matters involving indigenous people and their ownership of biological resources.

- Address issues of access to biological resources within commonwealth areas, including through regulations under the *Environment Protection and Biodiversity Conservation Act* 1999.[9]

Box 7

Regulating access to biological/genetic resources

Environment Australia's objectives

The proposed scheme for regulations under s 301 of the EPBC Act is based on the recommendations of the Voumard Report and modifications resulting from EA's consultations with Commonwealth agencies following the release of the Report. The objectives of the proposed scheme are to:

- facilitate and thereby promote access to, and benefit sharing from, biological resources in Commonwealth areas,
- harmonise existing Commonwealth access arrangements; and
- develop an access and benefit-sharing scheme which would serve as a basis for State and Territory schemes, thereby promoting the establishment of a nationally consistent approach.

Criteria for the proposed scheme

To ensure that the scheme meets these objectives, it was developed with the following criteria in mind:

Minimisation of transaction costs

The Voumard Report recommended that fees for access permits be set at a moderate level, consistent with other fees under the EPBC Act regulations. This should not act as a deterrent to bioprospecting, particularly for independent researchers.

The Voumard Report recommended that a model contract be developed. Use of the model contract is not mandatory. This should minimise parties' costs by limiting the time and therefore costs involved in drafting a new contract for each transaction.

Maximisation of certainty

The requirements of the scheme will be set out clearly in the s 301 regulations. Explanatory documentation will also assist parties to understand and use the scheme.

Regulations will provide a legislative basis and therefore clear authority for benefit sharing agreements. (The authority to do this has not been clear in some existing legislation).

The regulations will not alter existing property law in Australia, but legal advice provided to the Inquiry (and included as Chapter 4 of the Voumard report) sets out

[9] Commonwealth of Australia (2000: 26)

and clarifies the common law and legislation regarding ownership of biological resources in Australia. Industry interests, in particular, have expressed concern to ensure that they have legitimate title to any resources which they obtain from the original owners and holders of resources. For this reason, the original owners and holders of resources need to be clear as to their own rights to deal with these resources.

Transparency and accountability

The Voumard Report recommended that, to the extent possible, allowing for concerns about confidentiality, information about access and benefit sharing agreements should be made public.

The Voumard Report recommended that where there are potential environmental impacts from access activities, environmental assessment should be required, permitting public comment on the proposed activity.

The Voumard Report recommended that the administrative processes and the factors which must be taken into account in decision making about permits be set out clearly in the regulations.

Flexibility

The number of permits that an applicant may require will be minimised through arrangements that will allow access in a range of areas for lengthy or even unlimited periods (subject to review).

Avoidance of duplication

Accreditation provisions will be designed to ensure that there is no duplication of requirements on applicants or resource providers.

Simplicity, accessibility and efficiency

Environment Australia will be the administrator of most permits under the scheme, except where accreditation is provided for. However, harmonisation (through accreditation provisions) will ensure consistency at the Commonwealth level and make access arrangements easier to understand and use.

Environment Australia will develop an access page on its website which will allow applicants to apply for permits on line and include links to other permits under the EPBC Act and accredited schemes.

The Inquiry recommended that there be timeframes within which access decisions should be made.

The EPBC Act provides that the Minister may delegate to an officer or employee of the Environment Department the power to make decisions under s 301 of the Act.

Issues affecting traditional owners

The Voumard Report took into account the concerns of Indigenous organisations and communities by recommending that:

- the Minister take certain factors into account (in particular, that there has been prior informed consent), when deciding whether to grant or refuse an access permit; and
- the decision of the owners of biological resources to deny access to their resources is not reviewable.

Industry and research issues

The Voumard Report took into account the major concerns of industry and research interests by including:

- proposals for benefit sharing which would allow the parties to negotiate a wide range of benefits; including terms which allow benefit sharing to be negotiated where research is undertaken for non-commercial purposes
- provisions which would ensure industry's interest in environmentally sensitive access to biological resources; and
- freedom for the parties to negotiate contracts which would meet their own interests and, which through clear and agreed terms, promote certainty.

Environmental issues

The Voumard Report considered possible adverse environmental impacts of bioprospecting, as well as possible benefits to the environment from requirements under the scheme.

The Report took environmental concerns into account by recommending:

- that the Minister be satisfied that the proposed access will, taking into account the precautionary principle, be ecologically sustainable and consistent with the conservation of Australia's biological diversity;
- in appropriate cases, that there be environmental assessment of proposals, and
- that the Minister be able to attach conditions to permits, through which a wide range of environmental objectives can be met, including, for example, the requirement to lodge voucher specimens in Australian public collection institutions and the provision of information about the specimens.

<u>Towards a nationally consistent approach to access and benefit sharing</u>

The importance of a nationally consistent approach to access and benefit sharing has been recognised for several years. The CSWG concluded in October 1996 that

> After careful examination of current mechanisms, the CSWG considers that there

are significant benefits to be gained from a nationally consistent approach, but that these must be weighed up against the cost of changes to regulations in each jurisdiction. A set of broad principles have been developed with the CSWG considers should underpin a nationally consistent approach.[10]

The Voumard Report recommended that the Minister for the Environment and Heritage endorse these principles.[11]

(The need for a nationally consistent approach applies at both the Commonwealth level, for example, with regard to ex situ collections, Norfolk Island, the Australian Antarctic Division, and the Great Barrier Reef Marine Park Authority, and at the State and Territory level).[12]

Harmonisation of arrangements at the Commonwealth level

A major issue which the Voumard Inquiry addressed and on which the Report made several recommendations was that of harmonisation at the Commonwealth level in those cases where there are existing access schemes (and, to the extent to which they exist, provisions for benefit sharing). The relevant areas are the Great Barrier Reef Marine Park, the Australian Antarctic Territory, Norfolk Island, and Australia's marine areas.

Harmonisation of Commonwealth, State and Territory approaches – the current situation

As one of the objectives of the National Biotechnology Strategy is to establish a nationally consistent system of access to genetic resources the Inquiry sought the views of Commonwealth agencies and State and Territory Governments on the issue.

In submissions to the Voumard Inquiry, State and Territory Governments which have considered access issues supported the development of a nationally consistent approach.

Environment Australia understands that several States will be making submissions to the present Inquiry. South Australia provided the following statement regarding the current status of work on access issues.

South Australia

In 2000 South Australia prepared a Discussion Paper on the issue of access to its biological resources. The paper, prepared by a working group drawn from a number of government agencies, was submitted to the South Australian Minister for Environment and Heritage for consideration and released for public comment in September through to November 2000. 13 comments were received. It is anticipated

[10] CSWG, October 1996: 34
[11] Voumard, July 2000: 118, recommendation 55
[12] A case study of problems currently experienced by collecting institutions, provided by the Australian National Botanic Gardens (ANBG), is at Appendix 4. Information provided to the Voumard Inquiry by other collection institutions such as CSIRO suggests that these problems are shared by other similar organisations.

that the submissions will be considered by an interdepartmental committee and a recommendation made to Cabinet on the way to progress the matter further.

Improved Access through the Australian Virtual Herbarium

Australia's Virtual Herbarium (AVH) is a national collaborative project to computerise Australia's botanical collections, and to develop an internet platform to disseminate this and other herbarium-based information outputs to achieve biodiversity conservation aims. This will unlock repositories of information of key importance.

The establishment of a virtual herbarium will assist industry and science by making it easier to know what plants there are in Australia and where they are found. Many are not named or bear different vernacular names and reliable information about their location is not easy to obtain. The ability to access this information online reduces the cost of intial research about plant distribution. Knowing what grows where is a good key to understanding broader issues, such ecosystem distribution.

For example, this information allows researchers and bioprospectors to deduce what sort of plants may be also growing in association with the identified species in particular areas. Such knowledge is important when selecting where to survey. It allows for more informed decisions ie. locating the lowest cost areas to survey with the greatest chance of finding targeted species or genera.

To take a more specific example, if a bioprospector were aware of a bioactive compound found in a species found outside of Australia but was also aware that related species existed in Australia, the researcher could go online to the AVH and identify the Australian variants and their distribution (or at least the exact location from which the original samples had been collected). From that information, a decision could then be made whether it was worthwhile considering conducting a literature search and organising to collect samples for analysis for similar bioactivity.

The information to be available in the AVH includes geographic distribution and other collections-related data, plant names and checklists, flora treatments and related material, identification keys, illustrations, colour photographs and other species-linked information. Availability of this information has other practical benefits including design of revegetation projects, development of threatened species recovery plans and other land restoration activities and research projects.

Information to be used in the AVH is based on the existing and growing resources held by individual herbaria involving data on plant names, plant occurrences and distribution, plant images, plant descriptions and associated bibliographic and other authority files.

The AVH will provide users with transparent, real-time, distributed and shared on-line access to botanical data held in each of the herbaria while respecting custodial responsibility of the herbarium concerned. The data then remains current and can be managed by experts in each herbarium. The AVH will provide a common user-friendly interface, including searching and interrogating facilities, and report-delivery functions.

The Virtual Herbarium is being developed under the auspices of the Council of Heads of Australian Herbaria (CHAH) and involves the State Herbarium of South Australia (AD), Queensland Herbarium (BRI), the Australian National Herbarium in Canberra (CANB), Herbarium of the Northern Territory (DNA), Tasmanian Herbarium (HO), National Herbarium of Victoria (MEL), Western Australian Herbarium (PERTH) and the National Herbarium of New South Wales (NSW). CHAH also includes representatives of the university herbaria and herbaria in New Zealand, allowing for the possibility of extending the AVH concept in future.

TERM OF REFERENCE 3: CAPACITY TO MAXIMISE BENEFIT THROUGH INTELLECTUAL PROPERTY RIGHTS AND OTHER MECHANISMS TO SUPPORT THE DEVELOPMENT OF HIGH TECHNOLOGY KNOWLEDGE INDUSTRIES IN AUSTRALIA

Benefits to Australia from access and benefit sharing arrangements

Following Australia's signature of the Convention on Biological Diversity in 1992, the Australian and New Zealand Environment and Conservation Council (ANZECC) submitted a report to First Ministers in February 1993 on the *Implementation of and Implications of Ratification of the Convention on Biological Diversity*. In addressing Article 15 of the Convention on Access to Genetic Resources, the report emphasised the importance of ensuring that Australia receives appropriate returns on our genetic resources:

> The control of access to genetic resources is an issue of national importance requiring urgent attention. While not necessary for the ratification of the Convention, the introduction of procedures governing access … would enable Australia to take full advantage of the opportunities provided by this article and also protect our interests. Currently, under existing legislation and guidelines it is possible to export a large range and volume of genetic resources for use in overseas research and development without appropriate returns to Australia.
>
> Commonwealth, State and Territory legislation should be developed to ensure that appropriate returns on our genetic resources are obtained. Matters which need to be covered include regulating access to, collection and export of genetic resources, particularly those of potential commercial benefit. The requirements of "mutually agreed terms" and "prior informed consent" provide a legal basis on which a fee generating permit system could be constructed for the provision of genetic resources and research and development based on these. Fees could be made payable commencing with initial use of genetic material regardless of commercial applications. Where a permit to access genetic resources is granted it should be subject to adequate returns in the form of payments for access and use, royalties on derived products, or opportunities to participate in research and share in intellectual property based on the genetic resources.[13]
>
> Box 8

Support for benefits to Australia from access to our biological resources

A wide range of submissions to the Voumard Inquiry expressed strong support for ensuring that Australia benefits from access to our biological resources. These included Commonwealth government agencies, State governments, and environmental, industry and Indigenous interests. The following are a few representative examples:

Agriculture, Fisheries, Forestry – Australia stated that

> In deciding on the nature of any regulations under the EPBC Act, including in matters to facilitate access, rights to deny access, benefit sharing and terms and

[13] ANZECC, (February 1993: 32-33)

conditions of access, it will be important to protect the capacity of Australia as a nation to benefit from access to its biological resources.

Box 9

The Queensland Government stated that:

Queensland is interested in utilising the ecologically sustainable use of the State's biological resources to facilitate incremental capacity building in the State's biotechnology industry, and capturing the potential financial and non-financial benefits from those bioprospecting activities.[14]

Box 10

The South Australian Department for Environment and Heritage discussed benefit sharing at some length in a policy discussion paper released in March 2000 stating that

In order that [South Australia] may more effectively capture the potential benefits arsing from access, and to better fulful the requirements of the Convention, a framework underpinned by the objectives of the Convention needs to be developed …[15]

Box 11

The Tasmanian Conservation Trust put the view that

Policies, laws and institutions should enhance the capacity of the Commonwealth to ensure that the full rental value of the use of Australian biological resources, including genetic resources, is captured by Australian governments, landholders, companies and most importantly Indigenous communities.

Box 12

AstraZeneca R&D Griffith University stated that

We are undertaking a drug discovery project based on access to biological resources. This project has resulted in significant benefits to Australia in the biotechnology area.

We support access to biological and genetic resources for research in Australia only.

The discovery part of pharmaceutical/biotechnology can be undertaken in Australia. Australia can benefit commercially be effective husbandry of the intellectual property.

[14] Queensland Bioindustries Office, Department of State Development , *Biotechnology in Queensland*
[15] Government of South Australia (March 2000)

The development part is more efficiently undertaken by industry. This must involve the major pharmaceutical companies due to the globalisation of drug regulation and the high cost.

The Convention on Biodiversity reaffirms that countries have sovereign rights over their own biological resources.

We believe that the on selling of Australian resources is likely to increase if samples are allowed to be exported.

We support regulation of bioprospecting to ensure that samples and extracts remain in Australia.

Box 13

Lack of adequate benefit-sharing arrangements

Legislation which regulates access to biological resources (ie natural resource management legislation covering issues such as environmental conservation or fisheries management) has generally not been specifically designed to cover access to genetic resources in the sense understood by the CBD. Nevertheless, many Commonwealth areas have permit schemes under such legislation which are used for these purposes. It appears, however, that there is generally less or no provision for benefit sharing arising from the use of these resources.

AIMS's submission to the Voumard Inquiry identified a lack of adequate benefit sharing arrangements (as distinct from legislation governing access to resources) as a factor contributing to:

… a trend of increased reluctance on the part of some marine access controlling agencies within Australia (including Commonwealth agencies) to grant permits for biodiscovery research at AIMS. This reluctance has … been over concerns that adequate benefit sharing will not take place, should commercialisation of a discovery occur. In other words agencies (particularly natural resource management agencies) sense that they have some ownership which should in the long run lead to a financial return to them directly.

This situation has created impediments to biodiscovery research at AIMS and elsewhere, and resulted in lost opportunities through stalled projects, sometimes after leads have been identified.

Box 14

To address this situation AIMS developed and adopted a benefit sharing policy which states

When AIMS receives benefits from conducting research into the discovery and development of new products from Australia's marine biogenetic resources, it will

equitably share those benefits with the owner of those resources.

Box 15

EA's Australian Antarctic Division has also expressed concern that legislation applying to Australia's Antarctic areas provides for a system for research permits but does not provide for benefit sharing arrangements. In view of the huge costs of this research (costs met by the AAD), and the commercial outcomes of some of this work, (sometimes benefiting overseas organisations rather than Australian organisations), the AAD has expressed an interest in a system which will enable them to ensure that at least some benefits flow back to Australia.

Examples of benefit-sharing agreements in Australia and their contribution to the development of high technology knowledge industries

Despite these obstacles, some examples of benefit sharing contracts do exist.

AIMS and the Queensland Government

AIMS's contract with the Queensland Government (signed in July 2000) is the only Australian benefit-sharing arrangement whose text has been made public. Although the contract includes agreement regarding the payment of royalties, other benefits focus on research and biotechnology development opportunities, particularly in Queensland. It is too early to evaluate the outcomes of the contract but it should be noted that the context in which it was negotiated was the interest of the Queensland Government in promoting biotechnology industries in that State. The benefit sharing clauses are highlighted in bold text in Box 16 below but a summary of the whole contract has been included as an indication of the kinds of matters that benefit sharing contracts include.

AIMS is now developing agreements with the Governments of Western Australia and the Northern Territory.

Outline of the agreement between AIMS and the State of Queensland

Recitals

- AIMS' marine research activities include biodiscovery (or bioprospecting) research whose goals include to discover biologically active molecules that can be developed as useful products by and with industry collaborators
- AIMS' research has the potential to deliver benefits (both monetary and non-monetary) to Qld
- When AIMS receives benefits, it seeks to equitably share those benefits with the resource owners
- Qld is interested in facilitating ecologically sustainable access to and use of its biological resources for biodiscovery purposes; utilising its biodiversity to facilitate incremental capacity building and value adding in the State's biotechnology industries; and capturing an equitable share of the benefits derived from the use of Qld's resources for biodiscovery purposes.

Purpose and scope of the agreement

- The purpose of the agreement is to set the framework within which AIMS and Qld fairly share in the benefits of biodiscovery research using Qld samples
- Qld samples are samples obtained from coastal areas determined by the *Seas and Submerged Lands Act 1973* and the *Coastal Water (State Titles) Act 1990*

Duration

- The agreement commences on the date of the agreement and continues until terminated by one or both parties pursuant to the terms of the agreement

Review

- The agreement is subject to review by both parties after it has been in operation for one year and every two years hereafter, at which time amendments can be negotiated by the parties
- After 5 years, the operations of AIMS biodiscovery research will be independently reviewed (State to choose reviewer, cover costs and keep information commercial in confidence – AIMS will have access to all information)

Access Arrangements

- AIMS has exclusive right to access Qld samples for its research (this does not extend to the species that are represented by the Qld samples)
- AIMS may collect new Qld samples for the purpose of biodiscovery research, subject to any requirements to obtain permission from the appropriate Qld government agency
- AIMS has the exclusive right to supply biodiscovery research samples that are Qld samples to third parties for biodiscovery research in which AIMS is a collaborator (third parties may include industrial and/or commercial collaborators in Australia or overseas)
- If AIMS provides Qld samples to third parties, AIMS must ensure that under the third party agreement it is acknowledged that the State is the owner of the resource from which the Qld sample was derived; and
- Under a biotechnology benefit-sharing arrangements with the State, AIMS has the right to access and conduct scientific research on the sample
- Before attempting to negotiate collaborative agreements with third parties outside Australia, AIMS must use all reasonable endeavours to satisfy the following criteria:

- Similar collaborative opportunities are not available on reasonable terms, firstly in Qld and secondly elsewhere in Australia
- The option of transferring the technology from overseas, first to Qld and second elsewhere in Australia, to eliminate the need to send Qld samples overseas is not possible on reasonable terms
- The quantity of material sent overseas is restricted to the minimum required for pre-agreed work and the overseas collaborator is required to return any unused material
- Data accompanying the material sent overseas will be limited to data reasonably required by the overseas collaborator to achieve the agreed

objectives of the collaboration

- AIMS agrees to use reasonable endeavours to ensure any commercial arrangement with a third party complies with the following criteria:
- Opportunities for intellectual property development are maximised, first, in Qld and second, elsewhere in Australia
- Opportunities are captured first for Qld and second for elsewhere in Australia for re-supply of material for a nominated sample; full taxonomic consignment for the nominated sample; and assessment of options for large scale long term supply of material for the nominated sample
- An appropriate Qld, first, or Australian collaborator, second, will share in any patent rights/terms to leads whose discovery and/or development has involved an overseas party
- The share of monetary benefits to be paid to AIMS or other Australian collaborator will be stipulated and fair and commensurate with their input to the process
- Development of any leads will recognise Qld's or other parts of Australia's rights as the place of origin

Benefits

- **AIMS will provide an annual report, summarising its biodiscovery research using Qld samples**
- **AIMS will provide appropriate Qld resource management agencies with detailed collection data for new Qld samples**
- **Where practical, or where stipulated in a permit or permission, a preserved voucher specimen shall be lodged with the Qld Museum with collection data and any other information that may contribute to furthering the State's scientific knowledge**
- **AIMS shall use its best endeavours to collaborate with the Qld Museum regarding the coordination and lodgment of preserved voucher specimens**
- **AIMS shall use its best endeavours to collaborate with appropriate Qld government agencies to maximise the taxonomic and biosystematic research benefits derived from these collections**
- **AIMS shall use its best endeavours to collaborate with non-AIMS scientists based in Qld in all aspects of its biodiscovery research relating to Qld samples**
- **AIMS shall use reasonable endeavours to inform the appropriate Qld government agencies of any opportunities for biotechnology industry capacity building, value adding or joint venture investments to allow those opportunities to be captured for the benefit of the state**
- **If a lead emerges and AIMS derives net royalty income, AIMS shall pay 1.5 % of the net royalty income to the state (if non-AIMS Qld-based scientists also make intellectual inputs to the discovery of such a lead, AIMS may negotiate a distribution of part of the remaining net royalty income to those scientists and/or their organisations)**
- **This clause continues to apply despite the possible termination of the agreement**

Intellectual property – confidential information

- Information provided by AIMS to Qld regarding its research will be AIMS intellectual property and in some cases AIMS will require the State to hold such information 'commercial in confidence'.

Box 16

AstraZeneca R&D Griffith University

AstraZeneca R&D Griffith University has contracts with the Queensland Museum and the Queensland Herbarium under which the Museum and the Herbarium collect biological resources. Key terms of these contracts include:

- Payment of a specified rate for samples;
- Payment, by Griffith University, of a percentage of all proceeds which it receives from any commercial exploitation of compounds obtained from samples supplied by the collectors (whether during or after termination of the agreement).
- Agreement, by the collectors, to keep confidential certain matters relating to samples and supply while ensuring that essential taxonomic information is placed in a public collection; and
- The University's exclusive right to the services of the collectors.

Box 17

AstraZeneca's investment at Griffith University provides significant employment and training in the pharmaceutical industry. Natural product screening was established in 1993 with 17 staff which grew to 43 staff in 2000. Over this time, AstraZeneca injected A$27 million into research at Griffith University. In 1998, the contract with the University was extended to 2003, resulting in proposed further investment of A$31 million in research and a further five highly skilled jobs during the period to 2000.

ExGenix

AMRAD Discovery Technologies (now ExGenix) was established in 1993 to secure access to Australia's diverse and extensive biota and to explore its potential for the discovery of novel pharmaceutically active compounds.

Collection agreements provide long-term and exclusive access to a significant proportion the genetic resources of Australia and other countries.

Ten Kate and Laird (1999) have documented AMRAD's benefit sharing agreement with CALM and the US National Cancer Institute:

The Department of Conservation and Land Management (CALM) in Western Australia (WA) is responsible for granting permits to collect and conduct research on WA flora. In 1981, a US Department of Agriculture botanist collected around 1200 plant specimens in WA. These were

processed by the WA herbarium and sent to the US NIH [National Institute of Health] for screening. In the late 1980s, a species of smokebush from WA showed promising activity in the NCI's anti-cancer screens. The NCI obtained a patent on concunvone, the active compound of the smokebush. At the same time, research by scientists in WA also revealed the potential anti-HIV activity of the smokebush.

CALM wished to ensure that WA would receive the maximum benefit from the use of its own biological resources. Not content with simply receiving royalties on production of any drug from the smokebush plant, CALM was determined that the development and production of any potential drug should be based and coordinated in WA. CALM entered into negotiations with AMRAD, an Australian pharmaceutical company. Drawing up the agreement required an amendment to the Conservation and Land Management Act, to allow CALM to grant exclusive rights to one company for the commercial development of a product derived from WA flora. CALM agreed to grant AMRAD access to the smokebush and permission to develop it commercially. In return, AMRAD agreed to provide US$730,000 to CALM, a share in royalties, and the right of first refusal for CALM to conduct any research in the active compound. In addition, AMRAD provided US$320,000 for further research by a consortium of WA scientists, in collaboration with the NCI, on some eight smokebush patents lodged by CALM. The research would explore the chemical structure of concunvone and the synthesis and development of analogues. The CALM/AMRAD agreement supported conservation and benefit sharing.

Conservation: Under the agreement CALM was responsible for ensuring the sustainable collection of the raw material. CALM used the funds received from the AMRAD agreement to support the conservation infrastructure in WA as follows:

- US$380,000 for the conservation of rare and endangered WA flora and fauna;
- US$190,000 for other conservation activities; including information technology such as geographical information systems, data capture and management to study population dynamics etc

Benefit-sharing: Benefit-sharing took two forms: research funding covering joint research and technology acquisition, and a share in royalties:

- Joint research: The consortium of WA scientists (ecologists, geographers, botanists, chemists, pharmacologists and immunologists) received US$150,000 to cover research conducted prior to the agreement that had led to several WA patents on concunvone. Over the year following the agreement, the consortium received an additional aus$500,000 for further research.
- Technology acquisition: government and university laboratories of consortium members were equipped with technology such as HPLC machines;
- WABEL: the remaining funds were used by CALM to establish the WA Biotic Extract Library (WABEL), a library of biotic extracts for

drug discovery.[16]

Box 18

ExGenix has entered into a large number of collecting agreements.

- Agreements relating to plant species:

Victoria: the Royal Botanic Gardens and Department of Conservation and Natural Resources (the Agreement with the Botanic Gardens provides access to approximately 11,000 species of exotic, non-Australian plants propagated in the Gardens in addition to the 4000–5000 native plant species which grow wild in Victoria).
Northern Territory: the Northern Territory of Australia and the Parks and Wildlife Commission of the Northern Territory, the Arnhem Land Aboriginal Land Trust and the Northern Land Council; and the Tiwi Aboriginal Land Trust.
Tasmania: the Tasmanian Herbarium through the Trustees of the Tasmanian Museum.
Malaysia: the Government of the State of Sarawak.
Papua New Guinea: the Kalam People of the Kaironk Valley, through the Australian National University.

- Agreements relating to micro-organisms:

Antarctic Cooperative Research Centre.
Australian Institute of Marine Science (agreement now concluded).
University of Hong Kong, Department of Ecology and Biodiversity.
Smaller scale and/or one-off arrangements with various microbiology centres around Australia.

- Agreements relating to marine macro-organisms:

Australian Institute of Marine Science (agreement now concluded

ExGenix provided the Voumard Inquiry with the following principles of the plant collecting arrangements into which it has entered.

- Enacted with relevant State Government and Indigenous authorities
- Samples collected by local botanical authorities;
- Voucher specimens maintained by local herbaria;
- Long-term and exclusive to ExGenix;
- Provide for sample/species recollection;
- Provide for maintenance of a register of ‘retained’ species after initial collection period;
- Intellectual property rights owned by or assigned to ExGenix;
- Benefits to custodians;
- Commercial – immediate (payment for samples) and long-term (royalties); and
- Non-commercial (flexible) – training, other benefits.

Box 19

BioProspect Limited

BioProspect Limited (formerly Bio-Gene Prospecting Limited) is a non-listed public company, formed in 1998, by a group of Western Australians for the sole purpose of

[16] ten Kate and Laird (1999: 76)

exploring Australia's unique flora for substances of value. The company is owned almost exclusively by Australians. BioProspect believes that its independence is significant to its success

> … in that [it is] not owned or controlled by any pharmaceutical company or any other organisation with a vested interest, either in Australia or internationally and that this independence allows [it] to operate … as a fair and honest broker of the biological resources to which [it has] access rights.

The company's website provides the following information:

> BioProspect has been and is negotiating licences with international sovereign states for access to their natural biological resources for the purposes of drug discovery, all the while, with the clear intention of adherence to the International Convention on Bio-Diversity. We now have such a license with the Government of Western Australia. This landmark licence makes us the broker of some of the most diversely unique and largely unexplored biota in the world. We intend to systematically bio-prospect this exciting Western Australian native flora for new and novel lead compounds for new drug discovery. Currently we have approximately 4000 species chemically extracted and ready for screening. Similar negotiations are underway with other countries and by next year, we expect to have over 9000 species available for drug discovery. In addition, our collections program will be, for the time being, expanding this extensive library by around 2000 new species every year. This will make BioProspect probably the largest source of extracts of novel plant species in the world today. Our existing library is largely extracts ready for pre-processing prior to screening. However, BioProspect is able to offer customised plant material extraction to our clients' specifications. Our policies regarding collections and processing ensure continuity of supply and repeatability of processing.[17]

BioProspect Limited's submission to the Voumard Inquiry identified the following as key elements of its contracts:

- Access on the basis of sustainable access;
- Primary ownership of all intellectual property derived from a biological resource remains in the hands of the State [WA] or its derivation;
- The State receives royalties from any commercial activity resulting or derived from that natural resource; and
- Wherever possible the infrastructure and human resources of the State are used to collect, process and value add to the primary biological resource.

Box 20

In November 1999, WA's Environment Minister announced the 'commencement of the largest scientific research for new medicines derived from Western Australian flora yet undertaken in Australia.' This would involve BioProspect testing plant extracts for a range of therapeutic activities in their Perth laboratory and supplying other drug discovery companies with samples for further testing. CALM would collect plant samples from crown land for the company, under a licence agreement.

The Environment Minister's statement said that the company was the successful respondent to CALM's call for expressions of interest in access to its plant extract

[17] Further information is available on the company's website: http://www.bioprospect.com

library and to future collections. Eleven responses were received from around the world, however only two submissions proposed the establishment of laboratories in Western Australia. The company now planned to invest about $40 million over the next five years to equip its screening facilities and employ scientific and administrative staff.

Under the licence agreement, the company would pay a fee for each sample provided, as well as a percentage of all revenue earned from other companies seeking access to the samples, and a royalty on the sale of the products derived from the samples. Funds received would be used to boost flora conservation and research.

The agreement would not prevent others from applying for permits to collect plants, including those wanting to pick wildflowers commercially, academics wanting to further their research and Aboriginal people wanting to use plants for traditional purposes. [18]

Monetary and non-monetary benefits

The Voumard Report included a list of monetary and non-monetary benefits which could be referred to when negotiating in benefit sharing contracts. This list was based on the list included in the report of the Panel of Experts on Access and Benefit sharing which met in Costa Rica in October 1999.[19] Variations on this list appear in other significant literature on the subject.[20]

It is important to stress that the list merely provides examples of the kinds of benefits which the parties to a benefit-sharing contract may wish to negotiate. The Voumard Report does not (and could not) specify the benefits that should apply in any agreement between a Commonwealth agency or Indigenous landowners and a bioprospecting or biodiscovery organisation. The nature – and value – of benefits will depend on factors such as the nature of the agreement, the circumstances of the parties and prevailing market conditions, and are appropriately negotiated on a case by case basis by the parties to the agreement, bearing their own interests in mind. The Report also addressed situations where research is of a non-commercial nature initially, recommending that while most contracts will be for commercial purposes, in some cases, terms which reflect non-commercially motivated research purposes may need to be drafted, and benefit sharing negotiated accordingly.[21] In cases of non-commercial scientific research, the benefit could, involve, for example, sharing the outcome of the research with the owner of the resource.

Intellectual property rights (IPRs) are also a potential significant benefit which are likely to arise in negotiations. IPRs are generally regarded as non-monetary benefits (see list, below). However, IPRs probably require better understanding. It is important to be aware that benefit sharing arrangements do not create or alter intellectual property rights. Benefit sharing is essentially about how value created from research into the biological resources should be shared with its original owner.

[18] Media statement, The Hon Cheryl Edwardes, Minister for the Environment, 9 November 1999, at www.bioprospect.com/press8
[19] The Panel meets again in March 2001.
[20] ten Kate and Laird (1999: 26-27)
[21] Voumard (July 2000): 23, para 2.27, recommendation 13

It is essentially a commercial agreement entered into by the parties for their mutual benefit. The mechanism used to create or maximise value, whether through creation of IPRs or reliance on trade secrets law, is incidental. Similarly, establishing a framework in which benefit sharing takes place in no way establishes new property rights.

A point made strongly by several submissions, particularly from industry/research interests but also by the Northern Lands Council and the traditional owners of Kakadu, was that it is important to avoid creating unrealistic expectations about the possible financial outcomes of agreements, for example, huge royalty payments arising from discovery of wonder drugs. In such circumstances, resource holders might wish to negotiate other forms of benefits (such as payments for samples or traditional knowledge) which are tangible and up front.

Examples of monetary benefits include:

- Up-front payments; such as payments for samples or traditional knowledge
- Milestone payments;
- Royalties;
- Research funding;
- Licence fees; and
- Salaries and infrastructure provided to owners of the resource, or landholders, as part of access arrangements;

Examples of non-monetary benefits include:

- Participation of Australians in research activities;
- Sharing of research results;
- A set of voucher specimens left in Australian CITES-accredited institutions;
- Support for research for conservation and sustainable use of biological diversity;
- Strengthening the capacities for technology transfer, including biotechnology;
- Strengthening the capacities of local and Indigenous groups to conserve and use their genetic resources and, in particular, to negotiate the benefits arising from the use of the intangible associated components of genetic resources and their derivatives;
- Assistance for language revival and maintenance programs for traditional owners;
- Recovery and recording of the biodiversity knowledge of traditional owners;
- Reasonable access by Australians to duplicates or, as appropriate, originals of specimens deposited in international ex situ collections;
- Receipt by providers, without payment of a royalty, of all technologies developed from research on endemic species;
- Donation to national institutions of equipment used as part of research;
- Reasonable access to technology and products resulting from the agreement;
- Information exchange;
- Protection of local existing applications of intellectual property rights;
- Building capacities in controlling aspects of bioprospecting methods, such as collection and preparation of samples, biodiversity monitoring, socio-economic monitoring, and/or

nursery and agronomic techniques (increased conservation capacity);

- Institutional capacity-building;
- Intellectual property rights; and
- Participation in commercialisation or product development or manufacture.

Some **other important non-monetary benefits** may include:

- Biological inventories and taxonomic studies, integral components of many bioprospecting activities, which can provide important benefits for conservation and sustainable use of biological diversity;
- Contributions to the local economy through value-added activities such as the cultivation of a species that is needed in large quantities for natural-products research, development and production as a commercial commodity;
- Public-health benefits, for example, in cases where access and benefit-sharing agreements encompass a commitment by a firm seeking genetic resources to invest in or support research on locally important diseases for which there is relatively little private sector investment;
- The institutional and personal relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities under it, such as between a local university and an international research centre, for example, are in themselves an extremely important non-monetary benefit. Often these relationships lead to important follow-on scientific collaboration and increased access to international funding sources; and
- Human and material resources to strengthen the capacities of personnel responsible for administering and enforcing access regulations.

Box 21

Proposed benefit sharing requirements

In response to specific concerns expressed in some submissions, particularly from environmental and Indigenous groups, the scheme recommended in the Voumard Report proposed that there be adequate benefit sharing arrangements, including benefits to Australia through improved knowledge and sharing of information about biodiversity.

Potential size of the commercial benefits from bioprospecting

Overseas examples suggest a number of things:

- royalties offer big potential pay-offs but only a very small proportion of samples can lead to the development of a successful drug (Table 1 –Appendix 6). Figure 1 (Appendix 5) provides a breakdown of possible payment structures and the distribution of returns to conservation practices, as suggested from recent bioprospecting arrangements.
- the development time of such drugs tends to be long.
- there is considerable variation in the estimated value of biodiversity for pharmaceutical research. Table 2 (Appendix 6) displays estimates of pharmaceutical companies' willingness to pay to preserve one additional hectare or species based on its potential R&D.

- up-front payments are useful for short time financial rewards (Figure 1 – Appendix 5).
- the potential to capture returns from bioprospecting depends in part on the degree of medicinal information provided. ten Kate and Laird (1999) estimate that the collection of "raw materials" only commands royalties of between 0.5 and 2 per cent of net sales. This share increases up to 15 per cent of net sales where clinical data can be provided with an identified bioactive compound.
  - For the period 1981−83, the US based Office of Technology Assessment (1993) estimated that each new drug developed between 1981−83 produced an (after tax) dollar return of US$36 million over and above R&D investment. Taking this as a proxy of the present value of net sales and using the royalty structure outlined in ten Kate and Laird, potential returns from bioprospecting returns may be calculated for a successful drug (Table 3 – Appendix 6). Such returns may be further diluted as they are distributed among various stakeholders.

Potential impact of bioprospecting on regional Australia

Bioprospecting can have an impact on regional Australia in three ways:
- payment to private landowners/traditional owners with a multiplier effect in regional communities. However, this is likely to be very small as most bioprospecting arrangements are with State/Federal Governments and tend to cover large areas of national parks etc. (see Figure 1 – Appendix 5).
- hypothecation of payments to State/Federal Governments to regional programs (eg. national park conservation, educational and research facilities, recreational facilities) may induce tourism in regional Australia as facilities and infrastructure are upgraded and the area is promoted in terms of its biodiversity.
- establishment of research facilities in regional Australia.
  - Recent examples of bioprospecting suggest that major pharmaceutical companies may contract bioprospecting organisations (for example, botanic gardens, universities) to undertake collection and preliminary screening of samples. Funding arrangement have tended to incorporate an element of venture capital to strengthen the research capacity of the bioprospecting organisation.
  - Such facilities may promote local employment opportunities to the extent that a skilled workforce is locally available.

Despite these possibilities, the potential for bioprospecting as a source of revenue to Australia's regional communities, whilst uncertain, is likely to be limited. Although the providers of in situ biological resources are located in rural and regional areas, most organisations which conduct bioprospecting activities and companies which conduct subsequent biodiscovery work are located in urban areas.

In addition, bioprospecting fees and royalties are likely to contribute a small share towards existing Commonwealth and State funded expenditures on conservation programs, rural infrastructure etc.

Conclusions

This chapter has addressed ways in which the Australian community can benefit from bioprospecting agreements. Although the potential benefits from bioprospecting –

particularly to rural and regional areas – should not be overstated, benefit sharing arrangements, established under legislation, will assist both providers of biological resources and local or locally-based research and industry to negotiate agreements on mutually acceptable terms, and help to ensure that the Australian community in general benefits from such agreements.

TERM OF REFERENCE 4: THE IMPACTS ON AND BENEFITS TO THE ENVIRONMENT OF BIOPROSPECTING

There are two aspects of environmental issues associated with bioprospecting:

- possible adverse impacts of bioprospecting on the environment, and
- benefits to the environment arising from benefit-sharing agreements.

The submission discusses each of these issues.

Possible adverse impacts of bioprospecting on the environment

The major environmental issue raised in submissions to the Voumard Inquiry was the need for environmental assessment of bioprospecting applications and when and how this should be carried out.[22]

Possible adverse environmental impacts of bioprospecting

Professor David Farrier and Linda Tucker, Centre for Natural Resources Law and Policy, Faculty of Law, Wollongong University presented evidence about the possible adverse environmental impacts of bioprospecting. Farrier and Tucker observed that:

> While the initial screening of biological material collected by bioprospectors may not involve significant amounts of biological material, larger quantities of samples which show useful biological activity must then be collected for detailed chemical and biological investigation. If large amounts of an organism have to be collected to isolate a particular chemical, or to determine its structure, this may undermine the claim to sustainable use.

The submission referred to an article by Mary Garson[23] which argues that the Convention on Biological Diversity 'has played a role in encouraging a more environmentally sensitive approach'. According to Garson,

> research groups and non-governmental organisations have now compiled guidelines for collection and these typically include a requirement to collect no more than is strictly necessary. Developments in bioprospecting practices and technology – particularly increased sensitivity to the bioassays that test for bioactivity of compounds – have led to continuing reductions in the impact of prospecting and harvesting.

Farrier and Tucker commented, however, that,

> obtaining enough material is only the first stage of the process. Even if the initial prospecting is low impact, the nexus with sustainable use will be broken if subsequent product development demands quantities of material which can only be obtained by mining the resource.

[22] A useful survey of environmental issues associated with bioprospecting conducted under the Nature Conservation Act (Qld), based on interviews with researchers, is Judith S Jones, 'Regulating Access to Biological and Genetic Resources in Australia: A Case Study of Bioprospecting in Queensland', *The Australasian Journal of Natural Resources Law and Policy*, Vol 5, No 1, 1998

[23] See Garson M, 1996 and 1997.

In this context, they further commented that, 'replication in the laboratory of the biological material required for product development is legitimate, and entirely desirable where the alternative is unsustainable mining of wild strands'. Farrier and Tucker referred to the argument of one author that the focus should be on carrying out syntheses of bioactive chemicals isolated from nature or using them as lead compounds to trigger the design and synthesis of analogues.[24] However, some novel chemicals may be either too structurally complex or too expensive to produce synthetically, and in these circumstances management of wild strands or farming of the resource are the only alternatives.[25]

It should be noted that the act of collection of material from the field in bio-prospecting also has environmental risks, such as the spread of pathogens, soil compaction, unreasonable sampling, deliberate vandalism (to protect the collector's exclusive access to material), etc.

Environmental assessment, protocols and the precautionary principle

The Queensland Government said that most primary biodiscovery collections involve relatively small samples sizes of less than 100 grams per species and, provided the target species are readily available with a sustainable population in the target area, are not considered threatened or endangered, and proper collection methods are used, the environmental impact may be minimal. Secondary collections of a specific species, conducted after a lead has been identified, may first require an environmental impact and species distribution analysis to determine the viability and ecological sustainability of the proposed second or any subsequent collection.

The Australian Institute of Marine Science suggested that all access must be undertaken on a sustainable basis:

- for primary collections, it is desirable to set out allowable collection methods and procedures that will ensure minimal environmental impact and avoidance of rare species (the Institute has set out collection protocols for this purpose);
- for medium-scale secondary collection, the Institute would support the requirement for a separate permit as the re-collection would be targeted on a particular organism, species-specific environmental impact scrutiny becomes an option; and
- requests for large-scale collections should be subject to full-scale environmental impact assessment and mandatory concurrent investigation of alternatives (eg synthesis, culture) for long-term large-scale supply.

AIMS added that, 'In order to secure a level of confidence and certainty to attract industrial research support, generic conditions of secondary access should be set out at the time of permission for primary collection'.

Some submissions referred to the possibility of developing guidelines or collecting protocols for bioprospecting. Professor Helene Marsh, Professor of Environmental Science, James Cook University, and Chair, National Committee for the Environment, drew the Inquiry's attention to the report of a 1998 study by the Australian Science,

[24] Farnsworth, NF 1994.
[25] King S R and Tempesta M S 1994.

Technology and Engineering Council entitled *Environmental Research Ethics: National Principles and Guidelines for the Ethical Conduct of Research in Protected and Environmentally Sensitive Areas.*

Dr Jane Fromont, Curator of Marine Invertebrates, Department of Aquatic Zoology, Western Australian Museum, referred specifically to the paucity of information on marine invertebrate fauna, especially in the waters off Western Australia, as an argument for the importance of 'any collection for use as a resource [being] undertaken with precautionary concepts as fundamental to the project'.

Don Anton of the Environmental Defenders Office Network also specifically referred to the precautionary principle:

> … in deciding whether or not to grant a permit or to enter into a contract, it is important that the precautionary principle which applies under s391 of the EPBC Act in decision-making by the Minister also apply in relation to decision-making with respect to determinations about whether a permit should issue and whether or not a contract should be entered into.

The Voumard Inquiry's approach to environmental assessment of bioprospecting under the EPBC Act 1999

In the light of these considerations, the Inquiry considered that environmental assessment of bioprospecting proposals may be required in some situations.

Environmental assessment would be required under existing triggers in the Act.

- s12 World Heritage properties,
- s16 Ramsar Wetlands,
- s18 Listed threatened species and communities,
- s20 Listed migratory species,
- s23 Commonwealth marine areas, and
- s26 Commonwealth land.

The Minister has approved *Administrative guidelines for determining whether an action has, will have, or is likely to have a significant impact on a matter of national environmental significance under the EPBC Act* (ss12, 16, 18, 20 and 23 above).

The Inquiry considered that these Guidelines would need to be amended to indicate that, in some circumstances, bioprospecting may have a significant impact on the environment and would therefore require environmental assessment and approval before an access permit could be approved.

The revised guidelines should take into account that:

- bioprospecting collecting in Commonwealth marine and land areas may have a significant impact on the environment;
- in general, the initial collection stage (collection of small quantities of a wide diversity of organisms for primary screening) is not likely to have a significant impact; but

- subsequent re-collection stages (collection of larger quantities of targeted species) may have a significant impact.

Bioprospecting collecting, at any stage, is likely to have a significant impact if:

- the proposed methods of collection are likely to cause a significant impact;
- features of the proposed collection location make it particularly vulnerable to significant damage;
- the population size and nature of species to be collected is not likely to sustain the proposed collection quantities (for example, 100 grams of bark from a common and abundant tree may cause incidental damage, whereas the same weight of a small marine worm may cause a long-term local depletion of that species); or
- it is likely to involve collection of a species or community listed under Chapter 5 of the Act, or likely to adversely impact upon an important or substantial area of habitat of a species or community listed under Chapter 5 of the Act.

Once an action is referred to the Minister under the Act, the Minister has the following choices:

- an assessment on preliminary documentation;
- a public environmental report;
- an environmental impact assessment; or
- a public inquiry.

The Inquiry anticipated that assessment on preliminary documentation may often provide a satisfactory means of assessing the environmental significance of the proposed bioprospecting.[26]

In addition to the environmental assessment requirements discussed above, the Inquiry noted that the access permit system would provide an important source of environmental control, in particular through the application of environmental permit conditions. To this end, the regulations would require certain environmental permit conditions to be mandatory, including conditions that the bioprospector comply with collection protocols attached to the permit.

The Inquiry also noted that the access permit system would include the following safeguards. When considering whether or not to issue a permit, the Minister would be required to consider the precautionary principle. He or she would also be required to be satisfied that the collection protocols attached to the permit provide adequate levels of environmental protection. In addition, it would be an offence, with significant penalties, to fail to obtain a permit when one is necessary, or to contravene permit conditions.

Benefits to the environment arising from benefit sharing agreements

With respect to environmental benefits submissions expressed strong support for further taxonomic work and for using some part of benefits for environmental

[26] The Minister can also choose to make a ministerial declaration allowing another Commonwealth body (such as a government department or statutory authority) to carry out the environmental assessment if satisfied about the process to be followed by that body.

purposes. With respect to taxonomic work, the Tasmanian Conservation Trust recommended that inventory and taxonomic work be given a high priority. The Australian Research Council commented on the need for an increased rate of species identification and description, a need that could be met by increased funding to agencies engaged in taxonomic work.

The Queensland Government submitted that bioprospecting has significantly enhanced the discovery and documentation of Australia's biodiversity, in fact, that for some phyla most of our knowledge has been gained from biodiscovery. A significant example of this outcome of collecting agreements was provided by the submission from AstraZeneca R&D Griffith University. Benefits of its collaboration with the Queensland Herbarium to date are:

- discovery of 37 new plant species;
- new populations of threatened species in remote areas, providing the genetic material which can be used to propagate the species;
- records of weed encroachment in native forests – these records are useful for forest management; and
- creation of new distribution records in the Queensland Herbarium.

Benefits of the collaboration with the Queensland Museum to date are:

- discovery of approximately 1500 new species; and
- provision of infrastructure to accurately define distribution of marine sponges in Queensland and adjacent waters – this provides invaluable data which will eventually produce productive taxonomic expertise in these areas and is of great value to further understanding of marine biota.

To maximise potential scientific outcomes, Queensland recommended there be a strict requirement that representative samples of all taxa obtained from biodiscovery are lodged with an appropriate State or Commonwealth CITES-accredited museum, together with appropriate collection data and any other information that may contribute to furthering the scientific knowledge of Australian biodiversity. Ideally, there should also be further 'encouragement' for bioindustries to perform some level of taxonomic sorting of these collections, to make them more relevant and accessible to the scientific community.

The ACF also addressed ways in which benefits to the environment could flow from an access regime under s301 of the EPBC Act:

> … any access scheme should ensure that the benefits arising from a grant of access flow to the environment … this could be achieved by making it a condition of access that, for instance, an identified level of information about the process of modifying or using the resource is provided to the authorising body for use in a public database.

However, given the highly speculative nature of bioprospecting, it would be imprudent to rely on fees derived from such activities to be used for conservation and/or provision of regional services. In addition, recent bioprospecting arrangements as well as various studies demonstrate that there is considerable variation in the economic and commercial value to pharmaceutical companies from bioprospecting (see Table 2 – Appendix 6). This uncertainty means that, in the absence of a clear and

demonstrated royalty payment, park management cannot commit long-term funding. Clearly this also extends to funds intended to be directed towards rural and regional Australia, and Indigenous Australians.

Conclusions

In the light of evidence presented in this chapter (based largely on evidence presented to the Voumard Inquiry), that in some circumstances bioprospecting may have an adverse impact on the environment, it is submitted that access and benefit sharing schemes should ensure that environmental assessment is conducted in appropriate cases.

APPENDICES

1. The Voumard Inquiry into Access to Biological Resources in Commonwealth Areas
2. Coverage of the proposed scheme for access to biological resources in Commonwealth areas
3. The Role of Botanic Gardens
4. Regulation of access to biological material: some problems with current permit systems
5. Potential distribution of benefits from bioprospecting
6. Values of biodiversity

APPENDIX 1

The Voumard Inquiry into Access to Biological Resources in Commonwealth Areas

Senator Robert Hill, the Minister for the Environment and Heritage, announced the Inquiry into Access to Biological Resources in Commonwealth Areas on 20 December 1999. The Inquiry was a major activity under the National Biotechnology Strategy and was funded through Biotechnology Australia. [27]

The terms of reference required the Inquiry to advise on a scheme that could be implemented through regulations under s301 of the *Environment Protection and Biodiversity Conservation Act* 1999 to 'provide for the control of access to biological resources in Commonwealth areas'.[28] The Inquiry Chair, Mr John Voumard, submitted his report on 4 August 2000. Senator Hill released the report on 6 September 2000.[29]

<u>The proposed access scheme</u>

The Inquiry's proposed scheme provides for an access permit and a benefit-sharing contract.

Under the scheme, a party seeking access to biological resources in Commonwealth areas is required to apply for an access permit. As the regulatory agency under the scheme, Environment Australia would assess the application, in consultation with any other relevant Commonwealth agency, and make a recommendation to the Minister for the Environment and Heritage to grant or refuse the permit.

While the assessment is underway, the applicant would be required to negotiate, with the holder (or owner) of the biological resources, a benefit-sharing contract which covers the commercial and other aspects of the agreement.

The Minister may issue the permit on being satisfied, among other things, that:

- environmental assessment (if required) was undertaken and the process is completed;
- submissions from interested parties have been taken into account; and

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[27] Biotechnology Australia was established to coordinate and undertake non-regulatory functions to position Australia to benefit from biotechnology. Biotechnology Australia was established in the Industry, Science and Resources portfolio but comprises five departments: Industry, Science and Resources, Environment Australia, Agriculture, Fisheries and Forestry – Australia, Health and Aged Care and Education, Training and Youth Affairs. It is overseen by a Ministerial Council, of which the Minister for the Environment and Heritage is a member, and a committee of departmental secretaries. In the May 2000 budget, the Commonwealth Government announced the allocation of an additional $30.5 million over four years to Australian biotechnology, for targeted initiatives under the Commonwealth's National Biotechnology Strategy.

[28] The terms of reference are at Appendix 2 of the Voumard Report.
[29] The Report is at Attachment 2 of this submission.

- there is a benefit-sharing contract between the parties which addresses prior informed consent, mutually agreed terms, and adequate benefit-sharing arrangements, including protection for and valuing of Indigenous knowledge and environmental benefits in the area from which the resource was obtained.

Consultations on the report to date

In the press statement announcing the release of the report, Senator Hill said that the government would consider all 71 recommendations of the Inquiry and make proposed regulations under the EPBC Act. These draft regulations would be released for public comment. Senator Hill also wrote to the Ministerial Council of Biotechnology Australia on 5 September 2000 inviting comments on the report.

To facilitate understanding and consideration of the report, Environment Australia held a series of meetings with the member agencies of Biotechnology Australia. This included separate consultations with CSIRO and IP Australia and the receipt of written comments on the proposed scheme from AIMS. (CSIRO, IP Australia and AIMS are key agencies in the Industry, Science and Resources portfolio). In addition, Environment Australia held consultations with, or sought comments from, the following other Commonwealth agencies with an interest in the report: the Department of Defence, the Aboriginal and Torres Strait Islanders' Commission, the Department of Foreign Affairs and Trade, AusAID, the Attorney General's Department and the Department of the Prime Minister and Cabinet.

With respect to the report's recommendations relating to the harmonising of access and benefit sharing at the Commonwealth level, consultations with the Australian Antarctic Division (a division of EA) and the Great Barrier Reef Marine Park Authority (an agency in the EA portfolio) were commenced. A meeting was held with the Department of Transport and Regional Services regarding the recommendations relating to Norfolk Island. Further consultations with the Norfolk Island Administration and the Australian Fisheries Management Authority (which has an interest in fisheries around the Island) are anticipated. Meetings were held with AFMA and AFFA to discuss the recommendations relating to Commonwealth marine areas.

Consultations were held with the heads of Australia's botanic gardens and herbaria with the objective of adopting a common position in relations to the *Common Policy Guidelines for Participating Botanic Gardens on Access to Genetic Resources and Benefit Sharing* which has been developed by the Royal Botanic Gardens, Kew in consultation with major gardens and herbaria around the world. These discussions included representatives of Kew Gardens and as a result the proposed Guidelines have been modified to take into account suggestions made by Australian botanic gardens and herbaria. The subsequent international meeting in Cartagena of representatives of botanic gardens supported the approach developed by Australian botanic gardens and herbaria.

APPENDIX 2

Coverage of the proposed scheme for access to biological resources in Commonwealth areas

The Voumard Report addressed the meaning of 'access to biological resources' in paragraphs 1.40 – 1.45, concluding that 'access to biological resources' refers to 'the process whereby samples from individual organisms are gathered, their genetic and bio-chemical make-up and other attributes determined, and their potential use assessed.'[30]

For the purposes of the draft s 301 regulations, Environment Australia has suggested that the issue be addressed by stating the object of the regulations is to provide for the control of access to biological resources in Commonwealth areas and then by defining access as follows:

> ***Access***, for biological resources, means to obtain samples of biological or other material containing genetic material or biomolecules for purposes of research on, conservation, commercial or industrial application of the genetic material
>
> Box 22

It is not proposed to use the term 'bioprospecting' but it should be noted that 'access to biological/genetic resources' and 'bioprospecting' have essentially the same meaning.

The proposed definition of access is based on a definition suggested by the IUCN in *A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources* which is : 'to obtain samples of biological or other material containing genetic material from areas within national jurisdiction for purposes of research on, conservation, commercial or industrial application of the genetic material'.[31]
(It is also consistent with definitions used in other national legislation.[32])

The IUCN has commented on this definition:

- It focuses on genetic material, as opposed to other biomolecules. However, the definition could be easily modified to include biomolecules.

- Access means to physically obtain genetic material.

- The definition emphasises samples of material containing genetic material. This implies obtaining a discrete amount of material or a limited number of specimens for subsequent use.

- Access is to occur within the national jurisdiction of the state. This could be in terrestrial, aquatic or marine areas.

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[30] Voumard (2000, para 1.43 at p 9)

[31] Glowka, 1998: para 3.1.3 at page 28

[32] For definitions used in Philippines, Andean Community and Costa Rican legislation, see ten Kate and Laird, 1999, Box 2.4 at page 19.

Biological and genetic resources

Also relevant to the purpose of the regulations are the definitions of biological resources and genetic resources in s 528 of the EPBC Act. These are as follows:

Biological resources includes genetic resources, organisms, parts of organisms, populations and any other biotic component of an ecosystem with actual or potential use or value for humanity.

Genetic resources means any material of plant, animal, microbial or other origin that contains functional units of heredity and that has actual or potential value for humanity.

Box 23

Native species

Also relevant is the definition of 'native species' in s 528 of the EPBC Act. The Inquiry recommended that the scheme apply only to biological resources which are native species. This is consistent with Articles 3 and 15(1) of the Convention, which recognise the right of sovereign states to exploit their own resources (see Box 5). Article 15(3) is also relevant (see Box 4).

Policy reasons also underlay this approach, first, that if Australia were to exploit our own holdings of other countries' biological resources, we would be vulnerable to accusations of biopiracy. Second, we would not wish other countries holding our biological resources to obtain benefits from their genetic content.

Native species means a species:

(a) that is indigenous to Australia or an external Territory; or

(b) that is indigenous to the seabed of the coastal sea of Australia or an external Territory; or

(c) that is indigenous to the continental shelf; or

(d) that is indigenous to the exclusive economic zone; or

(e) members of which periodically or occasionally visit:

  (i) Australia or an external Territory; or

  (ii) the exclusive economic zone; or

(f) that was present in Australia or an external Territory before 1400.

Note: A reference to Australia or an external Territory includes a reference to the coastal sea of Australia or the Territory. See section 15B of the Acts Interpretation Act 1901.

Box 24

Commonwealth areas

With respect to geographical areas covered by the scheme, s 525 of the EPBC Act includes a definition of Commonwealth areas, which limits the application of s 301 to terrestrial and marine areas under Commonwealth jurisdiction. The definition is as follows:

Section 525 Commonwealth areas

What is a **Commonwealth area**?

(1) Each of the following, and any part of it, is a Commonwealth area:

(a) land owned by the Commonwealth or a Commonwealth agency (including land owned in Norfolk Island) and airspace over the land;

(b) an area of land held under lease by the Commonwealth or a Commonwealth agency (including an area held under lease in Norfolk Island) and airspace over the land;

(c) land in:

(i) an external Territory (except Norfolk Island); or

(ii) the Jervis Bay Territory;

and airspace over the land;

(d) the coastal sea of Australia or an external Territory;

(e) the continental shelf, and the waters and airspace over the continental shelf;

(f) the waters of the exclusive economic zone, the seabed under those waters and the airspace above those waters;

(g) any other area of land, sea or seabed that is included in a Commonwealth reserve.

Territory Land in the ACT is not a Commonwealth area.

(2) Despite paragraph (1)(a), an area of land that is Territory Land, within the meaning of the Australian Capital Territory (Planning and Land Management) Act 1988 is not a Commonwealth area merely because of that paragraph, unless it is held under lease by the Commonwealth or a Commonwealth agency.

Coastal waters of States and the Northern Territory are not Commonwealth areas.

(3) Despite paragraphs (1)(d), (e) and (f), none of the following areas (or parts of them) are Commonwealth areas:

(a) the seabed vested in a State under section 4 of the *Coastal Waters (State Title) Act 1980*; and

(b) the seabed vested in the Northern Territory under section 4 of the

Coastal Waters (Northern Territory Title) Act 1980; and

(c) the subsoil under the seabed described in paragraph (a) or (b); and

(d) any water and airspace over seabed described in paragraph (a) or (b).

Box 25

The Voumard Inquiry was unable to obtain a detailed list or map of Commonwealth areas. However, submissions provided an indication of actual areas held (either owned or leased) by various Commonwealth agencies and, in some cases, an indication of their likely potential from a bioprospecting perspective. These include in situ and ex situ resources.

The Convention on Biological Diversity defines these terms as follows:

In-situ conservation means the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.

Ex-situ conservation means the conservation of components of biological diversity outside their natural habitats.

Box 26

Major Commonwealth areas (in situ) of potential or actual interest to bioprospectors are the:

- three national parks, Kakadu and Uluru Kata Tjuta (both in the Northern Territory) and Booderee (on the NSW south coast), which are lands owned by the traditional Indigenous owners but leased to and administered as national parks by Environment Australia;

- Great Barrier Reef Marine Park administered by the Great Barrier Reef Marine Park Authority (an agency in the EA portfolio);

- Australian Antarctic Territory administered by the Australian Antarctic Division (a division of EA);

- Land owned by the Commonwealth on Norfolk Island; and

- Australia's marine areas.

The Department of Defence provided a map indicating the locations (but not the dimensions) of defence training areas and indicated its willingness to permit bioprospecting in these areas, subject to safety, security and operational needs being taken into account.

Commonwealth areas (ex situ) may include collections held by the Australian National Botanic Gardens and Herbarium (administered by Environment Australia), CSIRO and AIMS. (It should be noted, however, that the exact nature of the ownership of these collections which are very diverse will depend on factors such as the jurisdictions from which they were obtained and any conditions which applied to their collection or acquisition).[33]

[33] Further information about the role of botanic gardens is at Appendix 3.

APPENDIX 3

The role of botanic gardens

Botanic gardens manage ex situ collections of living plants and germplasm (eg. seed) in a scientific manner. These collections have roles other than simple amenity and pleasure. Many also have extensive herbarium collections of scientifically important preserved plant specimens and data. The benefits to society that accrue from these collections are extensive and involve a large number of activities in the general fields of economic development, conservation, education and other community functions. These activities are supported by research programs and data management operations.

Typical roles for scientifically based botanic gardens include:

- conservation programs such as collection and ex situ holding of germplasm of species of economic or conservation concern, secure germplasm storage, monitoring ecosystems, species recovery projects, revegetation projects, monitoring of genetic erosion in wild species of special interest such as crop relatives, floristic exploration and eco-geographical surveys
- Assessment of the value of local crop species and of wild-collected plants of economic or cultural importance and economic development through plant introductions and the development of new crops and cultivars that may be used for ornamental, food, fibre cosmetic or medicinal purposes.
- Data collection and management that documents and allows access to information on what has been collected and its provenance, identifies deficiencies in the collections and opportunities for further development (eg. the adequacy of conservation collections), and records the exchange of material with other organisations.
- Research in the fields of taxonomy, ecology, and conservation biology.
- Management of research collections of preserved specimens (herbarium specimens)

Botanic gardens play a significant role in bioprospecting and historically have made major contributions to economic development through these activities. (A current example of bioprospecting in the ANBG collection of living plants is an ANU Department of Chemistry project to collect leaf specimens and screen them for endogenous (internal) fungi with antibiotic activity. The ultimate goal is to find more effective antibiotics to counter resistance being developed by microorganisms such as 'golden staph'.)

<u>Importance of ex-situ collections of live plants and germplasm</u>

According to the FAO[34] stored seeds represent approximately 90% of all "ex situ" plant accessions. Growing plants in arboreta, plantations and botanical gardens account for only 8%, and in vitro storage (cultures in a nutrient medium) account for only about 1%. Over 40% of the accessions in seed banks are cereals, and only 15% are non-domesticated plants or crop relatives. However, for nearly half of the two

[34] FAO 'State of the World's Plant Genetic Resources for Food and Agriculture', Rome, 1996.

million accessions to gene banks worldwide, the plant's characteristics and the location where it was collected are not recorded, and a significant proportion of the remainder are very poorly documented with regard to identification, provenance (details of the place where the specimen was collected), age and viability.

Seed collections are the most economical and efficient method of storing and preserving genetic diversity ex situ. The majority of plants seeds have "orthodox seeds" which can be stored in dry conditions for many years. Some species stored at extremely low temperature could last for many decades.

Ex situ seed collections are important for bio-prospecting because:

- Large quantities of different genetic material can be stored in a small space for a long period of time. (Compare the amount of space taken up by 10 Eucalyptus seeds and 10 Eucalyptus trees).
- Seed banks provide 'one stop shops' for researchers and plant breeders, reducing the need for administratively complex, time consuming and expensive field work
- Seed banks provides long-term, secure storage for rare or threatened species whilst other conservation techniques are being developed
- Seed provides genetic diversity not found in cloned material (cuttings). Seed banks are increasingly being seen as an important conservation tool for maintaining the diversity of the Australian Flora.
- Seed banks make it relatively easy to regulate supply (easy to keep records etc).

The increasing role for germplasm storage in conservation and for the supply of material for plant breeding and biotechnology has been recognised at many levels throughout the world. At an international level the most significant development was by the FAO in 1974 when the Consultative Group on International Agricultural Research (CGIAR), created the International Board for Plant Genetic Resources (IBPGR) which later established the International Plant Genetic Resources Institute (IPGRI). Its role is to promote an international network of genetic resource centres for the collection, conservation, documentation, evaluation, and use of plant germplasm. The International Agricultural Research Centres created by FAO hold over 600,000 seed samples in their genebanks, which is between 20% and 50% of all unique germplasm in storage worldwide. These gene banks are particularly valuable as the seed they contain is properly identified and documented.

The majority of nations support ex situ germplasm conservation with seed banks being run generally by their departments of agriculture and/or forestry. Botanical gardens are particularly significant in national efforts. Recently, many of the world's botanical gardens reasserted their commitments to both in situ and ex situ conservation by adopting guidelines developed in the Botanic Gardens Conservation Strategy (1989). Seed banks based in botanical gardens usually have the advantages of good access to herbarium, taxonomic and other scientific resources so that accessions are properly documented and identified. However, many gardens collections suffer from inadequate facilities for processing, storing and testing seeds and a lack of trained staff.

The prime example of a botanic gardens based seed bank is the Millennium Seed Bank project of the Royal Botanic Gardens, Kew. Recognising the urgent need to collect and store seed from the world’s flora RBG Kew's aims are:

- To collect and conserve seed of 10% of the world's flowering plants, mainly from arid regions (including Australia), by the year 2010
- To collect and conserve seed from the majority of U.K. species by the year 2000
- To make most of the seeds available for research through benefit sharing in accordance with the Convention on Biological Diversity
- To carry out research to improve seed banking methods and to assemble a seed information database
- To transfer technology to collaborating countries by providing research and training opportunities
- To build a facility by the year 2000, next to the present Kew seed bank, to house the above projects and to provide a place for public interpretation

The Millennium Commission, one of the UK's national lottery fund distributors, has provided much of the funding for this project, with significant inputs also from the private sector. The Commission has granted 30 million pounds ($80 million) for this project. A major Australian botanic garden is believed to have negotiated terms for the supply of Australian germplasm to this project.

In Australia the government sector germplasm collection is decentralised, comprising of a number of collections in State and Commonwealth research institutions and in universities. Although the combined collections of these institutions is significant it is far from comprehensive. Also, whilst a decentralised collection has security advantages, it is difficult to determine what is in these collections and where the deficiencies are, given different jurisdictions and priorities.

Non-governmental organisations, other than gardens, have also been increasingly important participants in germplasm collections. For example, in Australia, 'Greening Australia', in association with ANBG, CSIRO, the Australian Centre for Mining Environmental Research and the Natural Heritage Trust, has been particularly effective in combining in situ and ex situ conservation through the FloraBank and FloraData projects. These projects provide guidelines for the establishment and maintenance of community seed banks and a publicly accessible data set of germination techniques. Such "grass-roots" organisations can be effective educators, explaining the importance of germplasm and of conserving genetic resources to the general public. In contrast, most governmental programs are designed to serve the scientific research community and they tend to direct their "extension effort" to this community of technical users, rather than to a broader audience.

<u>The role of botanic gardens in the supply of biological material</u>

Botanic gardens have an important role to play in the regulation of access to biological resources. Although they generally do not control primary access to resources they act as conduits for supply. They are often the repositories of the resource inventory, and they frequently have ex situ holdings of desirable plant material. They generally conduct their activities in an ethical and responsible manner and are aware of and conform to all relevant policies and legislation. Botanic gardens could play a greater role in the administration of access to botanical resources given greater support for botanical inventory documentation, consolidation and coordination of state and Commonwealth inventory databases, and the management of transaction

records relating to material transfer agreements under the Convention on Biological Diversity.

The supply of plant material to organisations other than botanic gardens can also be beneficial. Botanic gardens are able to supply an extensive variety of plant materials of known origin, which has been collected legally and in a manner that minimises ecological impacts. For these reasons they are regularly asked to supply material for a variety of purposes. These include conservation projects (eg. species recovery projects or revegetation), educational purposes (eg material for university classes), research (eg. to CSIRO), and commercial opportunities. The latter not only benefit economic development but also can also subsidise botanic garden activities and facilitate other beneficial interactions with the private sector.

Obtaining plant material from botanic gardens has the advantages that supply is regulated and properly documented. Recipients are required to sign material transfer agreements that specify the terms under which the material has been supplied and restrict uses to which it may be put and the supply to parties that are not included in the agreement. There are usually publicly accessible records of transactions as well as other supporting data for particular taxa. However, as with supply to other botanic gardens, there are legitimate concerns that once material has been supplied there is potential loss of control over its further uses and there may be difficulties in the enforcement of material transfer agreements. It is desirable that the recipients of material from secondary sources such as botanic gardens should also enter into contractual agreements with the original owners of that material.

APPENDIX 4

Regulation of access to biological material some problems with current permit systems

Botanic garden activities require ongoing additions to their living collections and renewal of existing accessions. Sources of plant material include direct collection from wild populations, re-propagation of existing collections, exchanges with other botanic gardens and similar institutions or individuals, and the purchase of plants or seeds from private businesses. In the case of the Australian National Botanic Gardens, collections from wild populations are usually done on Commonwealth land or under permit from state governments.

There are a number of issues concerning the current access procedures for plant material that need to be addressed in order to facilitate the delivery of benefits by botanic gardens or provide benefits to the Australian community in general.

Obtaining permits is time consuming and complicated by the number of separate jurisdictions that control access. The different conditions that each jurisdiction and their agencies apply to permits further complicate the administration of what may be done with material after it has been collected. There is also a lack of uniformity of terms and conditions of permits (and material transfer agreements) across state and territory boundaries. As many plant species occur across state boundaries it can be difficult to enforce some of these conditions. Harmonisation of permit processes would facilitate access.

Policy and legislation governing the collection and supply of plant materials should continue to protect plants from unsustainable practices, but also facilitate sustainable commercial development of plant species. They should not hinder collection for study that leads to better conservation or sustainable economic development.

The current permit system does not meet these needs. There are too many separate agencies (mainly State departments) responsible for administering the system, and varying degrees of procedural efficiency. Permits are often required in circumstances that are inappropriate. There are sometimes long delays in processing applications. A recent example from ANBG experience was the requirement to get a permit to collect grass seed from roadsides that are routinely mown, and which had been mown by the time the permit was received. In another case it was necessary to get a permit to collect seed for revegetation in the same locality as the source material. The permit system needs to allow exploration of Australia's flora

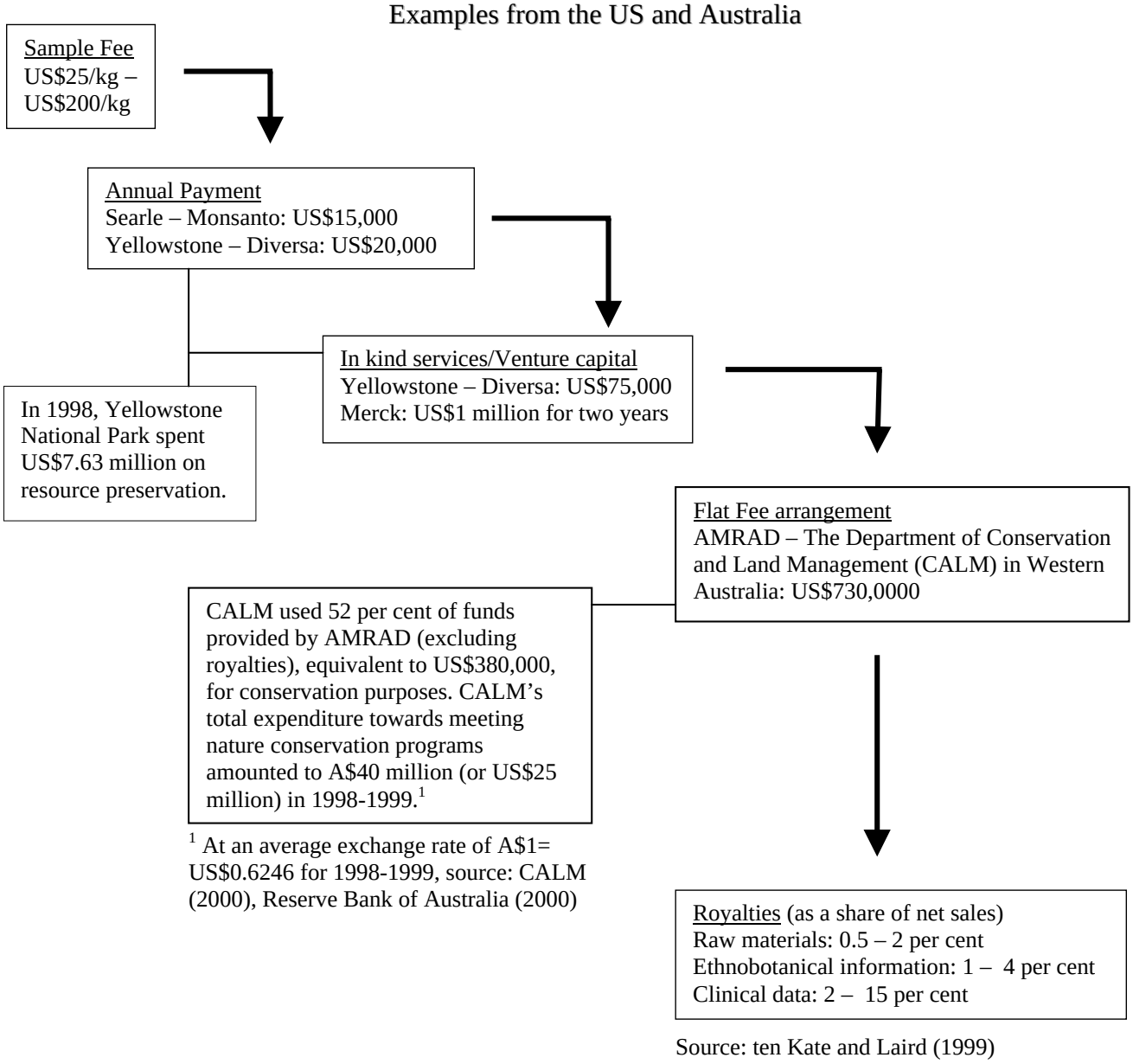
In some jurisdictions it is necessary to state on the application exactly what is to be collected and where and when it will be collected. This makes botanical exploration and collection of new taxa difficult and hinders the progress of compiling a resource inventory. Similarly commercial opportunities are being lost because the regulation of collecting within Australian jurisdictions is not sufficiently flexible to allow some rare or threatened taxa to be brought into cultivation and traded, even though this could be very beneficial from a conservation standpoint. Even exchanges between research agencies can be complicated by the conditions imposed by a permit. In a recent case

ANBG was unable to supply material collected from one state to another government agency in the state because the terms of the collection permit forbade it. Special approval by the State department that issued the permit would have been required.

The current system encourages fraudulent practices and collection without a permit, especially within national parks, and unless a particular taxon is endemic to one of these administrative units, enforcement is impossible.

APPENDIX 5

Figure 1: Potential Distribution of benefits from bioprospecting
Examples from the US and Australia



[1] At an average exchange rate of A$1= US$0.6246 for 1998-1999, source: CALM (2000), Reserve Bank of Australia (2000)

Source: ten Kate and Laird (1999)

APPENDIX 6

Values of biodiversity

Table 1: Stylised facts

Annual Sales Revenues for top selling drugs of natural origin	
Taxol	$0.9 billion
Zocor	$3.56 billion
Pravachol	$1.44 billion
Cost of developing a successful pharmaceutical drug (US$)	$231 million – $500 million
Years to develop a successful pharmaceutical drug	10 – 15 years
Probability of developing a single natural product	1:5000 – 1:10000

Source: ten Kate and Laird (1999)
[1] All figures in US$ 1997 numbers.

Table 2: Values of biodiversity for pharmaceutical research

Simpson et al (1996) – US$/ha	$0.2 – $20.63
Rausser and Small (2000) – US$/ha	$0 – $9,177
Pearce and Puroshothaman (1995) – US$/ha	$0.1 – $21
Per untested species (Aylward 1993, Principe 1989) – US$	$44 – $23.7 million
Southwestern Australia:	
Simpson et al (1996) – US$/ha	$0.14
Rausser and Small (2000) – US$/ha	$435

Table 3: Potential bioprospecting returns for a successful drug

Prospecting Stage	Royalties (per cent)	Returns (US$ millions)
Raw materials	0.5 – 2	0.18 – 0.72
Ethnobotanical information	1 – 4	0.36 – 1.44
Clinical data	2 – 15	0.72 – 5.40

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ATTACHMENTS

1. National Biotechnology Strategy
2. Voumard Report
3. Press release announcing the Voumard Report