The Parliament of the Commonwealth of Australia

Bioprospecting: Discoveries changing the future

Inquiry into development of high technology industries in regional Australia based on bioprospecting

House of Representatives
Standing Committee on Primary Industries and Regional Services

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Foreword

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

Australia is well positioned to participate in this new industrial development. It is richly endowed with biological resources; it is one of the few mega diverse countries in the world. It also has the skills to develop these resources. It is vital that Australia seize the opportunities to search (to bioprospect) its biological resources for new chemicals and processes, and then develop industries based on them.

The potential for building new industries on the discoveries made from biological resources is huge. Biodiscoveries hold the promise of new medicines and agrichemicals, more efficient and less polluting industrial production, and environmental remediation. Immense economic, social and environmental benefits can accrue from these discoveries. It is vital that Australia is part of this new future. Australia must be able to make the best use possible from bioprospecting its biological resources.

This is the context in which the House of Representatives Standing Committee on Primary Industries and Regional Services undertook to inquire into the contribution that bioprospecting might make to the development of new industries, especially in regional Australia. The committee has considered the opportunities and impediments to development of this kind and its likely impact on the natural environment, and has made recommendations to facilitate future developments.

The committee is excited about the possibilities that bioprospecting offers the nation.

Fran Bailey, MP
Chair

Membership of the Committee

Chair Fran Bailey MP

Deputy Chair Mr Dick Adams MP

Members

Mr Peter Andren MP

Mr John Forrest MP (from 7/8/2001)

Mr Alan Griffin MP

Mr Bob Horne MP

Hon Bob Katter MP (to 7/8/2001)

Mr Tony Lawler MP

Mr Ian Macfarlane (to 8/3/2001)

Hon Leo McLeay MP

Mr Gary Nairn MP

Mr Patrick Secker MP

Mr Alby Schultz MP (from 29/3/2001)

Mr Sid Sidebottom,MP

Mr CameronThompson MP

Dr Mal Washer MP

Mr Griffin and Dr Washer were appointed supplementary members of the committee for the purposes of the inquiry into the development of high technology industries in regional Australia based on bioprospecting.

Committee Secretariat

Secretary	Mr Ian Dundas
Inquiry Secretary	Dr Sarah Hnatiuk
Research Officers	Ms Katherine Harrington
Administrative Officers	Ms Marlene Lyons
	Ms Jeannie Brooks

Terms of reference

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;
- 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.

Referred by the Minister for Agriculture, Fisheries and Forestry on 4 October 2000.

List of abbreviations

AFFA	Department of Agriculture, Fisheries and Forestry - Australia
AZGU	AstraZeneca R&D Griffith University
ABBRC	Australian Biodiversity and Biodiscovery Resource Centre
AIMS	Australian Institute of Marine Science
API	Australian Property Institute
ARC	Australian Research Council
ASM	Australian Society for Microbiology
BA	Biotechnology Australia
CVP	Cellulose Valley Project
CALM	Department of Conservation and Land Management, Western Australia
CBD	Convention on Biological Diversity
CRC	cooperative research centre
EA	Environment Australia
EPBC Act	*Environment Protection and Biodiversity Conservation Act 1999*
FAO	Food and Agriculture Organization of the United Nations
FIP	Farm Innovation Program

GMO	genetically modified organism
GBIF	Global Biodiversity Information Facility
IP	intellectual property
ISR	Department of Industry, Science and Resources
IUPGR	International Understanding on Plant Genetic Resources
JCU	James Cook University
MNRF	Major National Research Facilities
MTA	material transfer agreement
NBS	National Biotechnology Strategy
NDIP	New Industries Development Program
PBR	plant breeders rights
R&D	research and development
RIRDC	Rural Industries Research and Development Corporation
SCU	Southern Cross University
SCUCP	Southern Cross University Phytochemistry Centre
UQ	University of Queensland
WIPO	World Intellectual Property Organization

List of recommendations

Overcoming impediments in establishing Australian bioindustries

The committee recommends that the Commonwealth government:

- increase funding for baseline studies of the Australian biota;
- target additional funds for collecting activities in bioactive hot spots;
- fund a larger volume of taxonomic work than at present and ensure sufficient young taxonomists are being trained to undertake this work;
- provide more funding to maintain and expand existing collections so that they provide a comprehensive coverage of Australia's biota, including microorganisms; and
- ensure that commercial users contribute in kind or financially, through benefit sharing arrangements, to growing and maintaining collections and databases.

The committee recommends that the Commonwealth government provide additional funding for digitising and networking information about all of Australia's biological resources.

Glossary

Bioactivity	An abbreviation of 'biological activity', meaning the elicitation of a biological response through modifying the function of an enzyme or receptor, or interfering with other physiological processes.
Biobased	An abbreviation of 'biologically based', meaning derived from organic matter.
Biodegradable	Describes any material able to be decomposed by natural biological processes, such as by being digested by bacteria or fungi.
Biodiscovery	The extraction and testing of molecules for biological activity, identification of compounds with promise for further development, and research on the molecular basis for the biological activity.
Biodiversity	The variety of the world's organisms, including their genetic diversity and the assemblages they form. The breadth of the concept reflects the interrelatedness of genes, species, and ecosystems.
Biofuel	An abbreviation of 'biomass fuel', meaning any liquid, solid, or gaseous fuel produced by conversion of biomass. Biofuels include ethanol, biodiesel, and methanol, methane, and hydrogen.
Bioindustry	An industry based on biodiscovery which has been successfully developed and scaled up for commercial production.
Bioinformatics	All aspects of gathering, storing, handling, analysing, interpreting and spreading vast amounts of biological information in databases. The information involved includes gene sequences, biological activity / function,

	pharmacological activity, biological structure, molecular structure, protein-protein interactions, and gene expression. Bioinformatics uses powerful computers and statistical techniques to accomplish research objectives, for example, to discover a new pharmaceutical or herbicide.
Biological resources	Include genetic resources, organisms, parts of organisms, populations and any other biotic component of an ecosystem with actual or potential use or value for humanity.
Biomass	Any organic matter which is available on a renewable basis, grown by the photosynthetic conversion of solar energy (for example, by plants), and organic matter from animals. Biomass includes forest and mill residues, agricultural crops and wastes, wood and wood wastes, animal wastes, livestock operation residues, aquatic plants, fast-growing trees and plants, and municipal and industrial wastes.
Biomining	The use of microorganisms to aid recovery of metals from ores.
Biopesticide	A pesticide in which the active ingredient is a virus, fungus, bacterium, or parasitic disease, or a natural product derived from a plant source.
Biopolymer	A high molecular weight organic compound found in nature, whose structure can be represented by a repeated small unit. Common biopolymers include cellulose and proteins.
Bioprocessing	The use of biological materials, generally microorganisms or enzymes, to carry out specific chemical reactions for industry, for example, to extract, process or purify.
Bioproduct	Product derived from biological materials.
Bioprospecting	The search for valuable chemical compounds and genetic material from plants, animals and microorganisms. The term is sometimes used more narrowly to refer only to the initial collection of biological material for subsequent use for biodiscovery,

	or more broadly to include the search for new bush foods.
Bioreactor	A contained vessel or other structure in which chemical reactions are carried out (usually on an industrial scale), mediated by a biological system, enzymes or cells. They are used to produce pharmaceuticals, antibodies, or vaccines, or for the bioconversion of organic waste.
Bioregion	An area of land or sea composed of ecosystems that occur in a repeating pattern throughout the region and can be distinguished from other regions with different patterns. They are described in terms of the dominant physical and biological attributes of the region (for example, climate, landform, vegetation, ocean currents, sea temperatures and salinities).
Bioremediation	The use of plants and microorganisms to consume or otherwise help remove materials (such as toxic chemical wastes and metals) from contaminated sites (especially from soil and water).
Biota	The combined flora and fauna of a region.
Biotechnology	The application of science and engineering principles to the processing of materials by biological agents to provide goods and services.
Bryozoan	Any of various small aquatic animals of the phylum Bryozoa that reproduce by budding and form mosslike or branching colonies permanently attached to stones or seaweed.
Combinatorial chemistry	The technologies that generate a large number of samples of (new) chemicals, which are then tested (screened) for potential use (for example, for therapeutic effect, in the case of a pharmaceutical).
Ecology	The study of the interrelationships between organisms and their environment.
Ecosystem	All of the organisms in a given area in interaction with their non-living environment.
Endemism	Being indigenous to only a specified area.

Enzymes	Proteins that act as catalysts, speeding the rate at which biochemical reactions proceed but not altering the direction or nature of the reactions.
Extremophiles	Organisms that require extreme (from a human perspective) environments for growth. They are found in environments characterised by high temperature, pH, pressure and salt concentration, or low temperature, pH, nutrient concentration, or water availability. Some can tolerate very extreme conditions including high levels of radiation or toxic compounds, or live in rocks 1.5 km below the surface of the earth. In addition, they may be found in environments with a combination of extreme conditions.
Fermenter	An apparatus that maintains optimal conditions for the growth of microorganisms. Fermenters exist in a wide variety of configurations, from experimental systems of less than one litre to large commercial towers, and are used in the commercial production of antibiotics and hormones.
Functional food	A food that has beneficial effects on target functions in the body, beyond adequate nutritional effects, in a way that is relevant to health and well-being and / or reduction in disease.
Gene	Each of the units of heredity which may be regarded as the controlling agents in the expression of single phenotypic characters. Genes are sequences of nucleotides within nucleic acid molecules, each of which determines the primary structure of some protein or polypeptide molecule.
Metabolism	The sum of all of the enzyme-catalysed reactions in living cells that transform organic molecules. The term covers the conversion of food and water into nutrients that can be used by cells, *and* the use of those nutrients by those cells (for example, to sustain life and grow).
Microorganism	An organism of microscopic or submicroscopic size, especially a bacterium or protozoan.
Nutraceutical	Any non-toxic food extract that is used as a dietary supplement and has scientifically proven health benefits for both disease treatment and prevention. In

	some uses of the term, whole diets; isolated nutrients; designer, biotechnology-enhanced foods; and functional foods are included.
Pathogen	A virus, bacterium, parasitic protozoan, or other microorganism that causes infectious disease by invading the body of an organism known as the host.
Peptide	Two or more amino acids joined by the sharing of one or more electrons between atoms. Polypeptides (protein) are chains of amino acids linked in this way. Each protein in nature is the ultimate expression product of a gene.
Petrochemical	A chemical derived from petroleum or natural gas.
Pharmaceutical	Relating to preparing and dispensing drugs.
Platform technology	A technology likely to have many applications. An example is a technology that links drugs with specialised fats to facilitate delivery of drugs and genes into cells could significantly enhance therapy in a number of human diseases.
Polyester	Any of numerous synthetic polymers in which the units are joined by ester linkages. Polyesters are used primarily as light, strong, weather-resistant resins in boat hulls, textile fibres, adhesives, and moulded parts.
Ramsar wetlands	Wetlands listed as internationally significant under the Convention on Wetlands of International Importance. This convention is known as the 'Ramsar Convention' after the city in which it was finalised.
Scale up	The transition step in moving a (chemical) process from experimental (test tube, small, bench) scale to a larger scale producing more or much more product than the bench scale (tons / year in a chemical plant). A process may require a number of scale-ups, with each scale-up producing more product than the last one.
Taxonomy	Theories and techniques of naming, describing, and classifying organisms. The taxonomic hierarchy is, from top to bottom: kingdom, phylum (for animals) or division (for plants and fungi), class, order, family, genus, species.

Sources:

Academic Press Dictionary of Science and Technology, Harcourt, http://www.harcourt.com/dictionary/.

Adams, C, Acting Chief Executive, CSIRO, *Business Review Weekly*, v. 22(13), 7 April 2000, p. 46.

Bioenergy glossary, http://rredc.nrel.gov/biomass/states/bio_glossary/glossary.html.

BiotechLife Science Dictionary, http://biotech.icmb.utexas.edu/search/dict-search.phtml.

Cavicchioli, R. and Thomas, T. 2000. Extremophiles. In *Encyclopedia of Microbiology, Second Edition* (J. Lederberg, ed.), Vol. 2, pp. 317-337. Academic Press, San Diego.

CSIRO briefing for the committee, 27 November 2000.

Environment Protection and Biodiversity Conservation Act 1999.

Nill, K R, *Glossary of Biotechnological Terms*, Technomic Publishing, 2001, http://biotechterms.org/.

Oxford English Dictionary.

Pacific Northwest National Laboratory and Battelle Pacific Northwest Division, http://bioprocess.pnl.gov/.

ten Kate, K & Laird, S A, *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing*, Earthscan Publications, London, 1999.

Australian Nature Conservation Agency, Canberra, *The American Heritage® Dictionary of the English Language*, Fourth Edition, http://www.dictionary.com/.

US Department of Energy, 'Glossary of energy terms', http://www.eren.doe.gov/consumerinfo/glossary.html.

Wondu Holdings Pty Ltd, *New Pharmaceutical, Nutraceutical & Industrial Products: The Potential for Australian Agriculture*, Rural Industries Research and Development Corporation, November 2000.

World Resources Institute, Washington, DC.

1

Introduction, definitions and inquiry scope

High technology products and processes from natural sources

1.1 Advances in mechanical technology dominated the nineteenth century; the information revolution was the driver of change in the twentieth. As we start the twenty-first century, an explosion in our understanding of biological processes seems likely to underlie future industrial developments.

1.2 Nature is a treasury of variety and complexity. As we understand it better, we can use biological processes to provide the basis or starting point for developing new processes and products. In doing so, we avoid reinventing wheels that have already been developed in the course of evolution and fine tuned over many years.

1.3 Bioproducts and their means of production are also environmentally friendly. This recommends them to a world where problems caused by conventional industries are increasing. The manufacture of bioproducts involves natural processes that occur at ambient temperatures and pressures; the energy required to produce them is modest and waste is minimal and biodegradable. There are environmental as well as economic advantages to using biobased products.

1.4 Considerable efforts are being made by advanced countries to research biological processes and to harness this research to advances in medicine, mining, manufacturing, agriculture, and environmental management. Australia is among these countries and in competition with them to reap the benefits. There is a window of opportunity here which Australia must utilise.

1.5 Australia has an advantage over other countries in that it possesses a unique, very diverse biota. Our plants, animals and microorganisms represent the only resource from which certain discoveries can be made, and an additional opportunity for Australia.

1.6 The committee's inquiry examines the opportunities for Australia to develop high technology industries based on bioprospecting, and to investigate the factors that are inhibiting these developments. Given the committee's rural and regional focus, it is appropriate that the inquiry's terms of reference place particular emphasis on the involvement of regional Australia in bioprospecting and bioindustrial development. The inquiry was referred to the committee on 4 October 2000 by the Minister for Agriculture, Fisheries and Forestry, the Hon Warren Truss, MP.

Definitions

Bioprospecting

1.7 The committee's first task at the start of the inquiry was to understand the meaning of the term, 'bioprospecting'. It soon became clear that there is no standard definition and 'there are different views on how far "bioprospecting" extends down the commercialisation path'.[1]

1.8 The term is sometimes used narrowly, for example by CSIRO and Environment Australia (EA), to cover only the initial collecting of biological material to use subsequently in biodiscovery and further development.[2] A more common use of the term, however, is to refer to the search for valuable chemical compounds and genetic material from plants, animals and microorganisms.[3] In some cases, as in biopesticides, biomining and bioremediation, whole organisms are employed rather than the chemicals and genetic material extracted from them. The broadest meaning of the term encountered by the committee was that used by the Commonwealth Department of Agriculture, Fisheries and Forestry - Australia (AFFA). AFFA suggested that bioprospecting also involved the identification of potential food sources among Australian native plants,[4] although the term is not usually used in this way.

1 Biotechnology Australia, Submission no. 25, p. 6.

2 CSIRO, Submission no. 14, p. 13; Environment Australia, Submission no. 29, p. 41.

3 For example, South Australian government, Submission no. 28, p. 1.

4 Department of Agriculture, Fisheries and Forestry - Australia, Submission no. 24, p. 7.

1.9 Notwithstanding CSIRO's preference for a narrower definition of bioprospecting than is used by most others, the committee has employed the term in its broader sense of the search for valuable chemicals and genetic material. The committee took this decision in order to reflect the way in which the term was most commonly used by those who contributed to the inquiry.

High technology

1.10 The bioproducts that can be developed from the discoveries from bioprospecting vary greatly in the degree of technological sophistication involved in producing them. At the most sophisticated end of the continuum, genetic material might be removed from an organism that produces a useful chemical and placed into microorganisms that can be cultured to mass produce the chemical. Alternatively, a chemical with pharmaceutical activity might be extracted and isolated, its molecular structure identified and modified for greater potency, and a means of synthesising it developed. At the other extreme, plants might be grown for their nutraceutical value, or for the essential oils that can be extracted from them.

1.11 The inquiry's terms of reference required the committee to consider 'high technology industries'. The committee has not confined itself in this report to the most sophisticated bioproducts. It believes that a more useful approach in examining options for regional development is to consider as wide a range of options as possible and to include some 'low technology' industries as well.

Bioindustry development

1.12 In its submission to the inquiry, CSIRO provided the committee with a sketch of the processes by which bioprospecting can lead to the discovery and eventual commercialisation of useful products (Figure 1.1). This sketch clarified for the committee the stages by which biological leads are researched, developed and commercialised as new bioproducts, as well as defining the meaning of the terms used in this process.

1.13 The meanings of many of the other specialist terms used in this report are provided in the glossary.

INSERT FIGURE 1.1 HERE

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Conduct of the inquiry

1.14 The inquiry was advertised at the beginning of November 2000 in capital city newspapers and state rural magazines. In addition, information about the inquiry and requests for submissions were sent to state premiers, territory chief ministers, and Commonwealth ministers and departmental secretaries with an interest in the inquiry topic. Also approached to make submissions were universities and research groups; businesses involved in bioprospecting, bioprocessing and related biotechnologies; and organisations representing primary producers, scientists, business, and environmentalists.

1.15 The committee provided an issues paper to all those invited to make submissions and made it available on the internet.[5] It was intended to assist and stimulate those interested in participating in the inquiry by outlining some of the matters that the committee anticipated the inquiry would address.

1.16 Thirty-nine submissions were received and eight exhibits taken; they are listed in Appendices A and B, respectively. Five public hearings were held in Canberra, one of which was carried out through an audio-visual connection with witnesses in Melbourne and Hobart. Details of these hearings are provided in Appendix C. The committee also met and held discussions with individuals and organisations involved in bioprospecting and businesses arising from it. These discussions occurred in Townsville, Lismore and Canberra. The committee was given further insights into bioprospecting during visits to CSIRO Entomology in Canberra, the Australian Institute of Marine Science (AIMS) in Townsville, and Southern Cross University (SCU) in Lismore. These events are listed in Appendix D.

Report format

1.17 In the next chapter, the committee outlines the potential that it sees in bioprospecting and the industries derived from it. Chapter 3 details the impediments at each stage of the chain of bioindustry development, and discusses ways of overcoming the impediments identified. In Chapter 4, the committee comments on the possibility of regional development based

5 *Bioprospecting and Regional Industry Development in Australia - Some Issues for the Committee's Inquiry*, Information and Research Service of the Department of the Parliamentary Library, 2000.

on bioprospecting. Chapter 5 deals with the impact of bioprospecting and related industries on the environment, and Chapter 6 covers some of the more general issues relevant to the development of biotechnology.

2

Potential for industrial development based on bioprospecting

The need for new products and processes

2.1 New products and industrial processes are needed because many of those currently in use are not sustainable.[1] They are not sustainable for several reasons.

- Supplies of raw materials may be limited, as in the case of petrochemicals which provide the feedstock for many industrial products. A time when oil will no longer be an economical raw material can be foreseen.
- The environmental impacts of current industrial processes are creating increasing problems, including contamination of air, land and water, and contributing to global warming. As the human population on the planet grows, these impacts are likely to become ever more intense unless changes are made.
- In the past, as resistance to commonly used drugs and agrichemicals developed, new products were found. More recently, prospects for development as replacements have been harder to find, and a different approach is called for.

2.2 The world's biota represents a source of raw materials that has the potential to replace petrochemicals as an industrial feedstock and to provide novel chemicals for use in drugs and other products. Australia is well placed to contribute these raw materials and to benefit from their use.

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1 Australian Academy of Science, Submission no.19, p. 1.

Australia's potential

Biological resources

2.3 With 10-13 per cent of the world's biodiversity, Australia is one of the 12 most diverse regions in the world.[2] Its biological resources include plants, animals and microorganisms living on land, below ground, in inland waters, and at sea. Australia's bioregions span a range of climates from tropical to Antarctic and from dry to wet.[3] Their species are adapted to these varied environments, having evolved metabolic pathways that produce the chemicals they need to survive. In such biodiversity, Australia has a rich source of chemicals and their means of production.

2.4 In addition, there is a high level of endemism among Australian species. That is, many of our species occur only in Australia - in the case of plants and animals, 75 per cent of them.[4] Figure 2.1 shows this endemism for several groups of organisms. With the right mix of scientific skill, commercial entrepreneurship and government regulation, Australia can capitalise on this uniqueness for the benefit of the nation.

2.5 We do not yet know how extensive the benefits from our biodiversity are. The soil, rainforests and the marine environment were nominated as probably the richest sources for biodiscovery,[5] but much of the biota is poorly known.[6] However, Australia has a vast exclusive economic zone in the waters surrounding the continent. This zone is the third largest of any country in the world.[7] According to scientists at the AIMS, marine biodiversity, especially from deep sea environments, represents one of the richest sources of novel compounds on the planet.[8]

2 Environment Australia, Transcript of evidence, 4 June 2001, p. 62; Australian Institute of Marine Science, Submission no. 27, p. 1.

3 Associate Professor Robert Capon, University of Melbourne, Submission no. 6, p. 5.

4 CSIRO, Submission no. 14, p. 14.

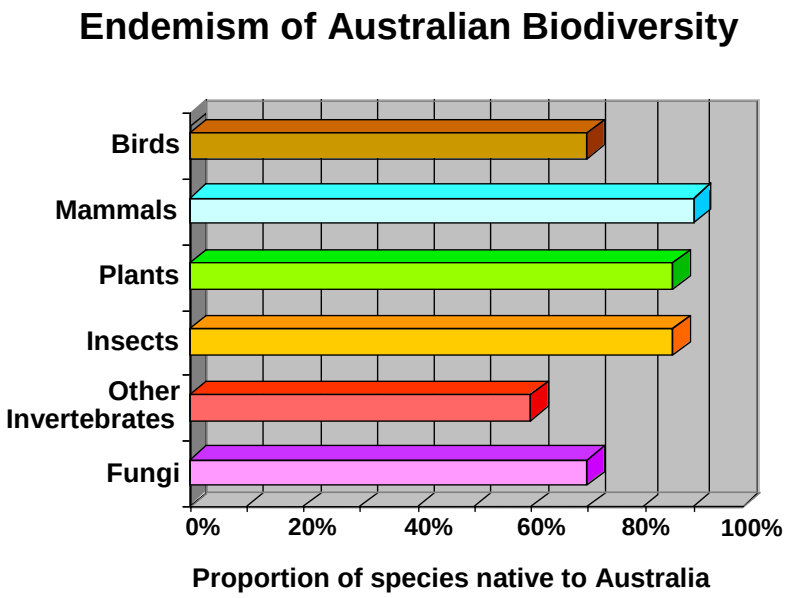
5 Victorian government, Submission no. 34, p. 1.

6 Royal Society of Western Australia Inc., Submission no. 8, p. 1.

7 CSIRO Marine Research, 'Oceans: Our need to know', http://www-ocean.ml.csiro.au/LeafletsFolder/oceansourneedtoknow.html, accessed 10 August 2001.

8 Australian Institute of Marine Science, Committee briefing, 3 May 2001.

Figure 2.1 Endemism of Australian biodiversity



Source: CSIRO, Submission no. 14, p. 14.

Supporting factors

2.6 Australia differs from the other mega biologically diverse regions of the world in being the only one of them that is a developed nation.[9] This gives Australia a head start over these other countries in our capacity to use our biological resources. It also puts us in a good position to compete with other developed countries in developing bioindustries based on biological resources.

2.7 Australia has a well developed science base with the skills, infrastructure and financial resources needed to catalogue the country's biological resources and to perform sophisticated research and development (R&D).[10] State and Commonwealth programs provide support for research into and conservation of biodiversity. Biotechnology R&D is funded by both the public and private sectors. Recent Commonwealth initiatives include the National Biotechnology Strategy (NBS), and the Biotechnology

9 Invest Australia, 'Biotechnology', http://www.isr.gov.au/invest/Industry_Sectors/Biotechnology/biotechnology.html, accessed 10 August 2001; Australian Institute of Marine Science, Submission no. 27, p. 1.

10 CSIRO, Submission no. 14, p. 9; Australian Academy of Science, Submission no. 19, p. 3; EcoBiotics Pty Ltd, Submission no. 18, p.1.

Centre of Excellence and the Biotechnology Innovation Fund announced in *Backing Australia's Ability*.[11]

2.8 Established chemical and biotechnology industries provide the potential for developing biodiscoveries from the local biota. In addition, an innovative, efficient primary industries sector exists that could cultivate any crops from which new chemicals might need to be sourced.[12] A stable political system, uncorrupted public administrative systems, and a well developed legal system provide intellectual property (IP) protection and a regulatory framework for bioprospecting and the commercialisation of biodiscoveries.[13] They also contribute to a financial climate conducive to investment.

Bioprospecting in Australia

2.9 According to Biotechnology Australia (BA), Australia has a relatively immature bioprospecting industry, in which only a small number of companies and organisations are involved. Table 2.1 lists a selection from the companies engaged in bioprospecting to illustrate the range of activity that is occurring. The industry is characterised by networks among companies, and links with universities and large drug and agrichemical companies.[14] Industries based on bioprospecting are, as CSIRO commented, 'only in their infancy'.[15]

2.10 Although significant bioprospecting activity is occurring, much of it results in the sale of unprocessed samples, and the financial returns on these sales are small. According to EcoBiotics, 'overall, the value or return from many of the current bioprospecting activities to the Australian economy and the broader community is highly questionable'.[16] More widespread value adding is needed and is possible.

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11 Biotechnology Australia, Submission no. 25, pp. 13-14; *Backing Australia's Ability: an innovation action plan for the future*, 2001, http://www.isr.gov.au/iap/Policy_Launch/backing_Aust_ability.pdf.

12 CSIRO, Submission no. 14, p. 9; Australian Academy of Science, Submission no. 19, p. 4.

13 Environment Australia, Transcript of evidence, 4 June 2001, p. 62.

14 Biotechnology Australia, Submission no. 25, pp. 5, 8.

15 CSIRO, Submission no. 14, p. 29.

16 EcoBiotics, Submission no. 18, p. 5.

Table 2.1 Some companies and organisations involved in bioprospecting in Australia

Institution	Partners	Research field
Australian Institute of Marine Science	AMRAD, Nufarm, National Cancer Institute	cancer, HIV, neuropathology, infectives
James Cook University	Pharmamar, Biomar	cancer, neuropathology
CSIRO Entomology	Rhone Poulenc Rorer, Biodiscovery	various
CSIRO Bioactive Molecules Initiative		infectives, cardiovascular
Southern Cross University Phytochemistry Centre (SCUCP)		Australian native plants
Flinders University	Novartis	
Venom Supplies Pty Ltd		venoms and venom products
BioProspect Ltd		plant products
Bio-Gene Technology Pty Ltd		various
Australian Phytochemicals Ltd (subsidiary of BioProspect, situated at SCUCP)		plant products
Novogen		legume plant products
University of Melbourne (Marine Natural Products research group)		algae and sponges
Chemistry Centre (WA)		foods, agriculture/ plants, general natural product chemistry
Griffith University	AstraZeneca, Queensland Herbarium and Museum	plant products

Source *Based on Llewellyn, 'Drug discovery from biodiversity in Australia', April 2000, from by Biotechnology Australia, Submission no. 25, p. 9.*

2.11 Several organisations and companies that made submissions to the inquiry are engaged in value adding to their bioprospecting activities. The value adding may include screening extracts from plants, microorganisms and marine organisms for bioactivity, and isolating the active compounds and characterising them. Some of these processes are carried out for the companies' own research programs; others are performed under contract to others.[17]

2.12 An example of value adding was provided by AstraZeneca R&D Griffith University (AZGU) which has collected over 24,000 samples, mostly from Australia. It has also identified the structure of over 460 compounds, of which 37 per cent are new to science. AZGU's high input screening laboratory can process 100,000 samples a week.[18]

17 Cerylid Biosciences, Transcript of evidence, 25 June 2001, pp. 84, 85.

18 AstraZeneca and Griffith University, 'Natural drug discovery in Australia's wilderness laboratory', pamphlet.

2.13 Bioprospecting is largely driven by the demands from subsequent biodiscovery processes, and tends to be cyclical. Bioprospecting activities are currently subdued, with a ready supply of material awaiting screening.[19]

Actual and potential Australian biobased products and processes

2.14 A range of bioproducts are on the market and more are being developed. They include drugs, cosmetics, herbicides, pesticides, and agents for bioremediation and mining.

- CSIRO's submission listed two cases of its work with bioremediation:
  - ⇒ using microorganisms to clean up the toxic effluent from gold mines; and
  - ⇒ removing pesticide residue from the surface of fruit and vegetables, from soil, from industrial wastes, from water, or from human effluents, by adding pesticide-degrading enzymes derived from insects and microorganisms.

  The latter is being commercialised by agreement with Orica.[20]
- Although microorganisms have been used for many years to extract copper and gold from ores, 'the real potential of biotechnology in mining remains to be realized'.[21] CSIRO and others are searching in hot terrestrial and underwater environments for novel microorganisms that can metabolise sulphides at high temperatures. The performance of these organisms may be improved by genetically modifying them.[22]
- CSIRO's work has also led to the production of biopesticides.
  - ⇒ Insect fungal diseases are being used to control insect pests. Biocane was developed from a strain of the soil dwelling fungus, *Metarhizium anisopliae*, and is being marketed to control greyback canegrub, a serious sugarcane pest.[23] Another Metarhizium based product developed by CSIRO is Green Guard for locust and grasshopper

19 Cerylid Biosciences, Transcript of evidence, 25 June 2001, p. 83; CSIRO, Submission no. 14, p. 21; Australian Institute of Marine Science, Submission no. 27, p. 8.

20 CSIRO, Submission no. 14, p. 27.

21 J A Brierley & C L Brierley, 'Present and future commercial applications of biohydrometallurgy', *Hydrometallurgy*, vol. 9(2-3):233-239, 2001 Feb.

22 CSIRO, Committee briefing, 27 November 2000.

23 CSIRO Entomology, 'Bio-control of cane pest a commercial reality', Press release, 2 May 2000.

control, which is being manufactured by Seed Grain and Biotechnology Australia Pty Ltd and tested by the Australian Plague Locust Commission.[24]

⇒ Ecogrow is CSIRO's partner in producing nematodes for the control of turf beetles.[25]

⇒ The *Bt* gene inserted into cotton varieties grown in Australia provides an alternative to applying chemical pesticides as a means of controlling the caterpillars of *Helicoverpa* species.[26]

- BioProspect has identified a Queensland eucalypt, the leaves of which contain compounds with insecticidal properties more powerful than pyrethrum. The same laboratory tests show that it is virtually non toxic to both mammals and plants. A selective breeding program is being commissioned by BioProspect in conjunction with the Queensland Department of Primary Industry, and further development of the compounds will be carried out by multinational companies in collaboration with and under license from BioProspect, but using expertise from Australian universities.[27]

- The extracts of several animals living on the Great Barrier Reef have the ability to selectively kill weedy plants while being harmless to crops. This property makes the active ingredient a potential candidate for use as a herbicide, and is being commercialised by the research team from AIMS and James Cook University (JCU) that discovered it, in association with Nufarm.[28]

- Many marine organisms are protected from damage by UV light by a group of compounds which they can synthesise or accumulate from their diet. The protective qualities of these compounds are the basis for AIMS' work on developing a sunscreen from them.[29]

- An example of the potential for drug development from Australian fauna is provided by the pain killing properties of peptides from cone shell venom. Some of these peptides operate differently from existing

24 'Fungal pesticides', http://www.ento.csiro.au/research/biotech/bot07.htm, accessed 9 February 2001.

25 CSIRO, Committee briefing, 27 November 2000.

26 CSIRO, Committee briefing, 27 November 2000.

27 BioProspect Ltd, Committee briefing, 6 July 2001.

28 Australian Institute of Marine Science, *Annual Report 1999-2000*, p. 15; Australian Institute of Marine Science and James Cook University, Committee briefing, 3-4 May 2001.

29 W C Dunlop, B E Chaler, W M Bandaranayake & J J Wu Won, 'Nature's sunscreen from the Great Barrier Reef, Australia', http://www.aims.gov.au/pages/research/projects/sunscreens/pages/sunscreens02.html, accessed 13 June 2001.

pain killers and offer promise for relief of intractable pain. They are being developed by AMRAD and the University of Queensland (UQ).[30]

2.15 From this small number of examples of biobased products and processes, it is clear that novel results have been obtained. More effective products have resulted, from processes which have less environmental impact, and they cost less than conventionally produced ones.

2.16 Other biobased industries that might be developed either from Australia's biota or from imported stock received relatively little attention in the evidence provided to the inquiry. (Perhaps these industries were not seen as 'high technology', as specified in the terms of reference.) Included here are medicinal plant products and functional foods for which a growing market has been identified. The proposed development of Cellulose Valley based at Lismore in northern New South Wales is based in part on the expansion of crops and processing facilities to supply this market.[31] Australia might also have the capacity to raise crops of plants genetically engineered to produce desirable substances, such as biopolymers.

2.17 Biofuels could become significant if the cost of petrol were to escalate greatly; ethanol is already being produced from sugar cane in small quantities.[32] In addition, large companies like Dupont are developing bioindustries which will use genetically modified bacteria grown on sugar to produce substances, such as polyesters, which are currently produced from petrochemicals. It is envisaged that the bioreactors involved in these industries would be situated regionally.[33]

How big is the potential?

2.18 Submissions to the inquiry were confident about the potential for using Australia's genetic resources.[34] AFFA referred to the 'clear potential for industries based on bioprospecting in Australia', and CSIRO to the 'huge potentials' offered by industries based on bioprospecting.[35] BA asserted

30 'Industry partnership provides next-generation painkilling drugs', http://www.uq.edu.au/research/world-class/collaborations/stories/1.html, accessed 13 June 2001.

31 Southern Cross University, Submission no. 17, p. 1.

32 Biotechnology Australia, Submission no. 25, p. 12.

33 Dupont Australia, Committee briefing, 6 June 2001.

34 For example, Faculty of Natural Resources, Agriculture and Veterinary Science, University of Queensland, Submission no. 31, p.1.

35 Department of Agriculture, Fisheries and Forestry - Australia, Submission no. 25, p. 2; CSIRO, Submission no. 14, p. 29.

that, 'through biotechnologies such as bioprospecting, bioprocessing and related biotechnologies, Australia is developing innovative products and fast-growing enterprises, attracting international investment and creating high-value employment'.[36] AIMS believed that Australia would become ' a world leader in how it facilitates, manages, and brings to commercial reality, discoveries made from bioprospecting'.[37]

2.19 It is well known that the multinational drug companies make very large incomes from successful new drugs, and about a quarter of all drugs have been developed from naturally occurring substances. In 1997, for example, the annual sales revenues from the three top selling drugs of natural origin varied from US$0.9 billion for taxol to US$3.6 billion for Zocor. However, the chance of successfully developing a drug from a natural product falls anywhere between 1:5,000 and 1:10,000, and successful development costs US$231 - 500 million.[38] As little as only 0.1 per cent of genetic resources examined may have potentially useful constituents. In addition, much of the development of drugs is carried out outside Australia, even when the initial discoveries are made here. According to the Western Australian government:

> [Pharmaceutical] production facilities tend to be concentrated in geographic hubs, either close to major markets or where government incentives and / or prevailing socio-economic conditions provide substantial cost savings. Australia does not conform to any of these scenarios.[39]

2.20 It was suggested to the committee that higher returns relative to costs might be generated in Australia from biodiscoveries made for purposes other than drug development. For example, the nematode biopesticide developed by CSIRO raised $200,000 in 1999, and was expected to raise $2 million in 2000-01 and $10 million a year thereafter.[40] Fine chemicals derived from marine organisms are sold for amounts ranging from US$316 to over US$20,000 per milligram.[41]

2.21 Some attempts have been made to estimate the global worth of discoveries that might be made from particular ecosystems. An example is

36 Biotechnology Australia, Submission no. 25, p. 13.

37 Australian Institute of Marine Science, Submission no. 27, p. 1.

38 Environment Australia, Submission no. 29, p. 53, quoting K ten Kate and S A Laird, *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing*, Earthscan Publications, London, 1999.

39 Western Australian government, Submission no. 32, p. 1.

40 CSIRO, Committee briefing, 27 November 2000.

41 Original Oceanz, Smart Ventures Industry Group, Committee briefing, 4 May 2001, quoting Calbiochem catalogue.

US$147 billion for rainforest, a figure that does not include the worth of fungi which is quoted at US$9 billion per year. AIMS pointed out that, given the much greater biodiversity in the sea, it is reasonable to assume that the value of natural products derived from it would be even higher than from rainforest.[42]

2.22 In addition to the economic value of bioprospecting to industry, value may also be extracted by the owner of biological resources in the form of fees paid for samples, annual or flat fee payments for access to particular areas or collections, royalties, and other deals. For example, in an agreement between the Western Australian Department of Conservation and Land Management (CALM) and the company, AMRAD, AMRAD was granted exclusive access to a species of smokebush that yields conocurovone. Conocurovone has anti cancer properties. In return, AMRAD agreed to provide CALM with US$730,000, a share in royalties, and first right of refusal to conduct research on the active compound. AMRAD also provided US$320,000 for further research in Western Australian on smokebush patents.[43]

2.23 It was suggested to the committee that monetary returns to the owner of the resource from these payments are unlikely to be large at this stage, and should not be seen as a significant source of funds.[44] Only a very small proportion of samples lead to the development of successful products, lead times are often long, and the returns from commercial successes may be diluted as they are distributed among various stakeholders.[45] The boom from bioprospecting that was predicted by some in the early 1990s appears not to have eventuated.[46]

2.24 However, while companies are not prepared to make large upfront payments for permission to bioprospect, payments for the recollection of material that yields promising leads can be expected.[47] In addition, royalties from successfully commercialised biodiscoveries can be secured through benefit sharing arrangements. Non monetary benefits, such as increased knowledge about the biota as a result of bioprospecting, also underscore the benefits that ownership of the resource can bring.

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42 Australian Institute of Marine Science, Submission no. 27, p. 18.

43 Environment Australia, Submission no. 29, pp. 24, 52, quoting ten Kate and Laird, 1999.

44 Victorian government, Submission no. 34, p. 2.

45 Environment Australia, Submission no. 29, pp. 28-9.

46 Biotechnology Australia, Submission no. 25, p. 17, quoting 'Bio-prospecting and benefit-sharing', report on a workshop organised by the United Nations Environment and Development and Novartis UK, 1999.

47 Australian Institute of Marine Science, Submission no. 27, pp. 5, 7.

Conclusion

2.25 The views summarised in the last section are optimistic about the potential of bioprospecting to contribute to economic development. They are tempered, however, by some caution about how, and how far, Australia will benefit. The committee is very concerned that this caution may inhibit bioprospecting and the development of industries based on biodiscovery. The committee believes that there is immense potential for Australia to use its biological and the other strengths enumerated earlier in this chapter to compete with the best in the world in an era dominated by biotechnology. This era is in its infancy but growing with immense rapidity. Australia must not be left behind in developing its biological resources, and the skills and knowledge to use them, in what will become the basic industrial technology of the future.

2.26 The committee's intention in compiling this report is to accelerate the nation's progress towards capturing the benefits of bioprospecting through the development of IP and bioindustries. Most of the report is devoted to considering what is needed for Australia to maximise the benefits that flow from bioprospecting, by making best use of its natural advantages and its strengths as an advanced nation.

2.27 The committee believes that it is imperative that bioprospecting and the downstream developments from biodiscovery are incorporated as vital parts of Australia's push to develop industries based on biotechnology. The wide range of applications to which biotechnology can be put offers a great wealth of benefits which Australia must capture fully before others do so. Were Australia to fail in this respect, it would not only deny itself access to the increasing revenues that can be expected from bioprospecting and bioprocessing, but also to improvements to individual health and welfare and to the environment.

3

Overcoming impediments in establishing Australian bioindustries

Introduction

3.1 The reader is referred to Figure 1.1 which shows the stages that lead to the establishment of bioindustries from bioprospecting. The committee has used this framework to guide the organisation of this chapter. In this chapter, the committee discusses the impediments that stand in the way of Australia capitalising on its biological potential, and how these impediments might be overcome.

3.2 The committee noted at the outset of the inquiry that some of the impediments to establishing bioindustries in Australia, were similar to those it had identified in two of its previous inquiries:

- the inquiry into infrastructure and the development of Australia's regional areas;[1] and
- the inquiry into primary producer access to gene technology.[2]

Between them, these two reports covered such issues as telecommunications infrastructure, the protection of IP, government support for R&D and its commercialisation, and public awareness of the issues raised by the use of biotechnology. These matters were discussed in

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1 House of Representatives Standing Committee on Primary Industries and Regional Services, *Time Running Out: Shaping Regional Australia's Future*, February 2000.

2 House of Representatives Standing Committee on Primary Industries and Regional Services, *Work in Progress: Proceed with Caution: Primary Producer Access to Gene Technology*, June 2000.

detail and recommendations directed to the government about how they might be better addressed.

3.3 The committee does not propose to consider these topics again in detail. This does not reflect any judgement by the committee that these topics are unimportant. It is an acknowledgment of the fact that more will be gained for industries based on bioprospecting by concentrating in this report on new issues that have been raised with the committee for the first time.

3.4 The committee has identified the following as issues that deserve special attention:

- the information available about Australia's biological resources;
- getting access to these resources and sharing the benefits from the discoveries derived from bioprospecting; and
- biodiscovery, bioprocessing and bioindustries.

A significant part of this chapter is taken up by access and benefit sharing issues, including uncertainties about the ownership of resources, establishing a nationally consistent regime, exclusive contracts to use resources, indigenous rights, and the export of Australian biota.

The knowledge base

3.5 Anyone wanting to undertake bioprospecting starts by reviewing what is known about the biota. This is possible only if the information has been collected, and is accessible.

3.6 There are many ecosystems in Australia that are not well known, and will not be until detailed surveys have been carried out.[3] This is particularly true of Australia's vast marine areas. Accumulating knowledge about Australia's biological resources is fundamental to Australia's capacity to build industries based on our native biota. It requires investment at early stages of bioprospecting.[4]

3.7 Information about Australia's biological resources is held in collections in herbaria, museums, public research institutions and businesses such as BioProspect and Cerylid Biosciences. The collections include DNA, plants, seeds, microorganisms, and marine animals, among others, as well as extracts from these organisms. In addition to the physical samples held in

3 Royal Society of Western Australia Inc., Submission no. 8, p. 1.

4 Australian Institute of Marine Science, Exhibit no. 2.

these collections is information about where and when they were collected and their identity, if known. Further information, such as their ecology and chemistry, may also be available.

3.8 Several deficiencies in Australia's information base were brought to the committee's attention. The information base is not comprehensive,[5] and much of the Australian biota is poorly known. Tens of thousands of species have still to be described, particularly among the microorganisms.[6] Yet relatively little taxonomic work is being carried out and there is a shortage of taxonomists in the country.[7]

3.9 Australia's collections need to be more adequately funded if they are to be better sources of information for bioprospectors,[8] as well for the managers who are charged with the conservation of biological resources. With more information available, there are greater prospects of success in identifying useful leads and conserving the ecosystems from which they come.[9] The information is also needed to enable further collection of the same source material, and to confirm the origin and ownership of any IP developed from the lead. Some of these points are illustrated in Box 3.1.

3.10 Scientists are using ecology driven bioprospecting based on two closely related ideas from evolutionary biology and ecology.

> The first is that specific molecules such as antimicrobials have evolved repeatedly and are deployed in a wide variety of ecological situations. … Second, although we are in the era of combinatorial chemistry, it is reasonable to suggest that evolution by natural selection is a natural analogue of this process that has been operating for hundreds of millions of years. … this suggests that the first phase of discovery is likely to be enhanced by the use of evolutionary and ecological modes of thought, employing the vast databases of natural history.[10]

Knowing what is in those 'vast databases of natural history' is obviously critical to success in bioprospecting.

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5 For example, Environment Australia, Submission no. 29, p. 48.

6 ExGenix Operations Pty Ltd (Cerylid Biosciences Ltd), Submission no. 13, p. 1; The Australian Society for Microbiology, Transcript of evidence, 25 June 2001, p. 88.

7 Northern Territory government, Submission no. 4, p. 6; Australian Academy of Science, Submission no. 19, p. 2; Royal Society of Western Australia Inc., Submission no. 8, p. 1.

8 Australian Academy of Science, Submission no. 19, p. 5.

9 Australian Institute of Marine Science, Submission no. 27, pp. 7, 17.

10 Professor A J Beattie, Submission no. 5, p. 1.

Box 3.1 Better information produces greater bioprospecting success

AIMS scientists told the committee that understanding marine chemical ecology and taxonomy can improve the odds of obtaining positive leads by 50-60 per cent. A similar situation exists with the clever use of knowledge about the ecology of tropical forests. Relying on this knowledge has given Ecobiotics a bioactivity hit rate in more than 67 per cent of samples, compared with less than eight per cent from 'traditional', non targeted bioprospecting.

By contrast, insufficient knowledge can hamper bioprospecting and biodiscovery. The committee was told of a 10 year delay in the development of the anti tumour drug, Bryostatin I, because of poor initial studies of the bryozoan from which it was sourced. Researchers failed to distinguish between different subspecies of bryozoan when the original collection was made, and they subsequently recollected and attempted further work on the wrong one.

Sources: Australian Institute of Marine Science, Committee briefing, 3 May 2001; Submission no. 27, pp. 13-14; EcoBiotics, Submission no. 18, p. 5.

3.11 Funding for making and maintaining collections has traditionally come from government. However, agreements are now being struck between public agencies and businesses involved in bioprospecting and biodiscovery, in which the businesses contribute to the work of the collecting institutions, or maintain their own collections. For example, specimens may be maintained in local herbaria which will allow the identity of new material to be verified.[11] Alternatively (or in addition), payments of the kind described in Chapter 2 may be made.

3.12 While payments for samples can contribute to the effort of public collecting institutions, the payments are often inadequate to build good collections.[12] Public funding is essential. Yet the committee received evidence of declining government support for bioprospecting and biodiscovery in Commonwealth institutions. For example, since the imposition of the efficiency dividend, AIMS has lost $1-1.5 million from its budget, and has been unable to hire new staff for at least five years. The committee also heard about the urgent need for additional funding for a national collection of microorganisms (Box 3.2).

11 Environment Australia, Submission no. 29, p. 25.

12 Australian Institute of Marine Science, Submission no. 27, pp. 3, 13.

Box 3.2 Collections of microorganisms

Microorganisms are the major source of antimicrobial agents, as well as producing other important pharmaceutical and therapeutic compounds. Products derived from microorganisms net US$35-50 billion annually in sales. Attention has turned in recent years to extremophiles (microorganisms from very hot, cold, acid, alkaline, salty or arid environments) as sources of novel substances and processes. Microbial collections are therefore a 'real biotechnological resource'.

An example of such a collection is the Australian Collection of Antarctic Microorganisms, which is dedicated to strains isolated from the Antarctic continent, subantarctic islands and the Southern Ocean. It currently holds about 5,000 Antarctic microorganisms, which exhibit a high degree of endemism and represent adaptations to extreme environments. They have already yielded leads to pharmaceuticals and polyunsaturated fatty acid production.

Another valuable culture collection is held by the Dairy Research and Development Corporation's Australian Starter Culture Research Centre, which very cost effectively supplies most of the Australian dairy industry's needs for cheese and yoghurt. Other special purpose collections are also maintained in other industries, and by state and territory governments for agricultural, medical and veterinary purposes.

In total, Australia has about 50 collections, which in 1998 maintained 65,000 cultures. It does not, however, have a national collection of microorganisms, nor adequate, accessible databases of information about the contents of the existing collections. In this, Australia differs from most developed and a few developing countries.

Australia's largest collection is at UQ, although, according to the Australian Society for Microbiology (ASM), 'that collection is now just about moribund'. As public funds have been withdrawn, its staffing has fallen from two to 0.5 and it now operates on the basis of full cost recovery. Overseas collections are substantially better staffed and 'recover around 25 per cent of their operational costs from sales and the balance is provided by government as an essential infrastructure requirement of science and industry'.

The curator of the UQ collection suggested that Australia needed 'a properly funded national collection to coordinate culture needs for science and industry in Australia and provide [a] range of services … underpinned by a network of specialists research collections'. ASM also recommended the creation of 'a national repository of organisms for biotechnological opportunities that allows us to protect the investment that has been made in collecting and preserving those organisms and to maintain their potential'. ASM estimated that the collection would require annual funding of one million dollars from public and private sources. An alternative model would involve a central coordinating centre for several physically distinct collections.

Source: Australian Society for Microbiology, Submission no. 10, pp. 2-4; Transcript of evidence, 25 June 2001, pp. 94-6; L I Sly, 'Australian microbial resources', *Microbiology Australia*, vol. 19(1), 27-35, 1998; Submission no. 37, p. 1.

3.13 Moves are under way to link scattered collections around the country. A virtual herbarium is being established by the state, territory and Commonwealth herbaria,[13] and links between other databases are mooted. For example, the committee was told of a proposal to set up a novel type of centre to serve biodiscovery and biodiversity conservation based on links between collections and databases. The proposed Australian Biodiversity and Biodiscovery Resource Centre (ABBRC) is described in Box 3.3. It was recently unsuccessful in a bid for funding from the Commonwealth government's Major National Research Facilities (MNRF) Program.

Box 3.3 A proposed Australian Biodiversity and Biodiscovery Resource Centre

The proposed ABBRC would comprise a complete library of research material from Australia's terrestrial and marine flora. It would act as a one stop shop for bioinformation, DNA and extract materials for commercial and non commercial research. As such, it would contribute to the conservation of the native flora, and drive the identification and development of the flora's commercial potential. ABBRC's establishment would also help to eliminate duplication of resources.

ABBRC would be based at Cellulose Valley, adjacent to SCU, which has centres for phytochemistry and plant genetic conservation. These centres are establishing plant DNA and plant extract banks. ABBRC would link SCU with:

- the Queensland Herbarium;
- JCU, which has expertise with biological databases;
- AIMS, which has the largest collection of marine extracts in the southern hemisphere, curated specifically for bioprospecting;
- the companies, BioProspect and its subsidiary, Australian Phytochemicals Ltd, which collect flora and supply extracts under agreements with state and territory governments; and
- other parties in the future, such as other Australian herbaria.

It is anticipated that ABBRC would require public funding for the first five years, but would then be self funded from access fees and royalties. It would be expanded in the future to cover the Australasian fauna as well as significant agricultural and horticultural species.

Source: Southern Cross University and Bioprospect Pty Ltd, Committee briefing, 6 July 2001.

13 Environment Australia, Submission no. 29, p. 15.

3.14 CSIRO also stressed the importance of building linkages between databases. It referred to the Global Biodiversity Information Facility (GBIF), which will provide electronic access to information held in separate collections, and pointed out:

> The ability to datamine biodiversity information across separate databases through GBIF for the first time will be a very powerful tool to source new information about where valuable traits can be found.[14]

> Progress in biodiversity informatics will enhance its predictive power and value of biodiversity knowledge to bioindustries.[15]

Others also made this point to the committee.[16]

3.15 The committee believes that it is important for Australia to have a well resourced, well coordinated system in place for **building its national collections and associated databases, with support from sufficient skilled personnel and appropriate infrastructure**. Ensuring that funding for such a system is available is the responsibility of government. Better government funding, with coinvestment by the private sector, is needed to give the basic support for bioprospecting that good information provides.[17] Government funds should be supplemented by the private sector as part of any permit issued for access to resources.

Recommendation 1

3.16 The committee recommends that the Commonwealth government:

- **increase funding for baseline studies of the Australian biota;**
- **target additional funds for collecting activities in bioactive hot spots;**
- **fund a larger volume of taxonomic work than at present and ensure sufficient young taxonomists are being trained to undertake this work;**

14 CSIRO, Submission no. 14, p. 12.

15 CSIRO, Submission no. 14, p. 20.

16 Australian Institute of Marine Science, Exhibit no. 2; Southern Cross University and BioProspect Pty Ltd, Committee briefing, 6 July 2001.

17 AstraZeneca R&D Griffith University, Submission no. 33, p. 2.

- **provide more funding to maintain and expand existing collections so that they provide a comprehensive coverage of Australia's biota, including microorganisms; and**
- **ensure that commercial users contribute in kind or financially, through benefit sharing arrangements, to growing and maintaining collections and databases.**

3.17 The committee is also concerned that the information available about Australia's biological resources be as accessible as possible. It recognises the efforts that are being made to coordinate and network national databases, but notes CSIRO's comment that 'the capacity to digitise and verify the information currently held in paper records' is a limiting factor.[18]

Recommendation 2

3.18 The committee recommends that the Commonwealth government provide additional funding for digitising and networking information about all of Australia's biological resources.

3.19 CSIRO reported to the committee that 'in the area of *biodiversity informatics*, Australian science is at the forefront' and 'technologically … in a good position to keep up with advances in this area'. For example, Australia is chairing the group that is establishing GBIF in Denmark.[19]

3.20 However, CSIRO also sounded some notes of caution in relation to Australia's capacity to undertake bioinformatics. (Bioinformatics involves the use of powerful computational and statistical techniques to process a wealth of biological information for particular research purposes. For a fuller definition see the glossary.) This is a serious issue affecting the national capacity to provide platform technologies for biotechnology.

- There is a 'critical shortage of people with the prerequisite skills and capabilities' in bioinformatics. Although steps are being taken to address the shortage of skilled people, CSIRO suggested that more needed to be done.

18 CSIRO, Submission no. 14, p. 20.

19 CSIRO, Submission no. 14, pp. 12, 20, 29.

- Attempts to bring together all those with an interest in bioinformatics have failed so far. CSIRO described how each of the states is independently developing a capacity in biotechnology when sharing core capacities would be more effective. Such sharing could be achieved with funding from the Commonwealth government. In such a situation, competitive funding models may not be the most effective way of providing national capabilities.[20]

CSIRO recommended 'the development of a national strategy for bioinformatics to deliver core skills and data access to Australian R&D organisations'.[21]

Recommendation 3

3.21 The committee recommends that the Commonwealth government, in consultation with state and territory governments, industry and the research community:

- **develop a national strategy for bioinformatics; and**
- **assist in funding its implementation so that the necessary infrastructure and skills are available to provide efficient access to information about Australia's biota.**

3.22 While Australia is relatively well placed in relation to biodiversity informatics, the same is not true of molecular informatics. (Molecular informatics is a branch of bioinformatics that deals with complex datasets in molecular biology and genetics to discover how specific genes express desired traits.) CSIRO drew attention to the fact that molecular bioinformatics are largely in private hands overseas. Australians need to be able to gain access to these data on favourable terms, and 'the bargaining chip that would be most effective would be collaborative arrangements in which we contribute to these databases with annotations relevant to our own biodiversity' from our own databases.[22]

20 CSIRO, Submission no. 14, pp. 12, 20; Transcript of evidence, 4 April 2001, pp. 40-41, 45.

21 CSIRO, Submission no. 14, p. 29.

22 CSIRO, Submission no. 14, pp. 4, 12, 20.

Getting access to biological resources

3.23 It is critical that all involved in the bioproduct development chain have confidence that access to biological resources can be gained swiftly, in such a way that the resources are used sustainably and the right to use them is absolutely secure. This is not currently the case in Australia, but needs to be.

3.24 The committee notes that large businesses, such as pharmaceutical companies, are increasingly requiring evidence of legality and certainty of title before investing large sums in developing products.[23] If this evidence is not available, or accessing resources is very time consuming and complex, overseas companies will go elsewhere and Australian companies, especially small ones, will be deterred.[24]

3.25 Difficulties in getting access to biological resources are a critical issue, and one of the most obvious and immediate impediments to bioprospecting in Australia.[25] The difficulties arise for a number of reasons.

- The ownership of the resources is complex and unclear.
- Different jurisdictions have different rules.
- The legislation governing access has often been developed for purposes other than bioprospecting; as a result, it does not immediately address bioprospectors' needs.[26] In addition, responsibilities for issuing the permits required by bioprospectors are often split between several agencies.[27]

3.26 As a result of the factors listed above, obtaining a permit to access resources may mean making many applications in different jurisdictions or to several agencies within one jurisdiction. Very long delays in granting permits have also been encountered, for example, two years to collect Antarctic microorganisms.[28] EA commented that:

> Obtaining permits is time consuming and complicated by the number of separate jurisdictions that control access. The different

23 J Voumard, *Access to Biological Resources in Commonwealth Areas*, Commonwealth of Australia, July 2000, p. 134.

24 Original Oceanz, Smart Ventures Industry Group, Committee briefing by 4 May 2001; Environment Australia, Transcript of evidence, 4 June 2001, p. 60.

25 Australian Institute of Marine Science, Submission no. 27, p. 13.

26 Environment Australia, Transcript of evidence, 4 June 2001, pp. 59-60.

27 Australian Institute of Marine Science, Committee briefing, 3 May 2001.

28 The Australian Society for Microbiology, Submission no. 10, p. 5.

> 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.[29]

3.27 These features of the access regimes currently in place were generally seen as a deterrent to businesses, particularly to smaller companies. In addition, the lack of uniformity between jurisdictions does not serve the national interest in that it may encourage bioprospectors to shop around for the best deal.

3.28 The cumbersome nature of current access regimes also fails to promote the conservation of resources as EA pointed out:

> 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.[30]

3.29 In light of the consensus in the evidence received by the committee, it was surprising to find AFFA contesting the view that access regimes can significantly affect the ease with which bioprospecting can be undertaken.

> Claims are made that access to the natural environment to search for and collect suitable material to assay is problematic, and that lack of clear title to the natural resources involved contributes to uncertainty and is a disincentive to undertaking bioprospecting activities. However, their potential impact is largely untested in the overall understanding of the broad range of factors affecting bioprospecting in Australia.[31]

3.30 The committee acknowledges the point made by the Great Barrier Reef Marine Park Authority that part of the delay in its issuing of access permits (two months to several years) is the time it takes to undertake a rigorous assessment. (Statutory waiting periods as specified in native title legislation also contribute to delays.) A rigorous environmental assessment is obviously important.[32]

3.31 The committee also noted that the two year delay referred to above in relation to Antarctic resources was due to the application for access being the first of its kind.

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29 Environment Australia, Submission no. 29, p. 50.

30 Environment Australia, Submission no. 29, p. 51.

31 Department of Agriculture, Fisheries and Forestry - Australia, Submission no. 24, p. 2.

32 Great Barrier Reef Marine Park Authority, Committee briefing, 4 May 2001.

> As a result of Australia's international commitments, it took about two years to arrive at a decision which would allow us to collect the samples and for those samples to be passed on to [a commercial organisation]. The major difficulty was the notion of exclusivity and the fact that Antarctica, under the Madrid protocol, is a world resource and no-one is supposed to have exclusivity of the resources from Antarctica.

ASM told the committee that eventual advice from the Department of Foreign Affairs and Trade and the Attorney-General's Department was that:

> … the actual soil or water samples that we took from Antarctica could not be given exclusively to a commercial organisation. But if we used our skills, our expertise, to isolate micro-organisms from those samples, then that was not infringing the Madrid protocol and those micro-organisms that we isolated from the samples could in fact be given to a commercial organisation.[33]

Ownership

3.32 Several submissions to the inquiry claimed that the ownership of biological resources is unclear, and urged that it be resolved.[34] Others commented on its complexity.[35] The ownership of microorganisms and marine and Antarctic resources were mentioned as presenting particular challenges, as was the question of indigenous rights.[36]

3.33 Similar observations were made to the Voumard inquiry into access to biological resources in Commonwealth areas, which reported in July 2000.[37] The report commented on 'a lack of understanding about who owns the resources'. It provided advice on 'the legal status of the elements of the terrestrial and marine biota affected by differing forms [of] land tenures and sovereignty in Commonwealth areas'.

> The effect of the advice is that in all Commonwealth areas, it is possible to determine either a legal owner of biological resources

33 The Australian Society for Microbiology, Transcript of evidence, 25 June 2001, p. 91.

34 EcoBiotics Pty Ltd, Submission no. 18, p. 1; ExGenix Operations Pty Ltd (Cerylid Biosciences Ltd), Submission no. 13, p. 2.

35 Australian Institute of Marine Science, Committee briefing, 4 May 2001.

36 Northern Territory government, Submission no. 4, p. 4; The Australian Society for Microbiology, Submission no. 10, p. 5.

37 In 1999 Senator Hill, Minister for the Environment asked John Voumard to carry out an inquiry into access to biological resources in Commonwealth areas which reported the following year (see footnote 23, this chapter).

> or a holder of the sovereign authority to control access and derive benefits from the biological resources.[38]

3.34 The committee believes that the advice provided in the Voumard report should be widely available. It is important that the perception of uncertainty and complexity is dispelled as far as possible as both are deterrents to making agreements about bioprospecting, and investing in it and the industries derived from it.

3.35 The Voumard report dealt only with areas under Commonwealth control. However, the lack of clarity about ownership applies to areas under state and territory jurisdiction as well. In addition, the legislative details vary from state to state. The committee notes that BA, as the manager of the NBS, has as one of its goals, resolving the legal issues surrounding the ownership of Australian biological resources.[39] The committee believes that BA should work with the Attorney-General's Department to ensure that information about ownership of biological resources in both public and private possession throughout Australia is compiled. This information should be available from a single, easily accessible source.

Recommendation 4

3.36 The committee recommends that Biotechnology Australia and the Attorney-General's Department, in conjunction with the state and territory governments, ensure that information about the ownership of biological resources is compiled, and made publicly available as a single, easily accessible source.

3.37 The Australian Property Institute (API) pointed out that ill defined rights in biota already reside with private landowners. It suggested that these should be recognised as 'property rights … constructed in such a way that they have features common to other more traditional property'. The API preferred the creation of privately held biota property rights to the option of government ownership of flora and fauna and licensing their use.[40] A South Australian government discussion paper on access to biological resources considered vesting the state's indigenous flora and fauna in the

38 J Voumard, p. 41.

39 Biotechnology Australia, Submission no. 25, p. 21.

40 Australian Property Institute, Submission no. 20, p. 8.

Crown, using mining legislation as a template.[41] The paper rejected this option.

3.38 The committee is not in a position on the basis of input to the inquiry to come to any conclusions about the need for changes to property right regimes in relation to bioprospecting. The committee is aware that economic growth can be facilitated by well defined property rights and the creation of new ones, particularly if they are nationally consistent. Changes to the existing regime of property rights might very effectively encourage the development of biobased industries in Australia, and position the country well in a bioindustrially dominated future.

3.39 The committee recognises, however, that any change to property rights is a complex matter and needs full and careful consideration. It believes that this matter should be researched and a report prepared by the Australian Law Reform Commission. This report could serve as the basis for discussion between the Commonwealth, state and territory governments and public consultation.

Recommendation 5

3.40 The committee recommends that the Attorney-General ask the Australian Law Reform Commission:

- **to inquire into the impact on the use of native biota of the different property rights regimes across Australia; and**
- **to recommend on a nationally consistent regime that would facilitate this use, with due consideration of the wider ramifications of any changes.**

A nationally consistent access regime

3.41 The committee was told repeatedly of the need to establish a nationally consistent access regime for Australia's biological resources.[42] EA, for example, claimed that:

41 *Access to Biological Resources in South Australia: A Discussion Paper for Public Comment*, Department for Environment and Heritage, Government of South Australia, 2000, p. iii.

42 For example, CSIRO, Submission no. 14, pp. 13-14; ExGenix Operations Pty Ltd (Cerylid Biosciences Ltd), Submission no. 13, p. 2.

> … 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.[43]

3.42 CSIRO commented that:

> … national consistency in the various State and Commonwealth permit schemes regulating access to biological resources must be achieved as a matter of urgency. This is particularly relevant to bioprospecting, as there are at present significant variations in both policy objectives and administrative systems between all jurisdictions. As a result, there is a real risk of international bioprospectors "shopping" between the various jurisdictions to suit their own needs.[44]

3.43 The need for a nationally consistent approach was recognised more than five years ago but progress in establishing it has been slow.[45] The South Australian government refers to the frustratingly long time taken to establish policy and the jurisdictional and legislative framework. Incidents of biopiracy demonstrate 'the need for an internationally / universal and national legislative and operating framework'.[46]

3.44 The committee notes that, under the NBS, renewed moves are under way to harmonise state, territory and Commonwealth arrangements. One element of these moves is the development of an access regime for Commonwealth areas which will be 'broadly compatible with existing and possible future State and Territory regimes'.[47]

3.45 The Voumard inquiry made recommendations about the nature of the regulations to be made under the *Environment Protection and Biodiversity Conservation Act 1999* (EPBC Act) for access to Commonwealth biological resources. The inquiry consulted widely, including with state and territory governments, before developing its recommendations for the access

43 Environment Australia, Submission no. 29, p. 5.

44 CSIRO, Submission no. 14, p. 21.

45 J Voumard, pp. 27-31. Following Australia's signature of the CBD, papers on access to biological resources were prepared by the Australian and New Zealand Environment and Conservation Council and the Chief Scientist. They were followed in 1994 by the setting up of a Commonwealth-state working group to consider the matter further. This group reported in 1996, its report was released in 1998, and submissions called for, but little further action had been taken by the time the Voumard inquiry was set up in December 1999.

46 South Australian government, Submission no. 28, p. 5.

47 J Voumard, p. 3.

framework. A wide ranging consultative process is also planned for the draft Commonwealth regulations once they are released. The committee believes that this is a useful approach to facilitating the development of nationally consistent arrangements.

3.46 As part of the harmonisation of arrangements, the committee believes that it is important to have a single point of information about the arrangements for applying for access permits anywhere in Australia. As Cerylid Biosciences commented, 'what would be helpful would be to make it easier to know who are the bodies that you need to talk to'.[48] It is also important that the permit system be streamlined, for example, with a single permit application acceptable to all jurisdictions and agencies.[49]

Recommendation 6

3.47 The committee recommends that Environment Australia, in consultation with state and territory agencies:

- **develop an electronic gateway to information about access arrangements in all jurisdictions; and**
- **take a lead in coordinating the development of a simplified, streamlined system of applying for permits.**

Benefit sharing

3.48 One of the factors that has complicated and slowed the granting of access to biological resources has been uncertainty on the part of those granting access permits about the benefits that should be required from bioprospectors, should commercialisable discoveries result. The emphasis on benefit sharing is relatively new and flows from the Convention on Biological Diversity (CBD).

3.49 The CBD, to which Australia is a signatory, came into force in 1993. With its introduction, the view that the world's genetic resources are the common heritage of mankind changed. Now, 'the conservation of biological diversity is a common concern of mankind'. This conceptual

48 Cerylid Biosciences, Transcript of evidence, 25 June 2001, p. 83.

49 Australian Institute of Marine Science, Committee briefing, 3 May 2001; Australian Academy of Science, Submission no. 19, p. 2.

shift led to the need to affirm national sovereignty over genetic resources, and the Convention provides the framework in international law under which national policies and legislation on access and benefit sharing are developed.[50]

3.50 EA pointed out that, while legislation exists in Commonwealth areas to control access to resources, 'there is generally less or no provision for benefit sharing arising from the use of these resources'.[51] A similar situation exists in South Australia.[52]

3.51 Uncertainty about, or overblown expectations of, the benefits that might be expected from the resources under their control has led some agencies in the past to delay the issue of access permits.[53] In some cases reported to the committee, the delays caused have amounted to many years.[54] In other cases, they have led prospective bioprospectors to work on material sourced from other countries. In both situations, Australia has failed to benefit from potential leads, and both in Australia and overseas, a perception has formed that Australia is a difficult place to bioprospect.[55]

3.52 Experience is now being gained in the development of benefit sharing arrangements. A number of them are listed in several submissions to the inquiry.[56] Notable among the agreements that have been concluded is that between AIMS and the Queensland government, which has been taken as a model for use internationally. The key element, from AIMS' point of view, was the separation of granting permits (on the basis of environmental considerations) from negotiating the benefit sharing arrangements with the owner (the Queensland government).[57]

3.53 The Voumard report made recommendations about an access and benefit sharing scheme for use in Commonwealth areas and as a possible model for other jurisdictions, where needed. The scheme provides that a person seeking access to Commonwealth areas would apply to EA for a permit.

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50 Environment Australia, Submission no. 29, p. 8.

51 Environment Australia, Submission no. 29, p. 19.

52 *Access to Biological Resources in South Australia A Discussion Paper for Public Comment*, Department for Environment and Heritage, Government of South Australia, 2000, p. 7.

53 Committee briefing by Original Oceanz, Smart Ventures Industry Group, 4 May 2001.

54 Australian Institute of Marine Science, Submission no. 27, p. 7.

55 Australian Institute of Marine Science, Committee briefing, 3 May 2001; Original Oceanz, Smart Ventures Industry Group, Committee briefing, 4 May 2001.

56 Northern Territory government, Submission no. 4, p. 4; Environment Australia, Submission no. 29, pp. 20-6; AstraZeneca R&D Griffith University, Submission no. 33, p. 2; BioProspect Limited, Submission no. 12, pp. 1-2.

57 Australian Institute of Marine Science, Committee briefing, 3 May 2001; Submission no. 27, p. 1.

He/she would negotiate a benefit sharing arrangement with the resource owner while waiting for the access permit to be issued. Before issuing the permit, the Minister must be satisfied, among other things, that there is a benefit sharing contract.[58]

3.54 A model benefit sharing contract is being developed by EA:

- to promote parties' understanding of the issues;
- to facilitate negotiations and agreement between them; and
- to promote certainty for industry by ensuring that agreements are based on prior informed consent, mutually agreed terms and adequate benefit-sharing arrangements, which will in turn provide an agreed set of standards against which industry's performance can be judged.[59]

The model contract will also help to reduce transaction costs and times.[60] EA saw such contracts as being of particular use to smaller companies that may not have many resources to devote to contract negotiations.

3.55 The benefits flowing from benefit sharing agreements may be monetary or non monetary. Some of the benefits most frequently demanded in evidence to the committee were the lodging and maintenance of specimens of bioprospected material in state institutions.[61] AZGU suggested that collecting should be restricted to professional agencies that can house specimens and undertake taxonomic work. Such an arrangement is used by several companies, including AZGU.[62] Additional information, derived as a result of bioprospecting, should also be made publicly available, subject to it not being commercial in confidence.[63]

3.56 Another demand was for royalties or up front payments by bioprospectors to be dedicated to conservation and research activities, or returned to the region of origin of the material. Agreements may also specify that downstream development from bioprospecting be carried out locally.[64]

3.57 The committee understands that the model benefit sharing contract will allow for flexibility in negotiations between resource owner and bioprospector. A menu of possible matters to consider for inclusion might

58 Environment Australia, Submission no. 29, pp. 39-40.

59 J Voumard, p. 103. More detailed information about the scheme is available in Appendix E.

60 Environment Australia, Transcript of evidence, 4 June 2001, pp. 60, 63.

61 For example, Royal Society of Western Australia Inc., Submission no. 8, p. 1; Royal Botanic Gardens Sydney, no. 1, p. 1.

62 AstraZeneca R&D Griffith University, Submission no. 33, p. 2.

63 Victorian government, Submission no. 34, p. 2.

64 BioProspect Limited, Submission no. 12, p. 3.

be made available for guidance.[65] The nature of a company's obligations under a contract will be influenced by the resource owners' IP and other contributions to discovery, as well as the owners' particular interests in each case. Different conditions will be imposed depending on whether the highest priority is, for example, conservation, regional development, or monetary returns.[66]

3.58 The committee noted that BioProspect has finalised access and benefit sharing contracts with the Western Australia and Queensland governments and is negotiating similar ones with the governments of the other states and the Northern Territory. Among the benefits that flow to the states under the agreements with BioProspect are:

- the collection of samples under strict protocols and state control which ensure the conditions of the CBD are met;
- payment to the states of 10 per cent of BioProspect's gross receipts from royalty and milestone payments made by the businesses to which BioProspect licenses extracts;
- the vesting of any IP patented in the name of the state of origin of the material, while giving BioProspect and its licensees exclusive rights to develop patents;
- undertaking as much further development of any biodiscoveries in the state of origin; and
- meeting performance criteria for screening and commercialisation activity.[67]

Criticism of the proposed access and benefit sharing scheme

3.59 The committee is aware that industry and some in the research community would not normally enter into serious benefit sharing negotiations until a biologically active molecule is found. For these organisations, the scheme recommended by Voumard would undoubtedly add to the bureaucratic processes with which they would have to deal. It might also adversely affect the way in which Commonwealth collections or collections sourced from Commonwealth areas are managed and any research activities using these collections, including plant breeding.

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65 Environment Australia, Transcript of evidence, 4 June 2001, pp. 66-9, 74.

66 Australian Institute of Marine Science, Submission to the Voumard inquiry, p. 7; Committee briefing, 3 May 2001.

67 BioProspect Ltd, Submission no. 17, p. 1-3; Committee briefing, 6 July 2001.

3.60 AFFA raised with the committee some concerns about the access and benefit sharing regime recommended by the Voumard report. AFFA was concerned that the proposed regime:

- might alter existing property rights and interfere with IP rights (or least give that appearance);
- might jeopardise Australia's ability to access genetic material from overseas for crop improvement; and
- was too onerous.[68]

3.61 At present, the FAO International Understanding on Plant Genetic Resources (IUPGR) is a non binding agreement that provides for unrestricted access to plant genetic resources. It is in the final stages of being revised to bring it into line with the CBD.

> The draft revised Undertaking attempts to maintain relatively unrestricted access to biological material under the control of governments in the public domain while securing reasonable benefits, particularly for developing countries which provide significant sources of agricultural biological material for development and research in developed countries.

If adopted, the Undertaking would be a binding agreement that would stipulate the payment of benefits into an international account by recipients who commercialise research based on material covered by the Undertaking. Material in public *ex situ* collections is expected to be free of charge.[69]

3.62 AFFA claimed that:

> … while such international developments do not preclude the application of an access and benefit sharing system in Australia, the need to reconcile any domestic system with such international developments is highly important to avoid having two systems of access and benefit sharing operating in Australia.[70]

3.63 Furthermore, Australia is 'a significant net beneficiary' from the current and likely future multilateral system for the exchange of plant genetic

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68 Department of Agriculture, Fisheries and Forestry – Australia, Supplementary submission, no. 36, pp. 11, 12.

69 Department of Agriculture, Fisheries and Forestry – Australia, Supplementary submission, no. 36, pp. 6-7.

70 Department of Agriculture, Fisheries and Forestry - Australia, Supplementary submission no. 36, p. 7.

resource.[71] 'If Australia were to charge for access to public biological material we should not be surprised if other countries were to do the same to us.'[72]

3.64 AFFA listed 'elements of the Voumard recommendations that if adopted could prove onerous and a disincentive to commercial bioprospecting':

- every interested person registered under s266A of the Act must be invited to make written submissions about whether a permit should be issued (on environmental grounds) and that these should be taken into account by the Minister in making his decision;
- the 'precautionary principle' must be applied, 'where appropriate';
- any variations to the model contract must be 'acceptable';
- a maximum of three years would be set for the validity of an access permit; and
- the permit may be transferred only with the approval of the Minister.[73]

3.65 AFFA suggested that:

> … a less onerous system than that proposed in the Voumard recommendations would achieve the benefits of consistency, certainty and a return to the community, while being more conducive to the further development of industries based on bioprospecting.[74]

3.66 AFFA described the scheme that it would prefer. The key elements of this scheme are:

- a model material transfer agreement (MTA) for access to *in situ* material (and *ex situ* material in some cases) under Commonwealth ownership or control;
- inclusion in the MTA of a flexible benefit sharing agreement contingent on the material being commercialised, for example, a percentage of the gross profits over the first five years of commercialisation;

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71 Department of Agriculture, Fisheries and Forestry - Australia, Supplementary submission no. 36, p. 11.

72 Department of Agriculture, Fisheries and Forestry - Australia, Supplementary submission no. 36, p. 8.

73 Department of Agriculture, Fisheries and Forestry - Australia, Supplementary submission no. 36, p. 11, quoting the Voumard report, pp. 17-18.

74 Department of Agriculture, Fisheries and Forestry - Australia, Supplementary submission no. 36, p. 3.

- exemptions for benefit sharing considered if the recipient company or institution is prepared to make the developed material publicly available for further research;
- access to, and benefit sharing of, biological resources on freehold property subject to private negotiation (although the model MTA for Commonwealth areas may serve as a model for the private sector); and
- encouragement extended to states and territories to adopt the Commonwealth approach as a basis to achieve a nationally consistent framework.

According to AFFA, a flexible approach to benefit sharing is vital so that the individual circumstances of particular projects and applicants are taken into account.[75]

3.67 AFFA stressed that, whatever approach the Commonwealth government eventually adopts:

> … it will be important that a detailed Regulatory Impact Statement examines the practical impact of any regulations on government, business and other users. Such cost benefit analyses would need to give due recognition to differential impacts within agriculture, fisheries and forestry sectors.[76]

3.68 The committee notes that EA responded to some points raised by AFFA. EA disputed that the scheme proposed by the Voumard report would replace common law with new property rights or interfere with IP protection.[77] EA also stressed that the proposed benefit sharing arrangements would allow for considerable flexibility in what should be included in contracts.[78]

3.69 With respect to the need to accommodate existing international obligations such as the IUPGR, the Voumard report recommended that material which is the subject of such agreements be excluded from the ambit of the regulations.[79] AFFA, however, took the view that this

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75 Department of Agriculture, Fisheries and Forestry - Australia, Supplementary submission no. 36, pp. 8-9.

76 Department of Agriculture, Fisheries and Forestry - Australia, Supplementary submission no. 36, p. 10.

77 Environment Australia, Transcript of evidence, 4 June 2001, p. 61.

78 Environment Australia, Transcript of evidence, 4 June 2001, pp. 74-5.

79 J Voumard, p. 131; Department of Agriculture, Fisheries and Forestry - Australia, Supplementary submission no. 36, p. 11.

approach would introduce complexity because it would establish 'multiple systems covering different biological material'.[80]

Additional issues of concern in access and benefit sharing arrangements

3.70 Several submissions to the inquiry listed issues of particular concern in relation to access and benefit sharing arrangements. They included:

- ensuring that arrangements made with commercial operators do not restrict non commercial research activities and do allow reasonable access to other commercial operators;
- accommodating indigenous rights;
- finalising benefit sharing arrangements with multiple parties;
- clarifying the conditions for accessing biological collections;
- the export of Australian material; and
- monitoring the performance of permit holders and contracting parties.

3.71 These issues are discussed in more detail below.

Exclusivity in accessing biological resources

3.72 Access and benefit sharing arrangements contain a degree of exclusivity. This concerned the Royal Botanic Gardens Sydney, which feared that its non commercial research activities might be restricted by contracts between resource owners and commercial operations.[81] This exclusivity also hampers other commercial operators as AIMS pointed out:

> A common scenario is for bioprospecting contracts to be arranged on an exclusive basis with a company where sample access by others is severely limited (samples are deemed to be exclusive property of the contracting company). This can prohibit the use of the biodiversity for many different research activities that would maximise the possibility of finding commercially promising chemicals.[82]

3.73 EA provided the committee with an example of such a contract: the Victorian government and a bioprospecting business 'signed an exclusive

80 Department of Agriculture, Fisheries and Forestry - Australia, Supplementary submission no. 36, p. 11.

81 Royal Botanic Gardens Sydney, Submission no. 1, p. 1.

82 Australian Institute of Marine Science, Submission no. 27, p. 3.

contract for access to any plant, any vascular or non-vascular plant on publicly owned land, anywhere in Victoria for the purpose of pharmaceutical screening'. A less exclusive contract would have diminished the level of benefit sharing that the Victorian government could demand.[83]

3.74 There was also a perception among some witnesses to the inquiry that the Western Australian government's agreement with BioProspect was tying up biological resources, and making it difficult for others to access them.[84] However, BioProspect's agreements do not prevent others from applying for permits to collect.[85] Similarly, in the case of the Victorian contract described in the last paragraph, bioprospectors would be able to collect from private land.[86]

3.75 Exclusivity of access is also reduced if conditions are attached to permits. Access is restricted, for example, if there are limits on how long the permit is current, what organisms or species may be taken, which areas visited, or the type of biodiscovery that may be carried out on the material collected.[87] As the ASM pointed out, it is important not 'to tie up everything in one hit with one company'.[88] AIMS suggested that companies could be required to make samples available to others once they have decided which ones are of no further value to them.

> Such a scenario maximises information, opportunity for science / community benefit (particularly through a knowledge base for better resource management …) and maximises opportunity for any one sample to be screened many times thereby enhancing the likelihood of a commercial success.[89]

3.76 The committee was concerned that the conditions attached to some access permits may also give such wide rights to the accessor, that all other bioprospectors are excluded and further research activity is excluded. The committee believes that care must be taken when setting the permit conditions and making benefit sharing arrangements to ensure that reasonable opportunities are available to all wishing to access a particular

83 Environment Australia, Transcript of evidence, 4 June 2001, p. 67.

84 Cerylid Biosciences, Transcript of evidence, 25 June 2001, pp. 82, 83-4; The Australian Society for Microbiology, Transcript of evidence, 25 June 2001, p. 91.

85 BioProspect, Committee briefing, 6 July 2001; The Hon Cheryl Edwardes, Western Australian Minister for the Environment, Media release, 9 November 1999.

86 Environment Australia, Transcript of evidence, 4 June 2001, p. 74.

87 Environment Australia, Transcript of evidence 4 June 2001, pp. 66, 68, 69.
The Australian Society for Microbiology, Transcript of evidence, 25 June 2001, p. 92;

88 The Australian Society for Microbiology, Transcript of evidence, 25 June 2001, p. 93.

89 Australian Institute of Marine Science, Submission no. 27, p. 3.

area. It is important that the right balance is found, such that access conditions grant sufficient exclusivity to encourage a bioprospector to make full use of resources, but not so exclusive a deal that activity by others is discouraged.

Indigenous rights

3.77 There are two elements to indigenous involvement in bioprospecting: one is the result of indigenous ownership of the land and the other comes from knowledge of the uses to which native plants and animals can be put.

3.78 In some parts of Australia, significant areas are owned by Aboriginal groups. This allows control of access to those lands and heightens the possibilities for controlling the use of traditional knowledge. For example, 42 per cent of Northern Territory land is under Aboriginal ownership and a further 11 per cent is under claim; 27 per cent of South Australia is Aboriginal owned.[90]

3.79 The EPBC Act does not recognise IP indigenous rights, as the Northern Territory government pointed out.[91] However, the Voumard report recommended that regulations under the act should specify that there must be a contract between the parties. The contract should include prior informed consent, mutually agreed terms, and adequate benefit sharing that protects and values traditional knowledge. The report also recommended that:

- decisions by indigenous communities to deny access to bioprospectors should not be reviewable; and
- advice be provided to indigenous communities on how to get the best deals possible with bioprospectors.[92]

Such an arrangement might help to resolve some of the 'complex matters [that] need to be addressed in respect of ensuring Indigenous interests are not compromised through individual agreements with entrepreneurs'.[93]

3.80 Traditional knowledge is a source of information that can help focus bioprospecting activities. Such information is available from indigenous Australians and in written records, although some of this knowledge will

90 Northern Territory government, Submission no. 4, p. 4; South Australian government, Submission no. 28, p. 7.

91 Northern Territory government, Submission no. 4, p. 7.

92 J Voumard, pp. 83, 90-1.

93 South Australian government, Submission no. 28, p. 7.

disappear as older people die and their languages are lost.[94] While several submissions to the inquiry called for rewards to flow to indigenous groups from biodiscoveries that arise from traditional knowledge,[95] others were interested only in collecting species from indigenous land.

3.81 A requirement to respect traditional knowledge stems from Commonwealth obligations under international agreements such as the CBD. Article 8(j) of the CBD recognises that indigenous people should be involved in approving the use and application of their traditional knowledge and should share equitably in benefits from its application. The National Strategy for Ecologically Sustainable Development and the National Strategy for the Conservation of Australia's Biological Diversity reflect these requirements.[96]

3.82 There has been some criticism and dispute in the past about the unacknowledged use of traditional knowledge in Australia. An example is provided in Box 3.4.

3.83 Further criticism of Western Australian practices came from the Royal Society of Western Australia. It related to the contract between the state government and the firm, BioProspect, which the society claimed appears not to allow for the recognition of indigenous knowledge.[97] However, a national trust fund, such as BioProspect has proposed (see later in this chapter), would address this problem. Furthermore, BioProspect does not rely on traditional knowledge to guide its bioprospecting. It prefers to use high throughput screening associated with knowledge about an area's biodiversity; this strategy is more effective in discovering bioactive materials than using traditional knowledge.[98]

3.84 The committee gained the impression that most bioprospectors place relatively little, if any, reliance on indigenous knowledge. This appeared to be in part the result of difficulties in benefit sharing and the lack of IP protection for traditional knowledge.

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94 Royal Society of Western Australia Inc., Submission no. 8, p. 2; Australian Institute of Marine Science, Committee briefing, 3 May 2001.

95 Mr Shane Bawden, Submission no. 11, p. 3; South Australian government, Submission no. 28, p. 7.

96 H Fourmile, 'Indigenous interests in biological resources in Commonwealth areas - synthesis of submissions and related information', Appendix 10 to Voumard report, p. 200.

97 Royal Society of Western Australia Inc., Submission no. 8, p. 2.

98 BioProspect, Committee briefing, 6 July 2001.

Box 3.4 Modern use of a traditional cure: the case of the Western Australian smokebush

'The Smokebush [*Conospermum*] grows in the coastal areas between Geraldton and Esperance in Western Australia. Indigenous people from this region have traditionally used Smokebush for healing. … in the 1960s, the Western Australian Government granted the US National Cancer Institute a licence to collect plants for screening purposes. In 1981, specimens of the Smokebush plant were sent to the National Cancer Institute to test for the presence of cancer-fighting properties.

'The specimens were found to be ineffective, but were held in storage until the late 1980s when they were tested again in the quest to find a cure for AIDS. Out of 7,000 plants screened from around the world, the Smokebush was one of only four plants found to contain the active property Conocurovone, which laboratory tests showed could destroy the HIV virus in low concentrations. This 'discovery' was subsequently patented. The US National Cancer Institute has since awarded Amrad, a Victorian pharmaceutical company, an exclusive world wide licence to develop the patent.

'Under amendments to the Conservation and Land Management Act 1984 (WA) in 1985 and the National Parks and Wildlife Act (WA), the Western Australian Minister of the Environment has the power to grant exclusive rights to Western Australian flora and forest species for research purposes. In the early 1990s, the Western Australian Government also awarded Amrad the rights to the Smokebush species, to develop an anti-AIDS drug … Amrad paid $1.5 million to the WA government to secure access to Smokebush and related species … if *Conocurovone* is successfully commercialised, the WA government will recoup royalties of $100 million per year by 2002.

'Indigenous people are concerned that they have not received any acknowledgment, financial or otherwise, for their role in having first discovered the healing properties of Smokebush.

'The current legislation disregards the potential intellectual property rights that Indigenous peoples in WA have in flora on their lands. Furthermore, multinational drug companies could be sold exclusive rights to entire species of flora, preventing anyone from using these species for any other purpose without the consent of the companies.

'Indigenous peoples in WA face the possibility of being prevented from using any of the flora which is the subject of an exclusive agreement.'

The argument developed above has been rebutted by those that claim that Aboriginal knowledge related only to the general curative properties of smokebush and not to its potential to cure specific diseases like cancer and AIDS.

Source: Quoted from an ATSIC commissioned report, *Our Culture, Our Future: Report on Australian Indigenous Cultural and Intellectual Property Rights*, 1998, pp. 24-5.

3.85 Australia's IP regime does not currently protect traditional knowledge. Nor do the IP regimes of foreign countries. They fail to recognise collective rights and provide protection for only limited periods of time. Furthermore, traditional knowledge would not generally be regarded as patentable because it lacks the requisite newness.[99]

3.86 What may therefore be needed is a new category of rights that protects traditional knowledge from unauthorised use, recognises its origin, and provides just compensation. *Sui generis* methods of IP protection, such as those used for plant varieties, have been recommended in this context, for example, in an ATSIC commissioned report on indigenous cultural and IP.[100]

3.87 The committee noted that a recent report by the House of Representatives Standing Committee on Legal and Constitutional Affairs recommended that it be given a reference to inquire into mechanisms for protecting indigenous cultural and IP.[101] How to protect traditional knowledge in a rigorous fashion is also under discussion in international forums, such as the World Intellectual Property Organization (WIPO).

3.88 Two major concerns have been articulated by WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore.

- Those who hold traditional knowledge should be able to protect it.
- Parties other than the traditional knowledge holders should not be able to protect unmodified traditional knowledge based innovations.[102]

3.89 Work is under way to identify how far traditional knowledge can be protected by existing IP systems. IP Australia reports that:

> … although there are at present no clear, specific international IP standards for protecting such knowledge, there are a growing number of instances where individuals and organisations are resorting to existing patent … systems to protect their knowledge.[103]

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99 S Farquhar, IP Australia, 'Traditional knowledge, herbal medicines and IPRs protection', paper given to the International Symposium on Intellectual Property and International Trade in the New Millenium, Bangkok, 29-30 November 1999.

100 T Janke, *Our Culture, Our Future: Report on Australian Indigenous Cultural and Intellectual Property Rights*, 1998, pp. xxx-xxxi.

101 House of Representatives Standing Committee on Legal and Constitutional Affairs, *Cracking Down on Copycats: Enforcement of Copyright in Australia*, November 2000, p. xv.

102 IP Australia, Supplementary submission no. 39, p. 1.

103 IP Australia, Supplementary submission no. 39, p. 2.

In addition, market research is being conducted to establish what information is needed by traditional knowledge holders in Australia to increase their awareness and use of IP protection.

3.90 Other work by the intergovernmental committee includes examining the feasibility of how far traditional knowledge can be considered as 'prior art'. Prior art is the information that a patent is compared against to determine whether the invention is novel and inventive. IP Australia reports that:

> The existence of traditional knowledge that may deprive an invention of its novelty or inventiveness generally is not readily available to the examiners. Therefore WIPO is looking at the possible options for establishing a database to record this information and thereby make it available to patent examiners.[104]

3.91 The committee supports IP Australia's work in promoting the use of existing IP protection among Australia's indigenous people, and assisting WIPO's efforts to provide a more comprehensive system for protecting traditional knowledge.

Accommodating the interests of multiple parties

3.92 Benefit sharing arrangements may involve a number of parties, as Cerylid reported to the committee:

> … in the Northern Territory we have an agreement to collect samples on the Tiwi Islands, so that involves the Tiwi Islands Land Council, Parks and Wildlife Commission in the Northern Territory, Northern Land Council and any other people who either have ownership or would claim to have ownership of those resources. Quite often there are a number of parties that are signatories to the collecting agreements.[105]

3.93 BioProspect pointed out that benefit sharing in these circumstances is complex, and proposed that a national trust fund be established that would channel payments to those with claims to the original resource. BioProspect outlined:

> … a model whereby the sovereign states share of royalty income derived from bioprospecting resides, wholly or partly, in a suitable independently managed fund or pool from where this resource is distributed to further protect the diversity of the nation's biota and

104 IP Australia, Supplementary submission no. 39, p. 2.

105 Cerylid Biosciences, Transcript of evidence, 25 June 2001, p. 81.

> to directly reward the use of indigenous knowledge in the sustainable development of that biota. …
>
> Advantages of such a model would include an easily implemented equitable mechanism for fair recognition of input from several sources regarding the same material. This is perhaps the biggest hurdle in private enterprise's attempt to fairly reward similar input from several diverse parties. A Commonwealth sponsored model would clearly overcome this difficulty.[106]

3.94 It is not clear to the committee how extensive a problem this matter may be, nor that a trust would be the most appropriate solution to it. However, the committee believes that this issue should be tracked.

Access to biological collections

3.95 There are some difficulties in applying an access and benefit sharing scheme, such as that recommended in the Voumard report, to the contents of public collections. This is because the ownership of some parts of some collections is hard to establish. The committee noted that 'Principles on access to genetic resources and benefit-sharing for participating institutions' have been drawn up by an international group of botanical institutions to guide their dealings.[107] The World Federation of Culture Collections is examining how to address the requirements of the CBD in relation to the conditions under which access to collections of microorganisms is allowed.

3.96 The Voumard report recommended that, as far as possible, Commonwealth collections of native species be covered by regulations under the EPBC Act.[108] The committee understands that work is continuing to find mechanisms whereby the regulations will allow access and address benefit sharing in situations where ownership is unclear. As noted above, there are concerns that plant breeding research and the management of collections might be adversely affected were the Voumard scheme to be implemented.

Export of biological material

3.97 One of the means by which access to biological resources by overseas interests can be limited is through export controls. The committee recognises that, with the small amounts of material needed for

106 BioProspect Ltd, Submission no. 12, p. 3.

107 Royal Botanic Gardens Sydney, Submission no. 1, pp. 1-2.

108 J Voumard, pp. 128-132.

biodiscovery, it is very easy for the determined person to remove it from the country. Although biopiracy of this kind cannot be prevented, it is no excuse for not ensuring that the controls are as comprehensive as possible.

3.98 The export of plants and animals is currently controlled by the *Wildlife Protection (Regulation of Exports and Imports) Act 1982*. This Act will be repealed on 11 January 2002 when amendments to the EPBC Act come into effect. These amendments have the effect of incorporating the provisions of the Wildlife Protection Act into the EPBC Act.

3.99 The Voumard report drew attention to the fact that the export of biological resources is only partially controlled. Microorganisms can be exported without a permit. As a consequence, there is no opportunity to require a share for Australia in any commercial success derived from them. Furthermore, as microorganisms can be fairly readily cultured, the exporter may never need to refer back to Australia for further supplies, and control of those organisms will be lost by Australia. The report recommended that export controls be extended to microorganisms.[109] The committee supports this recommendation, particularly in view of concerns about the export of genetic material expressed to it in submissions to the inquiry.[110] The committee makes a recommendation on the export of genetic material later in this chapter.

Conclusions about access and benefit sharing

3.100 The committee supports the moves that are being made to put a nationally consistent access and benefit sharing scheme in place. It is unfortunate that the regulations to s301 of the EPBC Act have not yet been issued for comment. The committee would have welcomed the opportunity to test them against the evidence received during the inquiry and to comment on them.

3.101 The committee supports the concept of sharing the benefits derived from bioprospecting with the owner of the resource and regional communities. It appreciates the simplicity of the model proposed by the Voumard report and the attempt made to accommodate the concerns of interest groups, such as indigenous owners and the curators of *ex situ* collections.

3.102 The committee was concerned, however, by AFFA's claims that the system proposed in the Voumard report is too onerous, and does not adequately address the impact it could have on Australians' access under the IUPGR

109 J Voumard, pp. 132-4.

110 For example, Australian Institute of Marine Science, Submission no. 27, pp. 14, 17; Submission no. 18, pp. 4-5.

to plant genetic resources from overseas. These are serious claims and deserve careful investigation. Although AFFA did not raise these concerns with the committee until the final stages of the inquiry, the committee wishes to highlight them.

3.103 Drawing on the discussion earlier in this chapter and the last two paragraphs, the committee recommends some of the considerations that should guide finalisation of the regulation. In doing so, the committee is concerned to maximise the opportunities offered by bioprospecting. The committee recognises that the regulations recommended by the Voumard Report break new ground. It believes that it is imperative that the new approach to access and benefit sharing does not have any undesirable consequences. The regulations must not impede the development of the bioprospecting opportunities.

Recommendation 7

3.104 The committee recommends that the regulations governing access and benefit sharing under section 301 of the *Environment Protection and Biodiversity Conservation Act 1999* be subject to review after 12 months to ensure that they are not impeding the development of opportunities arising from bioprospecting.

Recommendation 8

3.105 The committee recommends that, when finalising the regulations under section 301 of the *Environment Protection and Biodiversity Conservation Act 1999*, the Commonwealth government:

- **ensure that the regulations do not create new property rights;**
- **obtain a detailed regulatory impact statement; and**
- **examine fully the implications of the regulations for Australia's access to overseas plant genetic material.**

3.106 The committee regrets that AFFA did not raise its reservations about the scheme recommended in the Voumard report when it made its first submissions to the inquiry and during its two appearances before the committee. The committee is concerned by the time that it took AFFA to

address access and benefit sharing issues when these are such significant issues. AFFA's first submission to the inquiry made no reference to access and benefit sharing. The second submission did not clearly address the issues and made only two passing references to the Voumard report and recommendations. Yet the latter are the major input to the draft regulations to the EPBC Act. It was only when the committee requested responses to specific questions in order to gain AFFA's views, that their concerns were raised.

3.107 Given AFFA's role, along with other government departments, in finalising the regulations, the committee believes that AFFA should have been better informed and raised its concerns with the committee at the first opportunity.

Recommendation 9

3.108 The committee recommends that Environment Australia and the Department of Agriculture, Fisheries and Forestry - Australia give a high priority to:

- **finalising the regulations on access to biological resources and the sharing of benefits from them, under section 301 of the *Environment Protection and Biodiversity Conservation Act 1999*; and**
- **working with state and territory governments to establish nationally consistent arrangements.**

3.109 The committee also makes a number of more specific recommendations. The first two spell out important principles which the committee believes should underpin a nationally consistent access and benefit sharing regime. They relate to ensuring that a balance is found between competing objectives in the best interests of all concerned. It is important to get the mix of exclusive rights versus open access to use resources that will promote bioprospecting effectively. On a similar note, a balance must be struck between encouraging industry to bioprospect and benefiting the owners of biological resources. The committee believes that an important part of any benefit sharing arrangement must be a requirement for information and specimens derived from bioprospecting to be publicly accessible, provided commercial in confidence is not involved.

Recommendation 10

3.110 The committee recommends that, when granting access to biological resources, the Commonwealth government:

- **ensure access for non commercial activities; and**
- **with commercial activities, ensure a balance between open competitive access and restricting access by granting exclusive use.**

Exclusivity should be restricted by permit conditions such as duration, area or species collected, and uses to be explored.

Recommendation 11

3.111 The committee recommends that, when finalising benefit sharing arrangements, the Commonwealth government ensure that commercial activity is not discouraged by the benefits bioprospectors are required to provide.

When negotiating non monetary benefits, emphasis should be placed on providing support for regional development and the lodging of information and specimens in publicly accessible databases and collections (see recommendation 1).

Recommendation 12

3.112 The committee recommends that the *Environment Protection and Biodiversity Conservation Act 1999* be amended to extend export controls to all elements of Australia's non human, native biota, with particular reference to microorganisms.

Finding and using bioactive substances

3.113 The previous sections of this chapter have dealt with topics that impinge on accessing biological material. In this and the following sections, the later stages in the chain of industry development are considered.

Biodiscovery

3.114 The term, biodiscovery is used here to refer to the extraction and testing of molecules for biological activity, identification of compounds with promise for further development, and research on the molecular basis for the biological activity. Significant value adding is often possible at the biodiscovery stage. The perception that value adding occurs only with commercialisation and production is wrong.[111] Value adding can, in fact, be ongoing as samples are repeatedly screened for new clients and targets, and as new circumstances arise. Value increases both in terms of the financial returns from research as well as adding to knowledge about the resource.[112]

3.115 Furthermore, as AIMS pointed out, 'if funding is available at early phases of the bioprospecting / biodiscovery process, then IP is also captured early'.[113] As Figure 3.1 shows, Australian research organisations can exercise strategic leverage as products are developed through the IP positions they hold. A tenfold increase in value can be expected from the biodiscovery stage to final product development, as the figure also indicates.[114]

3.116 Value adding to bioprospected material was mentioned as being very important in many submissions, discussions and hearings during the inquiry.[115] So too was maintaining control over the uses to which discoveries from Australian material are put. Even if further development of promising leads goes overseas, biodiscovery will provide much greater, lasting returns to Australia than the sale of samples and extracts, particularly if discoveries can be taken as far as patenting. The further value adding can be taken along the bioproduct development chain, the greater the return to Australia.[116]

111 ExGenix Operations Pty Ltd (Cerylid Biosciences Ltd), Submission no. 13, p. 1.

112 Australian Institute of Marine Science, Submission no. 27, pp. 4-5.

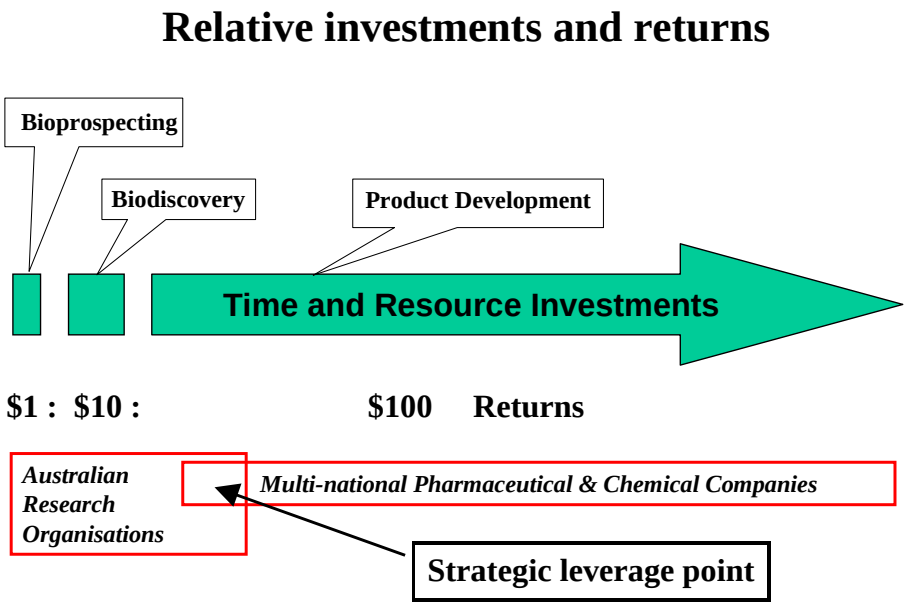
113 Australian Institute of Marine Science, Submission no. 27, p. 16.

114 CSIRO, Submission no. 14, p. 17.

115 For example, Original Oceanz, Smart Ventures Industry Group, Committee briefing, 4 May 2001.

116 Environment Australia, Submission no. 29, p. 30; AstraZeneca R&D Griffith University, Submission no. 33, p. 1; Australian Institute of Marine Science, Submission no. 27, p. 1.

Figure 3.1 The relative investment in lead time and expenditures (size of the arrow) and the relative returns at each step.



Note: Whilst the down-stream operators are often multinational companies, Australian research organisations can exercise strategic leverage through the overlap in activities and IP positions.

Source: CSIRO, Submission no. 14, p. 17.

3.117 The committee was told, however, that there are frequently insufficient funds to carry research far enough to obtain IP protection, and then to meet the costs of obtaining patents. According to Professor Palmer, Vice Chancellor of JCU, universities are not well enough funded to patent IP (and have a very conservative attitude to IP management), so they licence overseas and the IP is lost to Australia.[117] AIMS agreed that research grants do not cover the costs of obtaining IP protection.[118] According to BA, however, some assistance is now available to assist with these costs.[119] Commercial partners in joint ventures with public sector research institutions have also sometimes met the costs of patenting.[120]

117 James Cook University, Committee briefing, 3 May 2001.
118 Australian Institute of Marine Science, Submission no. 27, p. 15.
119 Biotechnology Australia, Transcript of evidence, 2 April 2001, p. 15.
120 Australian Institute of Marine Science, Committee briefing, 3 May 2001.

3.118 The potential of plant breeders rights (PBR) for protecting biodiscovery was also brought to the committee's attention. According to AFFA, 12 per cent of the applications received by the PBR Office relate to native species. AFFA suggested that considerable growth would occur in the selective breeding of native species, but reported poor understanding of PBR among those carrying out this work.[121]

3.119 Biodiscovery requires equipment and skills, but 'there are classic signs of stress on infrastructure, skill development and retention, and competition between national centres'.[122] The committee noted the view that Australia lacks the financial capacity to support an approach to biodiscovery that relies heavily on high throughput random screening.[123] Nonetheless, as the Western Australian government pointed out:

> … the establishment of a small number of international standard screening and extraction facilities and the development of world class researchers … would increase Australia's capacity to generate commercialisable IP and exert meaningful controls over access to Australia's biological resources.[124]

3.120 CSIRO recommended more collaborative research between public and private sectors be sought so that expertise and facilities could be pooled and bioactive molecules developed further along the product development pipeline.[125]

3.121 According to CSIRO, biodiscovery is dominated by the global R&D system more than any other stage in the development of bioindustries.[126] In this context:

> Australia cannot hope to be a world leader across all major biotechnology areas, but must carefully select the most appropriate niches and then be smart in the way that Australian intellectual property (IP) positions are used to exercise leverage over multinational companies.[127]
>
> Nationally, it is critical to clearly identify the market niches for *biodiscovery* projects that are of strategic importance to Australia.

121 Department of Agriculture, Fisheries and Forestry - Australia, Transcript of evidence, 2 April 2001, pp. 31, 34.

122 CSIRO, Submission no. 14, p. 22.

123 Faculty of Biological and Chemical Sciences, The University of Queensland, Submission no. 26, p. 2.

124 Western Australian government, Submission no. 32, p. 4.

125 CSIRO, Submission no. 14, pp. 30, 34.

126 CSIRO, Submission no. 14, p. 21.

127 CSIRO, Submission no. 14, p. 3.

> Furthermore, international collaborative ventures are important … to ensure Australia retains a seat at the negotiating table when dealing with multinational companies that are active in this area.[128]

CSIRO called for 'strong, national leadership directed into areas and niches where our global contribution makes a significant difference'.[129]

3.122 This section has identified a number of issues that require attention if the most is to be made for Australia from biodiscovery. These issues include:

- the need for screening and extraction facilities of an international standard;
- the cost of obtaining and maintaining patents;
- the lack of public understanding about the potential of PBRs to protect IP;
- the selection of market niches; and
- the need for greater collaboration among researchers.

Some of these issues are relevant to a larger range of endeavours than just biodiscovery, and are discussed further in Chapter 6. The committee makes one recommendation relating specifically to biodiscovery.

Recommendation 13

3.123 The committee recommends that the Commonwealth government ensure that the major publicly funded research organisations are sufficiently well funded to purchase the equipment needed to meet present and future demands.

3.124 The committee considered IP protection at some length in its report on primary producer access to gene technology. The matters brought to the committee's attention in relation to IP protection for biodiscoveries cover some of the same concerns. In its report on gene technology, the committee made two recommendations dealing with providing information about IP issues to small producers, and monitoring initiatives to improve IP skills. The committee was pleased that both

128 CSIRO, Submission no. 14, p. 4.

129 CSIRO, Submission no. 14, p. 9.

recommendations were supported in the Government's response to the report.[130]

Bioprocessing and bioindustries

3.125 Bioprocessing involves the development of industrial processes to manufacture new biological products on a commercially viable scale, often using fermentation or enzyme processes.[131] Brewing and cheese making are old technologies based on bioprocessing. An example of modern bioprocessing approaches was given to the committee by Dupont Australia (Box 3.5).

Box 3.5 New approaches to bacterial bioprocessing

Genes have been identified that drive the production of widely used substances, currently synthesised from petrochemical or other non renewable feedstocks. These genes have been inserted into bacteria which are housed in a bioreactor and fed on sugar. Dupont Australia reported that the first commercial plants using these bacteria will open in 2003; they will produce herbicides, plastics and nylon.

The advantage of this mode of manufacture is that it is more efficient than conventional manufacturing processes. Production is carried out under ambient conditions, compared with the high temperatures and pressures that are often required conventionally. The bacteria's biochemical pathways yield products with high specificity, and may have conversion rates as high as 98 per cent. The bioprocesses thus produce very little waste, and all the end products are biodegradable.

Biobased sources of chemicals are an attractive alternative to petrochemicals as the cost of oil rises and the pollution caused by it and industries based on it increase.

Source: Dupont Australia, Committee briefing, 6 June 2001.

3.126 One estimate is that biobased products will be competitive in 30 per cent of the chemical market by 2010, especially in the market for fine and speciality chemicals.[132] With technological advances over coming years, the cost of producing other biobased products is expected to fall and

130 House of Representatives Standing Committee on Primary Industries and Regional Services, *Work in Progress: Proceed with Caution: Primary Producer Access to Gene Technology*, June 2000, pp. 94, 122.

131 CSIRO, Submission no. 14, pp. 15, 32.

132 R Bachmann, E Bastianelli, J Riese &W Schlenzka, 'Using plants as plants', *McKinsey Quarterly*, 22 March 2000.

become competitive with those derived from petrochemicals. A study carried out for the US National Research Council suggested that liquid fuels might follow commodity chemicals into biobased production.[133]

3.127 The committee's attention was drawn to the potential for producing liquid fuels from various types of biomass. The technology needed for this has been known for a number of years, but has been little used in Australia until recently. Small plants produce ethanol from sugar for blending with petrol but, although exempt from excise, large scale ethanol production is not cost effective. However, a scenario can be imagined in which this would change, for example, if petrol costs were to rise significantly, more efficient production processes were developed, or carbon credits acquired a greater value. Research is also being undertaken in Australia into ethanol production from other sources, such as wheat starch and woody material. Support for this research and for the establishment of biologically sourced ethanol plants is being provided by the Commonwealth government.[134]

3.128 CSIRO identified two impediments to bioprocessing in Australia. The first is the predominantly small to medium size of the enterprises involved in bioprocessing. Such enterprises do not have access to sufficient capital to undertake high risk, commercial developments.[135] This point was made by others as well.[136] Considerable R&D is needed to take bioprocessing concepts from laboratory to commercial scale. It can take as long as 10 years and consume up to 90 per cent of the overall costs of developing a new product.[137]

3.129 The second impediment is the shortage in Australia of pilot plants to research the scaling up of fermentation processes. While CSIRO has good capabilities and facilities in this area, it has only sufficient to support its own research needs. It saw:

> … a need for some form of a national technology transfer centre or facility for bioprocessing R&D within the next few years to offer

133 Committee on Biobased Industrial Products, Board on Biology, Commission on Life Sciences, National Research Council, *Biobased Industrial Products: Priorities for Research and Commercialisation*, National Academy Press, Washington DC, 2000, pp. 1-2.

134 Biotechnology Australia, Submission no. 25, pp. 11-12.

135 CSIRO, Submission no. 14, p. 22.

136 University of Queensland, Faculty of Natural Resources, Agriculture and Veterinary Science, Submission no. 31, p. 1; Western Australian government, Submission no. 32, p. 1.

137 CSIRO, Submission no. 14, p. 15.

> such services to industry to commercialise research in Australia prior to the commercial manufacturing stage.[138]

Noting the difficulties in taking R&D to commercialisation, the committee is attracted to the idea of a national biotechnology transfer centre, incorporating a bioprocessing scale up facility.

Recommendation 14

3.130 The committee recommends that the Commonwealth government facilitate the establishment of a national biotechnology transfer centre that should include scaling up facilities for bioprocessing.

3.131 Impediments to the establishment of bioindustries were also identified in the regulatory regimes maintained by the Therapeutic Goods Administration and the National Registration Authority for registering new products. The cost of their processes and the time taken to complete them were criticised at a private committee meeting at SCU.[139] Participants at this meeting suggested that a scheme based on the same principle as the Higher Education Contribution Scheme would be a less punitive way of recovering registration costs, particularly from small companies.

3.132 The challenges typically faced in employing microorganisms and enzymes in bioindustries are increasing product yields, product concentrations, and processing rates.[140] Significant engineering challenges also exist in establishing new plants. In addition, as Dupont pointed out, bioprocessing needs to be integrated into the complex infrastructure of the chemical industry, and bioderived materials will not necessarily be 'drop in' replacements for petroleum based products.[141] The US National Research Council flagged the need for educational support and training for bioindustries.[142]

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138 CSIRO, Submission no. 14, p. 22.

139 BioProspect Ltd and Southern Cross University, Committee briefing, 6 July 2001.

140 Committee on Biobased Industrial Products, p. 10; CSIRO, Committee briefing, 27 November 2000.

141 Dupont Australia, Committee briefing, 6 June 2001.

142 Committee on Biobased Industrial Products, Board on Biology, Commission on Life Sciences, National Research Council, *Biobased Industrial Products: Priorities for Research and Commercialisation*, National Academy Press, Washington DC, 2000, pp. 11-12.

3.133 In its report on primary producer access to gene technology, the committee flagged the need for increasing numbers of people and levels of skills in biotechnology research.[143] The government supported this recommendation in its response to the report. It undertook to monitor emerging skill needs in the biotechnology sector and develop appropriate responses to them.[144] The committee believes that skills development continues to be critically important.

Recommendation 15

3.134 The committee recommends that the Commonwealth government:

- **audit the availability of skills needed in the biotechnology sector, including those required to develop bioindustries;**
- **ensure that relevant training is available; and**
- **promote uptake of training opportunities.**

3.135 CSIRO warned that the 'development of bioindustries may … require attention to public concerns about biotechnology and gene technology in particular'.[145] While this might not be an issue with processes that depend on genetically modified microorganisms contained in fermenters, greater concern might be felt about crops or animals modified to produce new substances. CSIRO recommended that BA's public awareness program be continued.

3.136 This is another topic covered extensively by the committee in its last report.[146] The committee's five recommendations that addressed the need for increased public awareness of biotechnology were all accepted by the government. It is the committee's view that this need still exists and is likely to continue to do so for some time to come. The provision of balanced, comprehensible, easily accessible information about the

143 Committee on Biobased Industrial Products, p. 88.

144 House of Representatives Standing Committee on Primary Industries and Regional Services, *Work in Progress: Proceed with Caution: Primary Producer Access to Gene Technology*, June 2000, pp. 14-15.

145 CSIRO, Submission no. 14, p. 30.

146 House of Representatives Standing Committee on Primary Industries and Regional Services, *Work in Progress: Proceed with Caution: Primary Producer Access to Gene Technology*, June 2000, pp. 38, 42, 43, 46, 47.

scientific, economic, social and environmental implications of biotechnology should continue to be made available.

3.137 The committee believes that bioprospecting and the development of bioindustries should be fully covered in material provided to the public by BA. This does not appear to be the case at present: the committee's impression is that the focus is largely on gene technology. It is particularly important that the bad image created by instances of biopiracy and past environmentally unsustainable activities be dispelled. [147]

Recommendation 16

3.138 The committee recommends that the Commonwealth government:

- **continue to provide extensive information about biotechnology in its public awareness program; and**
- **ensure that the contribution of bioprospecting and biodiscovery to economic development is covered in this program, including the benefits that bioindustries offer to the environment, medicine and agriculture.**

Conclusion

3.139 The recommendations in this chapter address some of the specific impediments associated with each of the stages in the bioproduct development chain (Figure 1.1). As foreshadowed in the last two sections, there is also a number of wider issues in the development of bioprospecting and bioindustries, which are covered in Chapter 6, along with some of the broader issues raised in the next chapter on regional matters.

147 Dr Kirsten Benkendorff, University of Wollongong, Submission no. 38, p. 6.

4

Regional activity

The potential

4.1 The committee heard a variety of views about the possibility of establishing industries based on bioprospecting in regional areas. All acknowledged that original collections and any recollections subsequently needed are made in the area where the organisms of interest occur naturally. However, once species are lodged in collections and associated information about them is in electronically accessible databases, researchers need go no further than to the collections, which are often in major cities. Bioprospecting does not at present generate much employment, and those involved in it are often based in the city.[1]

4.2 Biodiscovery and any resulting downstream development were also seen by some as being almost entirely city based activities. They argued that biotechnology will be carried out in the major cities because that is where the necessary skilled workforce and the equipment for screening, synthesis and processing are found. Bioindustries will be established in the cities where access to inputs and markets are also better than in regional areas.[2]

4.3 It was suggested that the major use for regional areas in bioindustrial development would be in mass producing raw materials and carrying out preliminary extractions from them. However, for many biodiscoveries,

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1 EcoBiotics Pty Ltd, Submission no. 18, p. 2.

2 Department of Agriculture, Fisheries and Forestry - Australia, Transcript of evidence, 2 April 2001, pp. 18, 29; Submission no. 24, p. 8; Western Australian government, Submission no. 32, pp. 1-2.

this was seen as being no more than a short term possibility, lasting only as long as it took to establish synthetic production of desired substances.[3]

4.4 A much more optimistic view of the possibilities for regional development and local employment also existed.[4] There are, for example, good arguments for having the necessary capacity in regional areas to carry out biodiscovery. Some material does not last well when removed from its environment, and better results are obtained from research on fresh material. Being close to the habitat of the organisms under study also means that seasonal changes and the impact of ecological shocks on organisms can be tracked more easily. These can be significant considerations, for example, because the concentration of bioactive molecules in certain organisms changes with the prevailing conditions, and the evolution of new metabolites may be stimulated by novel environmental challenges.[5]

4.5 Despite views to the contrary, regional Australia has great potential to become the supply base for bioindustries. There are, for example, compounds that are too complex or costly to synthesise.[6] They are sourced more cost effectively by harvesting from the regional sources from which they were first isolated.[7] Over 25 per cent of the modern drugs that were derived from natural product leads are still extracted from crops of the source plant, although they can be synthesised.[8] AZGU suggested that 'regional development would appear to be best placed to participate in the production side of new therapeutics'.[9]

4.6 AIMS told the committee about several compounds from marine invertebrates and algae that are currently undergoing clinical trials as anti tumour agents. Rather than harvesting fine chemicals from the wild, AIMS is involved with the Queensland Department of State Development and the Coolgaree Aboriginal Community in a project to source them from a sponge farm that is being established near Townsville. For maximum cost effectiveness, such farms need to be situated in the areas where the

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3 Department of Agriculture, Fisheries and Forestry - Australia, Transcript of evidence, 2 April 2001, p. 29; Western Australian government, Submission no. 32, p. 2; Associate Professor Robert Capon, University of Melbourne, Submission no. 6, p. 7

4 EcoBiotics Pty Ltd, Submission no. 18, p. 2; Southern Cross University, Submission no. 17, p. 2.

5 Australian Institute of Marine Science, Committee briefing, 3 May 2001; Submission no. 27, p. 10.

6 Australian Institute of Marine Science, Submission to the Voumard inquiry, p. 7; Environment Australia, Submission no. 29, p. 33.

7 Original Oceanz, Smart Ventures Industry Group, Committee briefing, 4 May 2001; Associate Professor Robert Capon, University of Melbourne, Submission no. 6, p. 7.

8 Australian Institute of Marine Science, Submission no. 27, p. 9.

9 AstraZeneca R&D Griffith University, Submission no. 33, p. 2.

sponges occur naturally.[10] A New Zealand example of the benefit that can accrue to a regional area from this type of development is described in Box 4.1.

Box 4.1 Regional benefit from mariculture for chemicals

'The Halichondrins are a novel family of compounds produced by a deep water New Zealand sponge *Lissodendoryx sp*, about to enter anti-cancer clinical trials. While the species is extremely rare in nature (the entire existing biomass is estimated at only 300 tonnes in a single limited range …), it is an ideal mariculture candidate. Research into the chemical ecology of these compounds in this species has resulted in optimum culture methods that can return a growth rate of up to 5000% in one month. A joint venture with local industry has been established to produce the 10 tonnes required to supply enough compound for the clinical trials. The cost of producing one kilogram (wet weight) of sponge, with a current value of up to US$400, is only 50 cents. Should the compounds survive clinical trials, this ratio will decrease as the production scales up to meet the projected annual global demand of up to 60 tonnes. Combined with other supporting commercial ventures established locally (eg plant for chemical extraction and refinement), the capture of value adding biotechnology industry is a potentially massive regional socio-economic benefit.

'… There is also evidence that growing this sponge amongst existing bivalve aquaculture (eg mussels) benefits production of both species and ameliorates some existing environmental impacts of mussel farming.'

Source: Quoted from Australian Institute of Marine Science, Submission to the Voumard inquiry, pp. 7-8.

4.7 Harvesting from aquaculture and plantations on land represents an opportunity for regional development. While plantations of native plant species, such as tea trees, have been established, aquaculture for bioactive molecules is a very new initiative. Fermentation is another option for sustainable production that is ideal for regional development. AIMS claimed that:

> If fermentation / harvest / aquaculture modes of production currently being investigated are found to be economic (even with synthetic post harvest manipulations) the options for substantial regional development are enormous.[11]

10 Australian Institute of Marine Science, Coolgaree Aboriginal Community and Queensland Department of State Development, Committee briefing, 3 and 4 May 2001.

11 Australian Institute of Marine Science, Submission no. 27, p. 5.

4.8 Several organisations made suggestions about the most appropriate focus for the regional development of bioindustries. AFFA and the Northern Territory government stressed that low technology options, such as growing crops for the alternative medicine market, should not be overlooked.[12] A recent report on the potential for Australian agriculture to supply new pharmaceutical, nutraceutical and industrial products reached the same conclusion. It concluded that 'the largest and lowest risk of the markets that Australia is immediately positioned to supply is for functional foods'.[13]

4.9 The UQ suggested that rural areas should focus on:

> … products which cannot be readily synthesized, and whose development or processing do not depend unduly on overseas technology. This generally means that it is necessary to look at products which consist of either bulk use of plant or animal parts or at least complex components derived from them. It would be important to value-add locally. …
>
> Apart from whole plant, animal, insect or microbial products, local industries need to focus on derivative products such as food, fibre and pharmaceutical products. The challenge is to identify and market new products which can compete with or displace traditional products. This is unlikely to apply to staple products but is more likely to apply to specialist niche markets and novelty or lifestyle consumer products.[14]

4.10 New bioproducts might also be developed by existing regional industries. For example, mineral companies have an interest in environmentally friendly technologies both for mining and remediation, and regional dairy, meat and sugar businesses could value add by producing new biotechnological products.[15] Some of the bioprocessing enterprises discussed in Chapter 3 are very likely to be established in regional areas, close to sources of supplies.[16] For example, ethanol plants are already in operation and more are being planned for the sugar growing regional centres in Queensland.

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12 Department of Agriculture, Fisheries and Forestry - Australia, Transcript of evidence, 2 April 2001, p. 25; Submission no. 24, p. 7; Northern Territory government, Submission no. 4, p. 8.

13 Wondu Holdings Pty Ltd, *New Pharmaceutical, Nutraceutical and Industrial Products: The Potential for Australian Agriculture*, Rural Industries Research and Development Corporation, November 2000, p. x.

14 Faculty of Natural Resources, Agriculture and Veterinary Science, University of Queensland, Submission no. 31, p. 1.

15 Australian Institute of Marine Science, Submission no. 27, p. 10.

16 Biotechnology Australia, Submission no. 25, p. 13.

4.11 A regional location has a number of other advantages:

> … operating costs in transport, freight, rates, other resources for industry are lower in the regions, storage handling is cheaper and ports / freight out facilities are usually more assessable [*sic*] and strategically positioned. There are a number of key regional towns … around Australia that are being identified as the best places for industrial investment because of their very regionality … .[17]

In some of these centres, the cost of living and quality of life are a means of attracting good staff.[18]

4.12 AIMS also pointed out that:

> There are many examples where biotechnological research and development of mega-clusters have simply been created *de novo* in regional areas (Maryland biotech villages sprang up on the outskirts of Bethesda, Biotech Valley was created in suburban / rural San Diego…). Land is affordable, there is investment and room to grow. Once established, these ensembles of science institutions, companies, scale-up facilities and production industry create their own momentum and infrastructure.[19]

This type of cluster development is sometimes referred to as technology parks.

4.13 Given the high unemployment rates in some rural and regional areas, prospects of new economic activities are very welcome. A couple of submissions to the inquiry came from rural areas that were anxious to expand the economic base of their communities and have some facilities and activities on which they felt an industry could be built.[20] In this context, the committee noted AIMS' comment that novel tools and products are:

> … likely to be accepted and or promoted first and with most ease … in areas where environment, agriculture, health, welfare and economics are most critical…i.e. the benefits and issues are best appreciated in the regions where there is usually urgent demand.[21]

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17 Australian Institute of Marine Science, Submission no. 27, p. 10.

18 Australian Institute of Marine Science, Submission no. 27, p. 15.

19 Australian Institute of Marine Science, Submission no. 27, pp. 10-11.

20 Western Plains Regional Development, Submission no. 7, pp. 2-3; Global Recycling Pty Ltd for Kangaroo Island Nature Lab, Submission no. 16, pp. 1, 5.

21 Australian Institute of Marine Science, Submission no. 27, p. 13.

4.14 The possibility of Aboriginal involvement in industries arising from bioprospecting was also raised with the committee. The sponge project mentioned above is being established near Palm Island near Townsville, and is expected to provide work for about 20 people initially and 10-12 on an ongoing basis.[22] Building industries based on traditional indigenous knowledge was also mentioned as a possibility.[23]

Case studies

4.15 The committee noted the Western Australian government's comment that there are limited opportunities for establishing regional high technology industries.[24] However, during the inquiry, the committee learnt of three regional centres where bioprospecting, biodiscovery and commercialisation of discoveries are being pursued. They are Townsville, Hobart and Lismore. Boxes 4.2 to 4.4 detail the features of each centre and the work they are performing that was brought to the committee's attention for this inquiry.

22 Queensland Department of State Development, Committee briefing, 4 May 2001.

23 Mr Shane Bawden, Submission no. 11, p. 3.

24 Western Australian government, Submission no. 32, pp. 1-2.

Box 4.2 Townsville, Queensland

Population. 135,100 (greater Townsville, June 1998)

Access to biological resources. Situated on the north Queensland coast, Townsville has easy access to the resources of three very different subtropical ecosystems: the Great Barrier Reef, inland savannah, and tropical rainforest. The marine environment is characterised by particularly high biodiversity. Many marine and rainforest organisms have developed chemical mechanisms for defence and attack, which might be used in bioindustries.

R&D resources. The scientific expertise needed to carry out bioprospecting and biodiscovery resides in AIMS, one of the leading institutions of its kind in the world, and JCU, which also has a campus in Cairns where the Rainforest Cooperative Research Centre (CRC) is located. Townsville's developing medical school will provide possibilities for clinical trials. AIMS and JCU scientists collaborate on some projects. AIMS has built a nationally significant bioinformatics database over the last 20 years which covers over 20,000 organisms.

State government support. Through its bioindustries strategy, the Queensland government is actively supporting the development of biotechnology in the state, including bioprospecting and bioprocessing. The state government recently concluded a benefit sharing arrangement with AIMS, which is seen as a model in facilitating the collaborative development of discoveries with international partners. Grant moneys have also been provided, for example, for establishing a local biotechnology network.

Local connections. Local industries with an interest or possible interest in biotechnology include aquaculture, mineral processing, waste recycling and management, and medical diagnostics.

Commercialisation. In addition to the sunscreen and herbicide mentioned in paragraph 2.14, a diagnostic kit for shellfish toxin is being commercialised by AIMS.

Sources: Australian Institute of Marine Science, Committee briefing, 3 May 2001; Submission no. 27, p. 4.

Box 4.3 Hobart, Tasmania

Population. 194,000 (metropolitan area)

Access to biological resources. The Tasmanian, sub Antarctic and Antarctic biota are readily accessible from Hobart. Antarctic microorganisms are of special interest because they are unique, and characterised by adaptations to an extremely cold environment.

R&D resources. There is a strong public sector research base in Tasmania, including the University of Tasmania, state government research laboratories and collecting institutions, the Australian Antarctic Division and CSIRO. Linkages exist between these institutions, including several CRCs. A critical mass of marine biologists, the CRC's collection of over 5,000 Antarctic, sub Antarctic and Southern Ocean microorganisms and CSIRO's collection of micro algae form a strong basis for bioprospecting.

State government support. The Tasmanian government provides support to the extensive public sector research base in the state. In addition, sixty per cent of private land in Tasmania is owned by the Crown, which is therefore in a position to influence access and benefit sharing over a wide area.

Local connections and benefits. Screening for pharmaceutical activity of microorganisms collected by the Antarctic CRC is being carried out by Cerylid Biosciences in Melbourne.

Microbial bioprospecting has brought over $1 million in research funding from public and private sources into Tasmania since 1997.

Commercialisation. Polyunsaturated acids extracted from Antarctic microorganisms represent a commercial possibility. An attempt to form a joint venture for their further development failed, for some of the reasons listed below.

Sources: Tasmanian government, Submission no. 23; The Australian Society for Microbiology, Submission no. 10; Transcript of evidence, 25 June, p. 95.

Box 4.4 Lismore, New South Wales

Population. 42,954 (1996 census)

Access to biological resources. The rainforests of Northern New South Wales represent a source of considerable biodiversity. In addition, this region and the neighbouring cooler inland areas have recently become a significant centre for growing and manufacturing medicinal plants. They produce much of the Australian sourced material for the medicinal plant market.

R&D resources. SCU is concentrating on developing a small number of centres of excellence with regional significance. One of them is the Cellulose Valley project (CVP), which 'will position the Northern NSW region and Australia, as the global hub of primary production, manufacturing and research for medicinal plant products and related products'. Several centres and schools at SCU contribute to the project, including centres for phytochemistry and plant conservation genetics, a school of natural and complementary medicine, an institute of health research, and an environmental analysis laboratory.

The colocation of plant genetic and phytochemical research capacity represents a powerful resource. Not only can bioactive chemicals be isolated and characterised, but their genetic basis identified. The two recently established centres for phytochemistry and plant genetics are expected to grow rapidly from their current staff of 100.

State government support. State (and local) government has assisted the development of the concept behind CVP and the technology park. The park is one of five research parks in the state, and the world's first park of its kind.

Local connections and benefits. Partners in CVP have strong links with businesses (such as Fauldings, Blackmores, Mediherb, BioProspect Ltd, Lane Laboratories, and Thursday Plantations) and with primary industry organisations such as the Organic Herb Growers and the Tea Tree Growers Association. CVP partners have attracted at least $16 million dollars in research grants to SCU.

Commercialisation and commercial opportunities. At present, most natural plant product manufacture is carried out elsewhere, but it is hoped that the technology park will house, among others, companies developing, commercialising and manufacturing products from crops developed and grown locally. As about 90 per cent of the Australian natural plant product market is supplied from overseas, there is the potential for significant increase in local production. In addition, the global market for medicinal plant products is growing fast.

Commercialisation of bioactive substances bioprospected from Australian material is already under way with BioProspect having recently established a presence in Lismore, close to Australian Phytochemicals Ltd, its joint venture with the university's Centre for Phytochemistry. The Centre for Plant Genetics is already selling genetic information over the internet.

Sources: Southern Cross University, Submission no. 17; Southern Cross University and BioProspect, Committee briefing, 6 July 2001; 'Cellulose Valley: The gateway …', Southern Cross University.

4.16 Another centre that is pursuing regional development through its access to marine resources is the University of Wollongong. This initiative includes bioprospecting the local marine flora and fauna, fundamental research, building 'an extensive collection database' for the temperate marine environments, similar to that at AIMS', and aquaculture.[25]

4.17 The common features of bioindustrial activity in all three centres are access to biological resources, a strong research base, government support, and links to businesses that can carry discoveries forward. In all cases networks are very important, both within the local area and further afield. The committee believes that, while considerable development based on bioprospecting is possible in certain regional areas, regional areas cannot manage on their own. As UQ pointed out :

> … benefits through IP-protected value-added industries in regional and rural areas will sometimes be maximised through intermediate steps in product research and development carried out in a biotechnology hub such as the UQ precinct.[26]

Impediments

4.18 Impediments to establishing regional bioindustries have been identified from the case studies and other information given to the committee. They are summarised below, along with the suggestions about how they should be addressed. Many of the impediments are not peculiar to bioindustries, but are faced by any type of novel, regional, industrial development. Some of the critical requirements for success that were lacking at all or some of the three centres are:

- support in the regions for early stage development of biotechnological leads;[27]
- access to grants;[28]
- appropriate research facilities, including the possibility of pooling equipment and infrastructure as happens in larger centres;[29]
- adequate salaries to attract and retain researchers;[30]

25 Dr Kirsten Benkendorff, University of Wollongong, Submission no. 38, p. 2.

26 Faculty of Biological and Chemical Sciences, The University of Queensland, Submission no. 26, p. 2.

27 Dr Kirsten Benkendorff, University of Wollongong, Submission no. 38, pp. 4-5; James Cook University, Submission no. 22, p. 2.

28 Australian Institute of Marine Science, Submission no. 27, p. 14.

29 James Cook University, Committee briefing, 4 May 2001.

- critical mass in the research community;[31]
- a skilled workforce, including skills in the research community in IP, project and financial management;[32]
- entrepreneurial skills and leadership;[33]
- interest in the local business community in biotechnology;[34]
- regional infrastructure, particularly high speed telecommunications links;[35]
- investment, including that needed to meet the high cost of venture capital and IP protection;[36] and
- links between the stages in product development, for example, between researchers and companies that might develop leads.[37]

Distance from the state and federal capital cities seemed to staff at regional centres to be an important reason for their failure to influence policy development and to make their case for funding.[38]

Solutions

4.19 Several suggestions were made to the committee about how the problems listed above might be resolved.

- Business development programs and support for start up companies need to be better targeted to regional areas.[39] Some assistance to start ups may come from the extra funding assigned for the redesign of CRCs to make them more accessible to small and medium enterprises.[40]
- Hiring a high flying researcher, providing equipment, and building an effective team around this person are a way of helping to create critical

30 James Cook University, Committee briefing, 4 May 2001.

31 James Cook University, Committee briefing,, 4 May 2001; Department of Agriculture, Fisheries and Forestry - Australia, Transcript of evidence, 2 April 2001, pp. 28-9.

32 James Cook University, Committee briefing, 3 May 2001.

33 James Cook University, Submission no. 22, p. 2.

34 James Cook University, Committee briefing, 3 May 2001.

35 Biotechnology Australia, Submission no. 25, p. 16; James Cook University, Submission no. 22, p. 2.

36 Australian Institute of Marine Science, Submission no. 27, p. 14.

37 Australian Institute of Marine Science, Submission no. 27, pp. 14-15.

38 Committee briefing by the Australian Institute of Marine Science, 3 May 2001.

39 EcoBiotics Pty Ltd, Submission no. 18, p. 2.

40 Biotechnology Australia, Transcript of evidence, 2 April 2001, p. 25.

mass and an attractive work environment for research. CRCs are also an excellent means of supporting networking.[41] In addition, the higher education white paper promoted the role of universities in regional development.[42]

- If university researchers had lighter teaching loads, the extra time they would have would enable them to take a more entrepreneurial approach to commercialising their discoveries.[43] The committee noted that the 1999 higher education white paper put in place a new policy framework which included enhancing the development of a more entrepreneurial culture in the higher education sector.[44]

4.20 The committee believes that attempts to establish regional industries based on bioprospecting need to be seen in the context of all the activity in biotechnological and other research fields across the country and all the efforts being made to commercialise Australian research.

4.21 A number of Commonwealth government programs were brought to the attention of the committee as open to application by those interested in biodiscovery and its commercialisation in regional areas. They include some dedicated to biotechnology alone, such as the $40 million Biotechnology Innovation Fund. This fund addresses the gap between research and commercialisation, for example, by providing pre seed funding for start up companies. The proposed Biotechnology Centre of Excellence, which is likely to comprise virtual elements as well as new, centralised infrastructure, could incorporate regional centres into its network.[45]

4.22 Other more generic programs are also open to biotechnology interests. Some of the Commonwealth government's annual input of $250 million into biotechnology is spent as:

- Australian Research Council (ARC) grants;
- Research Infrastructure Block grants for universities;
- funds for major national research facilities;
- funding for CRCs;
- the Innovation Access Program, which links Australian companies with overseas markets;

41 James Cook University and the Rainforest Cooperative Research Centre, Committee briefing, 4 May 2001.

42 Biotechnology Australia, Submission no. 25, p. 15.

43 James Cook University, Committee briefing, 4 May 2001.

44 Biotechnology Australia, Submission no. 25, p. 15.

45 Biotechnology Australia, Transcript of evidence, 2 April 2001, p. 14.

- pre seed funding for universities and public sector research institutions;
- the R&D Start and Commercialising Emerging Technologies programs;
- funding for research and development corporations in the AFFA portfolio;
- AFFA's Farm Innovation and New Industries Development programs (NDIP);
- support for education and training in IP management.[46]

4.23 In addition to the above are a range of Commonwealth programs that promote business development. They provide support for:

- 119 Pooled Development Funds, ten of which are devoted to biotechnology;
- the Export Market Development Grants scheme;
- the Innovation Investment Fund; and
- the Technology Diffusion Program.[47]

4.24 Some of the programs listed in the last two paragraphs will bring benefit to regional Australia. Examples of these are funding by the ARC and NDIP, and the MNRF programs. Furthermore, InvestAustralia, the Commonwealth government's national investment agency, has established a team to promote regional investment, both small and large.[48]

4.25 State programs also address some of the impediments identified in this chapter through their support for regional development and biotechnology.

4.26 The committee found that some of those it spoke to were not well informed about the range of programs available to support the development of bioindustries. The committee acknowledges that *National Biotechnology Strategy: Progress and Achievements*, which is accessible from BA's web site, contains information about grants schemes.[49] However, the committee believes that this information could be provided in a more accessible form, and recommends accordingly. The committee sees the dissemination of information as a significant issue and returns to it again in Chapter 6.

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46 Department of Agriculture, Fisheries and Forestry - Australia, Supplementary submission no. 35, pp. 1-2; Biotechnology Australia, Submission no. 25, pp. 14, 18-19.

47 Biotechnology Australia, Submission no. 25, pp. 22-3.

48 DTRS, 'Economic and business development', http://www.dotrs.gov.au/budget/regional/2001_2002/industry_science.htm, accessed 23 July 2001.

49 *Australian Biotechnology: Progress and Achievements*, Commonwealth of Australia, 2000.

Recommendation 17

4.27 The committee recommends that Biotechnology Australia make information about grant programs available on its web site in a clear and easily accessible form, and provide a link to the GrantsLINK web site.

4.28 The committee recognises that current funding programs and recent changes to them were introduced to address some of the impediments identified earlier in this chapter. Examples of this are funding for the early stages of commercialisation and support for better collaboration between researchers and between industry and researchers. The committee is also aware of a number of initiatives introduced to stimulate regional development since the Regional Australia Summit held in October 1999.

4.29 The committee believes, however, that more needs to be done to stimulate the development of regional bioindustries. Excellent regional R&D projects, such as those based on bioprospecting, should not be turned down because of limitations that arise simply as a function of their locality. The Commonwealth government should develop a new focus on bioprospecting, biodiscovery and bioindustries in its R&D and regional development programs.

4.30 One element of this new focus might be to support all the components of rural business development including the basic scientific R&D, the production sciences, and business and social infrastructure. This approach was put to the committee by UQ, which argued that sufficient funding must be available to see projects through to fruition, with project success being measured in terms of their social and economic contributions to rural communities as well as direct commercial returns. The University proposed that:

> One approach could be the establishment of a targeted R&D program with the charter of supporting research and innovation in bioprospecting / rural industries. This might be managed through an existing body (eg. RIRDC) or a new organisation. There should be a mix of funding models from full public funding to various levels of matching industry funds as happened for other rural industries already.[50]

50 University of Queensland, Faculty of Natural Resources, Agriculture and Veterinary Science, Submission no. 31, p. 2.

This proposal received the support of the Marine Bioprospecting Coordinator from the University of Wollongong.[51]

4.31 UQ observed that:

> Such a funding arrangement overlaps with existing research funding arrangements, but it provides the focus on bioprospecting and rural development. In the past otherwise worthy projects have not been funded because they fall in the gap between the existing funding bodies. While such a program could be spread across existing funding channels by designation of a national priority, such an approach is unlikely to achieve the same level of integration and focus.[52]

4.32 The committee is sympathetic to the problems of projects that are not supported because they 'fall in the gap between existing funding bodies'. It does not believe, however, that a new organisation is the best method of addressing the development of new rural industries, such as those based on bioprospecting.

4.33 The committee prefers the option of pursuing this issue through the Rural Industries Research and Development Corporation (RIRDC). The committee notes that the RIRDC's priorities include the development of biotechnology and its programs support new and emerging industries, such as tea tree oils. The committee's attention was drawn to the RIRDC's report on the potential for Australian agriculture to produce new pharmaceutical, nutraceutical and industrial products, published in November 2000. A workshop on the report is planned for September 2001 to consider what future action should be undertaken. The RIRDC is also organising a session on these industries for the 2002 Outlook conference.

4.34 In addition, the committee notes that the RIRDC also considers broader issues of concern for rural communities and industries. One of its priorities is the fostering of creativity and innovation. It has, for example, recently published a handbook on small town renewal.[53]

4.35 The committee congratulates the RIRDC on the work that it is carrying out to identify new industries and stimulate regional development. It urges the RIRDC to give a higher profile to promoting cropping and industrial development based on the bioprospecting of Australia's native biota. The RIRDC should also further pursue the possibilities for novel bioprocessing using introduced plants. The committee also believes that the RIRDC

51 Dr Kirsten Benkendorff, University of Wollongong, Submission no. 38, p. 5.

52 University of Queensland, Faculty of Natural Resources, Agriculture and Veterinary Science, Submission no. 31, p. 3.

53 Rural Industries Research and Development Corporation, Home Page, http://www.rirdc.gov.au/, accessed 24 July 2001.

should also enlarge its work on value chain and whole of community development.

Recommendation 18

4.36 The committee recommends that the Rural Industries Research and Development Corporation:

- **aggregate funds into a specific program for researching and promoting the development of industries based on bioprospecting Australia's native biota and bioprocessing using introduced plants; and**
- **implement this program in the context of all the components of business development involved in establishing a new industry.**

4.37 The committee further expands on its views on a new focus by the Commonwealth government on bioprospecting, biodiscovery and bioindustries in its R&D and regional development programs in the next chapter. In that chapter the committee proposes a national strategy for the development of biobased industries.

5

Environmental impacts

Introduction

5.1 There was a general consensus among the views put to the committee about the environmental impact of bioprospecting. This view was that, in the Australian context, bioprospecting is unlikely to have significant negative effects. If negative impacts are expected, they can be minimised or avoided by placing conditions on bioprospectors. In addition, bioprospecting was seen as having considerable positive environmental spin offs.

Possible negative impacts

5.2 Being an extractive activity, bioprospecting can harm the environment.[1] The harm may come from activities such as:

- overcollecting, which is a particular danger in relation to rare and endangered species;
- the introduction of exotic species and pathogens to habitats visited by collectors; and / or
- the use of inappropriate collection methods that result in collateral damage to habitats or biota other than those being targeted.[2]

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1 Australian Institute of Marine Science, Submission no. 27, p. 16; Department of Agriculture, Fisheries and Forestry – Australia, Submission no. 24, p. 12; Biotechnology Australia, Submission no. 25, p. 20.

The last point is a concern in relation to fragile ecosystems, and in marine environments where destructive collecting methods such as trawling are used.[3]

5.3 However, much bioprospecting involves the collection of only small quantities of material.[4] Once the structure of any active chemical found in this material has been established, it is often possible to synthesise it without needing to make further collections from the wild.[5] The impact of collecting can also be minimised by targeting only the most promising organisms or groups of organisms on the basis of information already available.[6] Furthermore, impacts can be monitored.

5.4 The danger of bioprospecting to rare and endangered species is mitigated by the fact that it is likely to be impossible to guarantee future supplies of material, if positive leads are found. As CSIRO pointed out, 'any cost-benefit analysis would quickly indicate the lack of commercial opportunity'.[7] No business would invest in biodiscovery from such material.

5.5 AIMS claimed that bioprospecting for chemical extracts can be 'almost based on a "zero impact"'.[8] It suggested that:

> … impacts on the environment from traditional bioprospecting by well trained research groups is negligible. Even recollections of kilograms to tonnes can be accommodated with appropriate preliminary environmental effects investigations, and adoption of alternate means of production [such as] aquaculture / fermentation … [9]

In addition to aquaculture and fermentation, plantations and cropping to produce supplies of needed materials are other means of minimising impacts on wild populations of target species.[10]

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2 Tasmanian government, Submission no. 23, p. 3; Environment Australia, Submission no 29, p. 33.

3 Royal Society of Western Australia Inc., Submission no. 8, p. 3.

4 Northern Territory government, Submission no. 4, p. 7; Associate Professor Robert Capon, University of Melbourne, Submission no. 6, p. 5; EcoBiotics Pty Ltd, Submission no. 18, pp. 8-9.

5 Victorian government, Submission no. 34, p. 2.

6 Australian Institute of Marine Science, Submission no. 27, p. 16.

7 CSIRO, Submission no. 14, p. 26.

8 Australian Institute of Marine Science, Submission no. 27, p. 16.

9 Australian Institute of Marine Science, Submission no. 27, p. 17.

10 Environment Australia, Submission no. 29, p. 33; Biotechnology Australia, Submission no. 25, p. 20.

5.6 The importance of developing sustainable sources of the materials needed in the commercialisation of biodiscoveries is illustrated by experience with sourcing supplies to manufacture the anti cancer drug, taxol (Box 5.1).

Box 5.1 Taxol

Taxol is the generic trade name for the compound, paclitaxel, which has been developed from the Pacific yew tree, *Taxus brevifolia*. It is a highly complex compound which cannot be economically synthesised, but is in high demand. In 1997 it was the 30th top selling drug in the world.

Taxol is produced from the bark of trees that grow from northern California to British Columbia. The amounts of bark collected increased as the drug went into production: from 2,273-6,818 kg per year up to 1985, to 27,273 kg in 1987-8 and 1989 to supply Phase 1 clinical trials, and on to 727,273 kg in 1991 and 1992. Although environmental studies in 1990 indicated that *Taxus brevifolia* was abundant, ongoing monitoring suggested that alternative sources of taxol would have to be found.

Taxol is now obtained from the needles of another species of Taxus. It was sourced at one stage from India but suppliers felled the trees, selling the wood to one party and the needles for taxol production. Taxol is now sourced from Europe.

Source: K ten Kate & S A Laird, *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit-Sharing*, Earthscan Publications, London, 1999, pp. 73-4.

5.7 Existing legislation in many parts of Australia already addresses negative environmental impacts and is being or could be used to control bioprospecting. The Victorian government, for example, reported that 'for the most part the systems and processes required to protect biodiversity and enable the sustainable management of Victoria's flora and fauna are already in place'.[11] Nonetheless, a recent parliamentary committee report found some gaps in the coverage of the legislation, for instance in relation to microorganisms and terrestrial invertebrates.[12]

5.8 Under the Commonwealth government's EPBC Act, the requirement for an environmental impact assessment could be triggered by bioprospecting activities in relation to world heritage properties; Ramsar wetlands; listed threatened species, communities and migratory species; and Commonwealth land and marine areas. However, the Voumard report

11 Victorian government, Submission no. 34, p. 1.

12 Environment and Natural Resources Committee, Parliament of Victoria, *Inquiry into the Utilisation of Victorian Native Flora and Fauna*, June 2000, p. 314.

concluded that the existing administrative guidelines relating to this trigger needed to be amended to address impacts from bioprospecting.[13]

5.9 Once activities that impinge on these areas are referred to the Minister for the Environment, he may order:

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

The Voumard report indicated that assessment on preliminary documentation may often provide a satisfactory means of assessing the environmental significance of bioprospecting.[14]

5.10 The conditions attached to access permits also provide a powerful means of controlling environmental impacts, especially if they are mandatory and penalties apply to anyone who fails to obtain a permit or contravenes the collection protocols specified in the permit.[15] Independent monitoring and auditing arrangements are important in this context.

5.11 The Great Barrier Reef Marine Park Authority commented in a private meeting with the committee that, in the marine environment with which it is dealing, it is very hard to know what is a reasonable limit to place on researchers' collections. Yet, as the Australian Academy of Science pointed out:

> The development of Australia's bio-diversity by or on behalf of commercial users must be sustainable. This can only be achieved through ongoing intensive and exploratory research into the growth and/or maintenance of organisms either *in situ* or *in vitro.* Industry and government sectors need to provide adequate funding for this research work.[16]

13 Environment Australia, Submission no. 29, p. 34.

14 Environment Australia, Submission no. 29, p. 35.

15 Environment Australia, Submission no. 29, p. 35.

16 Australian Academy of Science, Submission no. 19, p. 2.

Positive impacts

5.12 The activity of bioprospectors has contributed substantially to what we know about Australia's biological resources.[17] It has led to the discovery of new and rare species, the compilation of species inventories, the identification of biogeographic zones and biodiverse hot spots, deposits of specimens in publicly accessible collections, and taxonomic work. There are some areas in Australia where all that is known about their biota is what has been collected by bioprospectors.[18]

5.13 Under the access conditions and benefit sharing arrangements concluded with bioprospectors, the latter can be required to help build the nation's knowledge base about our biological resources. An example of this is provided by the contracts finalised by AZGU with the Queensland Museum and Herbarium (Box 5.2).

Box 5. 2 Knowledge contributed by AstraZeneca R&D Griffith University's benefit sharing arrangements

Under contracts negotiated in 1993 with the Queensland Museum and Herbarium, AZGU pays a specified rate for each sample collected and a percentage of all proceeds from the commercial use of compounds obtained from the samples.

As a result of these arrangements:

- 60 new plant species have been discovered;
- 3,800 species of sponges, soft corals and ascidians have been collected, 2,000 of them being new to science;
- distribution data for these species have been assembled, including records of new populations of threatened species; and
- records of weed encroachment in native forests obtained.

Source: AstraZeneca R&D Griffith University, Submission no. 33, p. 2; Environment Australia, Submission no. 29, pp. 23, 36.

17 Biotechnology Australia, Submission no. 25, p. 19; Australian Academy of Science, Submission no. 19, p. 5; North Territory government, Submission no. 4, p. 8.

18 Australian Institute of Marine Science, Committee briefing, 3 May 2001; Environment Australia, Submission no. 29, p. 36.

5.14 Some state governments and others have suggested that the lodging of voucher specimens with museums and herbaria should be required, together with collection data and other information about the properties of the biota accessed.[19] In the contract between the Antarctic CRC and Cerylid Biosciences, arrangements have been made for information derived from microorganims by Cerylid to return to the CRC.

> When the contract with Cerylid ends—I think it is three years after the end of the contract—those organisms revert to the ownership of the Antarctic CRC and, if Cerylid have not commercialised an opportunity from the organisms, then all the information that they have collected on those organisms also comes back to the CRC.[20]

5.15 As attention world wide increasingly focused on the commercial value of biodiversity, environmentalists hoped that royalties and the payments made for access to the resources would provide a source of revenue for conservation purposes. However, as EA commented, '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'. There is also considerable variation in the value of biodiscoveries and hence the royalties that would flow from them.[21] Despite this, some of the income from bioprospecting could be devoted to conservation research.[22]

5.16 The information collected in the course of bioprospecting may make a greater contribution to conservation than any monetary returns. According to EA, 'the public good outcomes and the public good potentials of assaying our biodiversity are enormous'.[23] With better information about species and the ecosystems in which they occur, the managers of biological resources are in a stronger position to make wise decisions about conserving these resources and allowing them to be used.[24] At a private meeting with the committee, AIMS outlined how information collected during bioprospecting is being used to support proposals to identify habitats under threat. For example:

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19 Australian Conservation Foundation and Queensland government quoted by Environment Australia, Submission no. 29, p. 36; Western Australian government, Submission no. 32, p. 4.

20 The Australian Society for Microbiology, Transcript of evidence, 25 June 2001, p. 92.

21 Environment Australia, Submission no. 29, p. 36.

22 Tasmanian government, Submission no. 23, p. 4; South Australian government, Submission no. 28, p. 6.

23 Environment Australia, Transcript of evidence, 4 June 2001, p. 72.

24 Victorian government, Submission no. 34, p. 1.

> … that biodiversity is under threat is … abundantly obvious to qualified bioprospecting teams. Sediment discharge from rivers onto the continental shelf, some trawling activity and invasion from opportunistic species introduced by shipping is having significant impact on biodiversity.[25]

5.17 Several witnesses to the inquiry also pointed out the environmental benefits that flow from biodiscoveries. They cited as examples:

- bioremediation;
- reducing waste and greenhouse gas emissions by using biological feedstocks instead of petrochemicals for industrial production;
- improving waste and waste water management;
- increasing the efficiency with which products are produced; and
- developing crop plants that are better adapted to marginal environments or resistant to disease compared with current varieties.[26]

The fact that many of the genetically modified organisms (GMO) that might be used in bioindustries would be contained in fermenters is an advantage in situations where GMOs are viewed negatively by the public.

Conclusion

5.18 Conservation of biodiversity is fundamental to biodiscovery and to building bioindustries based on these discoveries. If lost, biodiversity cannot be recreated. With its loss, numerous adaptations to different environments disappear. Many of these adaptations are the outcome of thousands, if not millions, of years of evolution.[27] They comprise a variety of successful solutions to the environmental challenges facing the organisms in which they are found. As the same challenges face humankind in its survival, the various adaptations to these challenges are potential starting points for the solution of our problems.[28] The conservation of biodiversity is therefore imperative.

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25 Australian Institute of Marine Science, Exhibit no. 2.

26 CSIRO Submission no. 14, pp. 4, pp. 26-27; Department of Agriculture, Fisheries and Forestry – Australia, Submission no. 24, p. 13; Transcript of evidence, 2 April 2001, p. 28; Biotechnology Australia, Submission no. 25, pp. 13, 19-20;

27 Faculty of Biological and Chemical Sciences, The University of Queensland, Submission no. 26, p. 1.

28 South Australian government, Submission no. 28, p. 1.

5.19 The terms of reference did not include a requirement for the committee to assess the adequacy with which biological resources are being conserved in Australia, and very little information was received on this point. However, the committee did receive some comments on this topic and they are noted here.

- The Western Australian government claimed that conservation is generally under resourced in Australia.[29]
- While a considerable number of protected areas have been declared on land, marine biodiversity is not adequately protected.
- Although a rich source of material for bioprospectors, microorganisms are not well protected.

5.20 The committee is aware that some of these issues are being addressed, for example, through the establishment of a National Representative System of Marine Protected Areas. Australia's governments are working together to set up a national system of protected areas throughout our entire marine zone. They will represent all the major ecological regions and the communities of plants and animals that they contain. The Minister for the Environment, Senator Hill, has called for an acceleration of action by all Australian governments in this effort.[30]

5.21 The committee believes that it is essential that state, territory and Commonwealth conservation programs comprehensively cover Australia's biodiversity and are adequately funded to maintain it. The combination of great biodiversity and an access regime encouraging to bioprospectors promises great possibilities for economic gain from bioprospecting. Without a strong, efficient conservation effort, Australia will lose out, both industrially, environmentally and socially.

Recommendation 19

5.22 The committee recommends that Environment Australia give a high priority to continuing its work with state and territory governments to develop a nationally consistent approach to establishing conservation areas that comprehensively cover all species and ecosystems.

29 West Australian government, Submission no 32, p. 1.

30 Environment Australia, 'A National Representative System of Marine Protected Areas', http://www.ea.gov.au/coasts/mpa/nrsmpa/index.html, accessed 16 July 2001.

6

A national strategy for the development of new biobased industries

Introduction

6.1 In Chapter 3, the committee identified impediments to the development of bioprospecting and industries based on biodiscovery. It recommended how the impediments at each stage in the development of the bioproduct chain might be overcome. Chapter 4 dealt with the regional possibilities for developing and producing new bioproducts. In this chapter, the committee considers some of the broader issues relating to the establishment of bioindustries and draws together its earlier recommendations in the context of recommending a national strategy to develop new biobased industries.

6.2 Value adding was a strong theme in the evidence received by the inquiry. The committee believes that it must be the underlying principle for a national strategy for developing industries based on bioprospecting. The strategy should be directed at obtaining the maximum value for Australia in terms of economic returns from the nation's biological resources, with due consideration given to the conservation and sustainable use of the resources.

Developing a strategy

6.3 The Australian Academy of Science commented in its submission on the lack of vision and forward planning by both government and industry in relation to bioindustries.[1] CSIRO made a similar point about:

> [a] lack of visionary industry leadership to think globally but act locally, for which there is a role for Governments to support. Whilst some recent initiatives by the Commonwealth and State Governments have sought to address this such as the recent Innovation Statement and the significant infrastructure investments in some States, CSIRO believes there is still a way to go.[2]

6.4 The committee believes that a greater emphasis on policy and planning for future development is needed. Policy development and planning should be carried out through consultation between Commonwealth, state and territory governments, industry, and the research community, with the Commonwealth government taking a leading role. They should clearly articulate a long term vision for the development of high technology industries based on bioprospecting.

6.5 This vision should incorporate the need to develop Australia's regions and foster new and innovative primary industries. It should also have regard to current and anticipated future events, such as global warming, land degradation, and the spread of salinity. As indicated in earlier chapters of this report, bioindustries offer opportunities to address aspects of these problems, for example, by:

- reducing greenhouse gas emissions;
- minimising industrial waste;
- increasing energy conversion ratios; and
- remediating polluted environments.

6.6 Submissions to the inquiry suggested some matters that the policies and plans should cover. The Western Australian government, for example, suggested that 'Australia's efforts in relation to bioprospecting will benefit from a focus on the early stages of the process, based upon early discoveries and development of leads'.[3] The South Australian government proposed that an Australian International Cooperative Biodiversity Group

1 Australian Academy of Science, Submission no. 19, p. 2.

2 CSIRO, Submission no. 14, p. 19.

3 Western Australian government, Submission no. 32, p. 4.

be established. The group would involve Australian governments and research and industry organisations, and 'facilitate Australia's bioprospecting competitiveness and effectiveness in the international bioscience market'.[4]

6.7 CSIRO nominated several important topics for the strategy to address:

- the selection of market niches in which Australia has or could have a competitive advantage;
- funding for the core technologies, infrastructure and skills needed to service those niches;
- a collaborative approach to R&D that helps to assemble critical mass, and link different elements in bioproduct development;
- a bioindustry development strategy, with financial support a necessary adjunct in the face of rapid overseas technology growth and competing international investments; and
- industry as the owner and driver of bioindustrial development.[5]

6.8 The committee agrees with those who made submissions to the inquiry that government support for bioproduct development from bioprospecting should focus on the earlier stages of development. It also believes that there is an important role for agriculture, fisheries and forestry departments to promote and facilitate the use of crops developed from bioprospecting.

6.9 The NBS was announced in July 2000 with the aim of ensuring 'Australia captures the benefits arising from the medical, agricultural and environmental application of biotechnology, while protecting the safety of people and the environment'.[6] BA, which is a collaboration of five Commonwealth Government departments,[7] was created in May 1999 to assist in coordinating the government's approach to the non-regulatory aspects of biotechnology. Having developed the NBS, BA is now responsible for the strategy's implementation by the collaborating departments.

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4 South Australian government, Submission no. 28, p. 10.

5 CSIRO, Submission no. 14, pp. 19, 29.

6 Biotechnology Australia, 'About Biotechnology Australia', http://www.biotechnology.gov.au/About_Us/index.asp, accessed 13 July 2001.

7 BA is part of the Industry, Science and Resources (ISR) portfolio and comprises the following departments: ISR; EA; AFFA; Health and Aged Care; and Education, Training and Youth Affairs. The Commonwealth Biotechnology Ministerial Council is chaired by the Minister for Industry, Science and Resources.

6.10 While Australia has a national biotechnology strategy, the committee believes that the opportunities for developing new industries offered by Australia's biodiversity merit much greater recognition and promotion. The committee proposes that Australia should also have a strategy for developing new biobased industries. The new strategy should be developed by BA under the umbrella of the NBS, in keeping with its 'active interest in biotechnology issues, including bioprocessing, bioprospecting and related technologies'.[8]

6.11 In overseeing the implementation of the NBS, BA is guided by its ministerial council, input from its five collaborating departments, and community, research and industry advice from the Biotechnology Consultative Group (to be replaced shortly by the Australian Biotechnology Advisory Council).[9] The committee envisages that these bodies would guide the development of a national strategy for developing new biobased industries under the umbrella of the NBS. Input from the state and territory governments would also be essential, together with extensive consultation with other interested parties.

6.12 There is an important role for the Commonwealth government in facilitating and funding the development of the national strategy and funding its implementation. Providing adequate funding at critical times for these activities, including for infrastructure and skills development, is vital. Some funding of this kind is already being provided as indicated earlier in this report, but more needs to be done. Some urgent requirements have been addressed in the recommendations made in Chapter 3. Additional funding will be needed for other items identified in the national strategy.

6.13 The committee envisages that the strategy would address a number of issues such as those listed in paragraph 6.7. It would also emphasise the development of IP from Australia's mega diverse biota and promote its commercial use for long term national and international impact. A vital element of the strategy should be the provision of a one stop shop for information about financial support for bioprospecting and the early stages of commercialising biodiscoveries.

6.14 As indicated in paragraph 6.5, the vision for new, Australian, biobased industries must be formulated in the context of current and anticipated events. The committee believes that, for maximum effectiveness, the strategy for these new industries will need to be fully integrated with those addressing other national issues. As CSIRO pointed out, governments can accelerate bioindustrial development by the broader

8 Biotechnology Australia, Submission no. 25, p. 2.

9 Biotechnology Australia, Submission no. 25, pp. 2-3.

agenda they set. For instance, the Commonwealth government, in the national interest, might set targets aimed at stimulating the move away from petroleum based feedstocks and their replacement by renewable raw materials.[10] Such targets could be met by greater use of some of the bioprocessing options mentioned in Chapter 3, and would greatly stimulate regional, bioindustrial development.

Recommendation 20

6.15 The committee recommends that:

- **a national strategy be developed to promote bioprospecting, bioprocessing and the establishment of industries based on these activities; and**
- **Biotechnology Australia sponsor the development and implementation of the strategy.**

The strategy should:

- **indicate how bioprospecting will be used over the next two decades to contribute to existing industries and develop new ones;**
- **provide information about the government support available for bioproduct development, especially for the earlier stages in the bioproduct chain;**
- **promote collaboration and networking; and**
- **address biobased industry development in regional Australia.**

Recommendation 21

6.16 The committee recommends that Biotechnology Australia be sufficiently funded to develop and implement the strategy.

10 CSIRO, Submission no. 14, p. 29.

Role of Department of Agriculture, Fisheries and Forestry - Australia

6.17 The committee envisages an important role for AFFA in the development and implementation of the strategy. The committee is concerned, however, that AFFA appears to lack the necessary vision and enthusiasm to make an effective contribution in this respect. AFFA gave the committee the impression that it was not pursuing new possibilities in the form of new biobased industries as proactively as it should have been. This failure appeared to the committee to reflect a view, articulated by CSIRO, that the primary industry sector, which could provide feedstock for industrial bioprocessing, is perceived as being largely an 'old economy sector'.[11]

6.18 AFFA told the committee that biotechnology was one of its priorities,[12] and drew attention to the work on new biobased industries that is being carried out through the RIRDC, the New Industries Development Program (NDIP) and the Farm Innovation Program (FIP) (Box 6.1). While acknowledging this work, the committee was disappointed by its small scale and by AFFA's lack of enthusiasm and knowledge about new technologies that can directly affect many traditional agricultural industries and have the potential to create new ones.

6.19 The committee believes that much more needs to be done. For example, the programs mentioned above are general ones which fund suitable projects based on bioprospecting, in competition with other types of project. Clearly a higher profile should be given to funding the development of industries based on bioprospecting within these programs.

11 CSIRO, Submission no. 14, p. 19.

12 Department of Agriculture, Fisheries and Forestry - Australia, Transcript of evidence, 2 April 2001, p. 30.

Box 6.1 Support by the Department of Agriculture, Fisheries and Forestry - Australia portfolio for R&D and establishment of new biobased industries

Past and present work supported by the RIRDC include projects on:

- a cholesterol lowering extract from garlic;
- the antimicrobial properties and flavours of native mint bushes;
- antiviral and antioxidant properties of bush foods and medicines; and
- the potential for Australian agriculture to supply new pharmaceutical, nutraceutical and industrial products.

The FIP is supporting the development of Australia's first native pepper plantation by Essential Oils of Tasmania. The NDIP is funding:

- Botanical Resources Australia to boost the commercial potential of its high value echinacea products, which are expected to earn the company $4 million within five years; and
- the Australian Cartilage Company to increase its production of a liquid form of bovine cartilage for use by arthritis and cancer sufferers.

AFFA has also pursued the potential for a range of crops, particularly grain and sugar, to produce industrial products such as ethanol, methanol and bioplastics.

Source: Department of Agriculture, Fisheries and Forestry - Australia, Submission no. 35, pp. 7-9; Rural Industries Research and Development Corporation, Completed projects and research in progress, http://www.rirdc.gov.au/comp00/, accessed 26 July 2001.

Recommendation 22

6.20 The committee recommends that Department of Agriculture, Fisheries and Forestry - Australia:

- **give a higher profile to promoting the development and establishment of industries based on bioprospecting and bioprocessing; and**
- **work closely with AusIndustry to promote opportunities for developing industries from bioprospecting and bioprocessing.**

Fran Bailey, MP
Committee Chair

22 August 2001

A

Appendix A – List of submissions

Submissions

Number	Organisation
1	Royal Botanic Gardens Sydney
2	Dr Eugene Dimitriadis
3	Queensland Nursery Industry Association
4	Northern Territory Government
5	Professor Andrew J. Beattie
6	Associate Professor Robert Capon
7	Western Plains Regional Development
8	Royal Society of Western Australia
9	Ms F C Murdoch
10	Australian Society for Microbiology
11	Mr Shane Bawden
12	BioProspect Limited
13	Cerylid Biosciences Ltd
14	CSIRO
15	Mrs Eleanor Betteridge
16	Global Recycling Pty. Ltd for Kangaroo Island Nature Lab
17	Southern Cross University
18	EcoBiotics Pty Ltd

19	Australian Academy of Science
20	Australian Property Institute
21	IP Australia
22	James Cook University
23	Tasmanian Government
24	Department of Agriculture, Fisheries and Forestry - Australia
25	Biotechnology Australia
26	The University of Queensland, Faculty of Biological and Chemical Sciences
27	Australian Institute of Marine Science
28	South Australian Government
29	Environment Australia
30	Aboriginal and Torres Strait Islander Commission
31	University of Queensland, Faculty of Natural Resources, Agriculture and Veterinary Science
32	Western Australian Government
33	AstraZeneca R&D Griffith University
34	Victorian Government
35	Department of Agriculture, Fisheries and Forestry - Australia
36	Department of Agriculture, Fisheries and Forestry - Australia
37	Associate Professor Lindsay Sly
38	Dr Kirsten Benkendorff
39	IP Australia

B

Appendix B – List of exhibits

1. Document tabled by CSIRO at a public hearing in Canberra on 4 April 2001.

Inquiry into Access to Biological Resources in Commonwealth Areas, CSIRO submission, March 2000

2. Documents provided by the Australian Institute of Marine Science at a meeting at Cape Ferguson on 3 May 2001:

'Maximising regional benefits from bioprospecting Australia's marine biodiversity', copies of power point presentation and accompanying text;

'Biotechnology benefit sharing agreement between AIMS and the State of Queensland', 5 September 2000; and

T Matainaho and S Saulei, 'Biological prospecting, conservation and economic development: a national biodiversity initiative (NBI) by the Papua New Guinea Biodiversity Network (PNGBioNET)'.

3. Documents provided by Dr Peter Murphy, Original Oceanz, Smart Ventures Industry Group at a meeting in Townsville on 4 May 2001:

'Access to biodiversity: the lucky country misses the boat 1996', copy of overheads; and

'Palm Island sponge project: an industry for the community', copy of overheads.

4. Paper and attachments provided by Dr Subhash Vasudevan of, James Cook University at a meeting in Townsville on 4 May 2001:

S Vasudevan, J Burnell and D Williams, 'Biodiscovery from snake venom'.

5. Document provided by Professor Nigel Stork, Chief Executive Officer, Rainforest Cooperative Research Centre at a meeting in Townsville on 4 May 2001:

N Stork, 'Vision for the Rainforest Centre of Excellence: Proposed name: the Australian Rainforest Institute', draft discussion paper, April 2001.

6. Document provided by Adam Smith, Manager, Environmental Impact Management, Great Barrier Reef Marine Park Authority at a meeting in Townsville on 4 May 2001:

'Inquiry - bioprospecting', copy of powerpoint presentation.

7. Document provided by Mark Day, Manager Business Development, CSR Townsville at a meeting in Townsville on 4 May 2001:

'Burdekin Ethanol Distillery Project', copy of powerpoint presentation.

8. Documents provided by Greg Eaton, Chief Executive Officer, BioProspect at a meeting at Southern Cross University, Lismore on 6 July 2001:

'Agreement between the Sovereign State of XXXXXX XXXXXX and BioProspect Australia Ltd'; and

'M Kealley, *Bioprospecting Global Collection Protocol: Version 1.0*, BioProspect.

C

Appendix C – List of public hearings and witnesses

Monday, 2 April 2001 - Canberra

Department of Agriculture, Fisheries and Forestry - Australia

Mr Andrew Pearson, Acting General Manager, Science and Economic Policy

Mr Robert Blazey, Policy Officer, Plant Breeders Rights Office

Ms Kristiane Herrmann, Project Manager, Access to Biological and Genetic Resources

Mr Nikolas Hulse, Senior Examiner and Deputy Registrar, Plant Breeders Rights Office

Ms Sandra Thomas, Senior Scientist, Food and Gene Technology Program, Bureau of Rural Sciences

Department of Industry, Science and Resources

Ms Sandra Radke, General Manager, Biotechnology Australia

Dr David Swanton, Manager, Projects, Biotechnology Australia

Wednesday, 4 April 2001 - Canberra

CSIRO

Dr John Curran, Assistant Chief

Dr Mikael Hirsch, Biotechnology Coordinator

Dr Paul Wellings, Deputy Chief Executive

Monday, 4 June 2001 - Canberra

Department of Environment and Heritage

Mr Maxwell Kitchell, First Assistant Secretary, Natural Heritage Division

Environment Australia

Mr Geoffrey Burton, Director, Access Task Force

Monday, 25 June 2001 - Canberra

Australian Society for Microbiology

Professor Thomas McMeekin, Member

Dr David Nichols, Member, National Scientific Advisory Committee

Dr Kevin Sanderson, Associate Member

Botanical Resources Australia Pty Ltd

Mr Brian Chung, Manager, Research and Development

Cerylid Biosciences Ltd

Ms Mary Harney, Operations Manager / Company Secretary

Dr Howard Wildman, Leader, Biotic Resources

Wednesday, 27 June 2001 - Canberra

Department of Agriculture, Fisheries and Forestry - Australia

Mr Brian Jones, General Manager, Science and Economic Policy

Mr Paul Morris, Executive Manager, Innovation & Operating Environment

Mr Andrew Pearson, Manager, Science and Technology Policy

Mr Bernard Wonder, Deputy Secretary

D

Appendix D – Inspections and discussions

Canberra – Monday, 27 November 2000

Inspections and discussions

The committee inspected CSIRO Entomology's laboratories in Canberra, and held discussions with staff from CSIRO Entomology and CSIRO Molecular Science.

Townsville – Thursday, 3 May 2001

Inspections and discussions

The committee inspected the facilities of the Australian Institute of Marine Science, Cape Ferguson, Queensland and held discussions with staff.

Meeting and discussions with:

Professor Norman Palmer, Pro-Vice-Chancellor (Research and International), James Cook University

Townsville – Friday, 4 May 2001

Meeting and discussions with representatives of:

Original Oceanz, Smart Ventures Industry Group

Department of State Development, Queensland

Coolgaree Aboriginal Corporation

Australian Institute of Marine Science

James Cook University (Biochemistry and Molecular Biology, Physiology and Pharmacology, and Organic Chemistry)

Rainforest Cooperative Research Centre

Great Barrier Reef Marine Park Authority

Canberra - Wednesday, 6 June 2001

Briefing by:

Mr Leo Hyde, R&D Manager, Dupont Australia

Lismore – Friday, 6 July 2001

Inspections and discussions

The committee inspected the laboratories of the Southern Cross University's Centre for Plant Phytochemistry, Centre for Plant Conservation Genetics and Cellulose Valley Technology Park. It held discussions with:

BioProspect Pty Ltd

Staff from Southern Cross University (the Vice-Chancellor, Cellulose Valley Project, Centre for Phytochemistry, Centre for Plant Conservation Genetics, and the School of Natural and Complementary Medicine).

E

Appendix E - Details of the access and benefit sharing scheme recommended in the Voumard Report

The following information is taken from Chapter 2 of the report by John Voumard on his inquiry into access to biological resources in Commonwealth areas.[1]

How the proposed scheme would operate

2.1 A major objective of the Inquiry was to develop an administration and decision-making system which is consistent, to the extent possible and appropriate, with other provisions in the EPBC Act, particularly the integrated permits scheme, environmental assessment provisions, and the objects in s3 which relate to Indigenous people.

Interaction with related provisions of the EPBC Act: the integrated permit scheme

2.2 The Inquiry has attempted to design a scheme which is consistent with, and can therefore be integrated into, the general permit scheme under the EPBC Act.

2.3 The Act provides for two main types of permits.

a) Permits for activities in Commonwealth areas including reserves, parks, conservations zones and external territories (reserve permits).

b) Permits for the taking, keeping, moving etc of listed threatened, migratory, marine and cetacean species and communities in Commonwealth areas (wildlife permits).

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1 J Voumard, *Access to Biological Resources in Commonwealth Areas*, Commonwealth of Australia, July 2000, pp 13-24, 168.

2.4 Proposed amendments to the Act would see the inclusion of the permits currently issued under the *Wildlife Protection (Regulation of Exports and Imports) Act 1982*.

Administration and decision-making in the proposed scheme

2.5 Many submissions favoured a centralised system of administration and decision-making for the scheme. Since most Commonwealth Government agencies have had limited experience with access and benefit-sharing arrangements, the Inquiry considers there would be value, at least for the foreseeable future, in making one agency (Environment Australia) responsible for administering the scheme. This would also be administratively convenient where more than one agency was involved in access negotiations. It is also consistent with Environment Australia's responsibility for assessing other permits under the EPBC Act.

2.6 In assessing access permit applications, Environment Australia would be required to consult with relevant agencies (including independent sources of advice, where necessary) and then prepare a recommendation to the Minister for the Environment and Heritage as to whether the permit should be granted or refused. This would include assessing and making a recommendation about the proposed benefit-sharing contract. Environment Australia's role would include being the first point of contact for information about the scheme.

2.7 It may be appropriate for some administrative and decision-making functions to be delegated (with Environment Australia retained as the first point of contact) when agencies have more experience in dealing with the issues.

Recommendations

2. That the Department of the Environment and Heritage be the central administering agency for the access scheme.

3. That the Minister for the Environment and Heritage be given responsibility under the EPBC Act to make decisions whether to grant or refuse applications for access permits.

4. That applications for access permits be handled through the Department of the Environment and Heritage's permits web site which should be linked to the Access to Biological Resources in Commonwealth Areas page on the Department's web site.

5. That the Department of the Environment and Heritage's standard permit application be amended to include the information that applicants must provide when seeking access to biological resources under s301.

Timeframes

2.8 The Inquiry acknowledges that applicants will want permit applications and contract negotiations finalised within reasonable timeframes. It considered, however, that it was not consistent with the principles of prior informed consent and mutually agreed terms to impose time limits on contract negotiations. In any event, commercial contracts are complex and often require considerable negotiation before they are concluded.

2.9 Once the parties have submitted a contract to Environment Australia, however, the Inquiry considered that some limits on the timeframes within which Environment Australia should make its recommendation to the Minister and within which the Minister should make a decision were reasonable and in the interests of both parties. These should be consistent with the timeframes which apply to comparable decisions under the EPBC Act.

Recommendation

6. That the regulations include timeframes (consistent with comparable decisions under the EPBC Act) within which:

a) after receiving the benefit-sharing contract, the Department of the Environment and Heritage is required to make a recommendation to the Minister about the permit, and

b) after receiving the recommendation, the Minister is required to make a decision to grant or refuse the permit.

Register of agreements

2.10 Several submissions recommended that the agency responsible for administering the scheme should maintain a register of agreements under s301 of the EPBC Act.

Recommendation

7. That the Department of the Environment and Heritage maintain a register of contracts under s301 of the EPBC Act and the permits which relate to them. To the extent possible, allowing for reasonable concerns of the parties about confidentiality (for example, for commercial, cultural or other reasons) information about the agreements should be made public.

Detailed description of the access scheme

2.11 The following is a description of how the proposed scheme will work. A flow chart of the scheme appears below.

a) **Applicant submits an application to Environment Australia** using standard form designed for all permit applications under the EPBC Act, with specific provisions for s301 access requests.

b) **Environment Australia assesses the application** — addresses threshold questions.

- Is the collecting in a Commonwealth 'area' under s525?
  - No — Environment Australia advises applicant where to seek permit, eg State or Territory government agency.
  - Yes — Environment Australia continues to assess the application.
- Does it involve a request for wildlife, reserve and/or export permits?
- Does it involve collection of threatened species (s201), migratory species (s216), cetaceans (s238) and/or listed marine species (s258)? (wildlife permits)
  - If yes, is an environmental assessment required? (environmental assessment procedures must be completed before the permit can be granted or refused).
  - Permit for these activities may be granted or refused.
- Does it involve a request to export samples?
  - If yes, procedures must be completed so the applicant is aware of whether they will be able to export samples before proceeding with the application for permit and benefit-sharing agreement.

[**Note**: At this point Environment Australia should ensure that the applicant is aware of the requirement to conclude a contract with the resource provider and, if necessary, advise the applicant of the provider's contact details etc.]

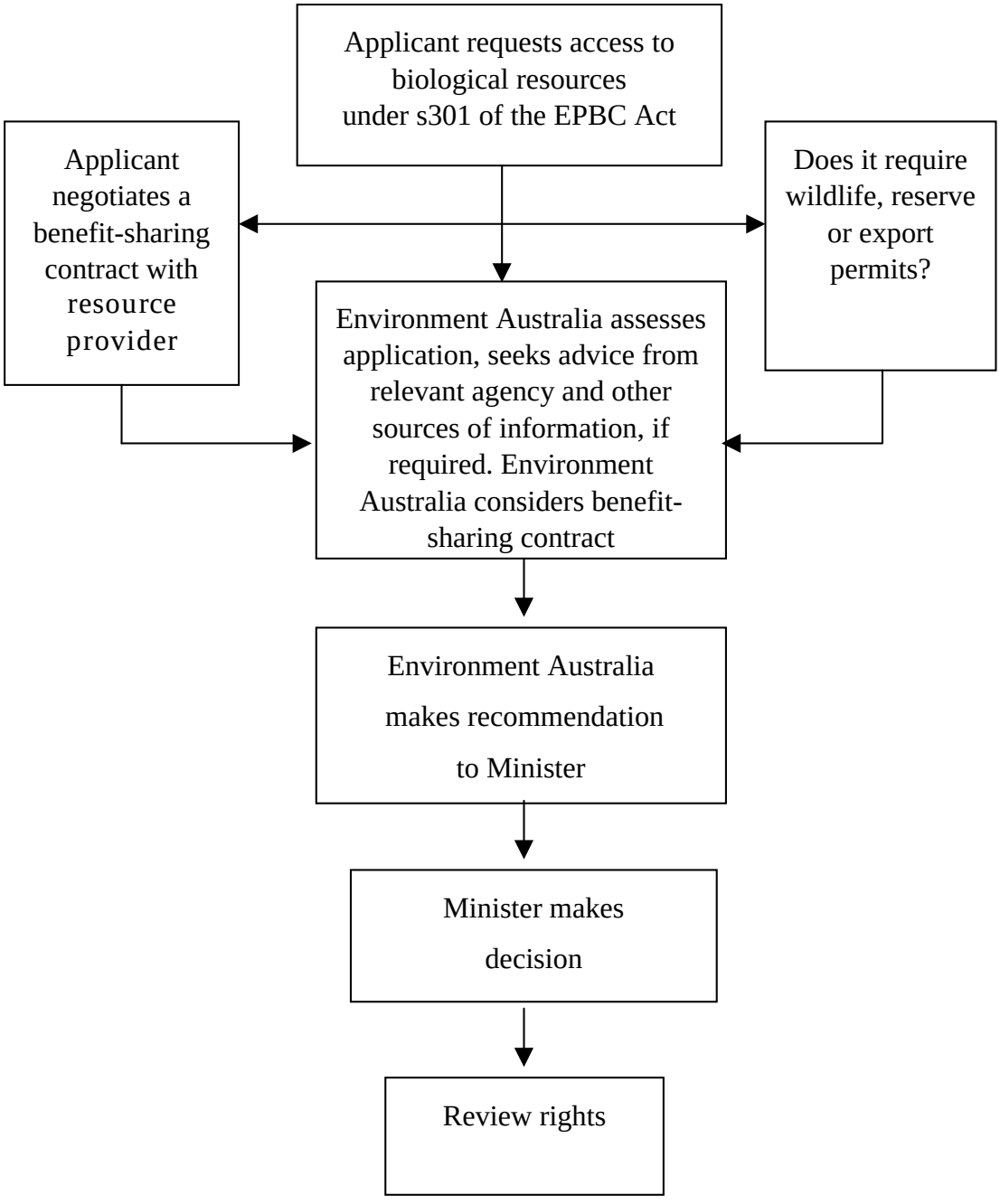
- Once these issues are resolved, **Environment Australia assesses application** to access resources under s301, **seeks advice from relevant area** (eg a division of Environment Australia such as Marine and Water Division, Parks Division, or other government agency) and **further information from other sources**, if required, as to whether the permit should be granted or refused.

  [**Note**: In 'areas' not administered by Environment Australia – Environment Australia refers the application to the appropriate agency, eg Department of Defence, CSIRO, GBRMPA, etc.]

- Following submission of the benefit-sharing contract, **Environment Australia makes a recommendation to the Minister** that the permit be granted or refused, including a recommendation regarding the contract.
- **Minister refuses or grants the permit.**
- Parties may seek **review** of the decision.

[**Note**: Applicants may need to seek further permits, eg for recollection. It is suggested, however, that as far as practicable there should be only one contract (when the first permit is sought) and that this contract should anticipate the possibility of further permits. Further permits would be granted on the basis that there is an existing contract which requires no further Ministerial assessment.]

Diagram showing the process for assessing access permits and benefit sharing contracts



Matters to be covered in s301 Regulations

2.12 The regulations should incorporate the general principles of ensuring that access to biological resources in Commonwealth areas is conducted in accordance with ecologically sustainable development principles, including environmental assessment procedures where applicable, and promotes the conservation of biological diversity and the sustainable use of its components.

2.13 With regard to **operational aspects of the scheme**, the regulations should:

a) set out a simplified outline of the access scheme;

b) set out the requirements for:

i) lodging voucher specimens in Australian public institutions accredited with the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES);

ii) information about the specimens collected; and

iii) ensuring at least some benefits are used for biodiversity conservation in the area from where the biological resource was obtained (Recommendation 27); and

c) stipulate that bioprospectors should not collect human remains (Recommendation 42);

2.14 With respect to **access permits**, the regulations should:

c) set out the requirement to obtain a permit to access biological resources in Commonwealth areas;

d) require use of the standard permit application form, while allowing scope to include conditions for particular circumstances;

e) require that the Minister give notice of each permit application to each person and body registered under s266A of the Act, and to invite them to make written submissions about whether a permit should be issued (addressing possible environmental concerns only), and to take these into account in making his decision;

f) set out conditions to be included in the permit, including:

- the requirement that applicants enter into a benefit-sharing contract with the resource provider;
- arrangements and conditions regarding access, eg who, when, where, what (including any follow-up collecting, if applicable);
- environmental conditions, including the collecting protocols to be observed; and

    - the requirement to report to Environment Australia, with a copy to the resource provider;
- stipulate that the Minister's decision to grant/refuse a permit must take into account that:
    - environmental assessment (if required) was undertaken and the process is completed;
    - the Minister is satisfied that the collection protocol attached to the permit will provide adequate environmental protection;
    - the submissions from persons and bodies registered under s266A of the EPBC Act have been taken into account;
    - the precautionary principle has been applied, where appropriate;
    - any variations to the model contract are acceptable;
    - there is a benefit-sharing contract between the parties and that it addresses major issues, such as:
    - prior informed consent,
    - mutually agreed terms,
    - adequate benefit sharing arrangements, including protection for and valuing of Indigenous knowledge (where provided by the owner); and
    - some benefits will be used for biodiversity conservation in the area from which the resource was obtained;
    - where access is granted, access arrangements meet the requirements of leases, management plans and any other relevant documentation, where applicable;
- stipulate that it is an offence to access resources without a permit or to breach the conditions of a permit (including a cross reference to civil and criminal penalties in the Act;
- set a timeframe within which the access permit is valid (a maximum of three years);
- allow transfer of the access permit only with permission of the Minister;
- detail the circumstances for revocation or suspension of the access permit by the Minister;
- detail provisions to request information or set conditions relevant to particular situations, eg Defence, such as:
    - issues of safety, security and operational needs;

- requirements in respect of the length of advance notice required for entry; and
- the need to consult with a range of management staff where a training area is involved; and

- set fees (fees should be consistent with other fees charged under the EPBC Act, with provision for differential fees depending on the length and complexity of environmental assessments).

2.15 With regard to the **benefit-sharing contract**, the regulations should:

- recognise and encourage use of the model contract (but note that its use is not mandatory);
- state that the contract must include a provision that it takes effect only if an access permit has been issued;
- set out indicia which may evidence that there is prior informed consent by the party which is providing access to biological resources:
  - **where traditional owners are involved**, the regulations should provide for:
    - adequate time to consider applications, consult with other parties (eg, owners who live outside the area) and seek advice;
    - adequate information from and consultations with the applicant;
    - benefit-sharing provisions to cover the costs of consultation;
    - minimum requirements for notification and consultation to be met if beneficiaries are wider than traditional owners,;
    - availability of information and education about access and benefit-sharing issues;
    - representation by the relevant land council;
    - independent legal advice;
    - advice from the Director of National Parks, if requested;
    - confirmation from relevant land council that these procedures have been followed; and
    - where access is refused, no review and a minimum time before another application can be made;
  - **in all other cases**, the regulations should deem prior informed consent to exist unless there is evidence to the contrary;
- ensure adequate benefit sharing, including benefits to Australia through improved knowledge and sharing of information about biodiversity;

- stipulate that distribution of benefits is for the traditional owners to determine, and
- include examples of possible monetary and non-monetary benefits.

Examples of monetary benefits include:

- up-front payments;
- 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.

Recommendation

8. That the proposed scheme be implemented through regulations under s301 of the EPBC Act.

Matters to be covered in the EPBC Act

Review provisions

2.16 Review provisions should provide:

- that the decision of the Indigenous owners of biological resources to deny access to their resources (ie not to enter into a contract) is not reviewable (and to prevent undue pressure on them to negotiate, there should also be a time limit before the application may be re-activated);
- merits review by the parties of the Minister's decision not to grant an access permit; and
- merits review by third parties of that part of the Minister's decision which relates to the conditions in the access permit itself, but not the conditions in the contract.

Recommendations

9. That the decision of Indigenous owners of biological resources to deny access to their resources (ie not to enter into a contract) not be reviewable.

10. That the parties to the contract be able to seek merits review of the Minister's decision not to grant an access permit.

11. That third parties only be able to seek merits review of that part of the Minister's decision which relates to the conditions in the access permit itself, but not the conditions in the contract.

Penalties

2.17 The Act should also provide for penalties for bioprospecting without a permit and for breaches of the terms and conditions of a permit which are consistent with other penalties in the EPBC Act for comparable offences. In this regard the level of penalty must be sufficient to deter biopiracy.

2.18 Biopiracy denies the community from which the resource originates the opportunity to share in benefits which may flow from its use. While its incidence is difficult to quantify, enough examples have been cited internationally and drawn to my attention in submissions and discussions for me to conclude that this is a matter which warrants a serious penalty response to create a deterrent.

Level of penalty

2.19 The EPBC Act contains both civil and criminal penalties, with the civil penalties having a lower standard of proof and higher maximum fines than the criminal offences. It also has some strict liability offences (see Division 1 of Part 13).

2.20 The civil penalties relating to listed biodiversity and protected areas range from 500 to 5,000 Penalty Units (PUs), and the criminal penalties range from 500 to 1,000 PUs, and two years' gaol. I suggest the Act include both civil and criminal penalties for accessing biological resources within Commonwealth areas without a permit.

2.21 To be consistent with the biodiversity provisions of the Act, the criminal penalties should probably be within the ranges indicated above (the criminal penalties mentioned above apply to various activities involving listed biodiversity unless the Minister has granted a permit for the activity).

2.22 However, I would support much higher civil penalties (eg, 50,000 PUs), given the amount of potential profit to be made from bioprospecting, and given the 50,000 PUs penalties set out in the environmental assessment provisions of the Act. This will require an amendment to the Act.

Recommendation

12. That civil and criminal penalties in the EPBC Act for unlawfully accessing biological resources be sufficient to deter such activities, having regard to the potential profits from biopiracy.

The proposed model contract

Comments about particular contractual issues

Exclusivity of agreements

2.23 With respect to the issue of 'exclusivity' of agreements, the Queensland Government commented as follows:

> 'Exclusivity' terms in agreements should be explicit as to the extent and duration of their exclusivity. In negotiating exclusivity, it would be more appropriate to offer biodiscovery agencies the exclusive utilisation of the samples collected for a stipulated period as opposed to providing exclusive access to natural resources, as has sometimes been the case. It should be explicit in any exclusivity agreement that access to particular biological resources is conditional and
>
> 1. assigned only to the physical samples and not extending to the species or localities from which they were collected; and
>
> 2. assigned for set periods after which time the resources become publicly accessible.

2.24 The Inquiry notes these comments, as well as the concerns of Indigenous communities that by allowing access to biological resources on their lands, they may be prevented from continuing to use the biological resources from which samples are derived. However, the Inquiry also notes that the parties to the contract are free to negotiate 'exclusivity' terms in whatever manner they wish and that a range of terms is possible. The example Queensland proposed is one possibility.

2.25 The Inquiry has decided that it is not necessary to make any recommendations on this matter as the proposed scheme requires the Minister, in deciding whether to grant or refuse a permit, to consider the fairness of 'exclusivity' clauses in the

contract, among other issues, against the indicia of prior informed consent, mutually agreed terms and adequate benefit sharing.

2.26 The Inquiry does suggest, however, that terms of a more 'exclusive' nature which benefit the bioprospector should be reflected in the nature and/or amount of benefits payable to the resource provider.

Research or commercial interests

2.27 Many submissions, particularly those from research organisations, commented on the importance of access to biological resources for scientific research and of ensuring that an access system does not inhibit access for such purposes. The Inquiry considered possible implications of these concerns for the proposed system and, in particular, for the model contract. In view of the fact that in many cases research will have unforeseen commercial implications or possibilities at some point, the Inquiry decided that, as far as possible, this should be considered at the outset of contract negotiations and reflected in the contract.

Recommendation

13. That terms in the proposed model contract anticipate that most contracts will be for commercial purposes but that in some cases, terms which reflect non-commercially motivated research purposes may need to be drafted, and benefit sharing negotiated accordingly.

Possible provisions

2.28 This section lists possible provisions for the model contract to aid later discussions with stakeholders.

- The parties – names and brief descriptions of functions and objectives. [Note: there may be cases where there are more than two parties to the contract, eg Environment Australia in relation to Norfolk Island (see discussion in Chapter 8 'Norfolk Island').]
- Definitions of, for example:
    - sample,
    - bioprospecting,
    - monetary and non-monetary benefits, and
    - resource owner.
- Interpretation.

- Purpose of the contract.
- Duration of the contract.
- Monitoring and review of the contract.
- Collector becomes owner of the samples/continuing rights of provider in relation to the samples and biological resources.
- Exclusivity or otherwise of the Agreement.
- Benefit sharing arrangements (Schedule), including provision to ensure at least some benefits are used for biodiversity conservation in the area from where the biological resource was obtained.
- Any other conditions, such as requirements for applicant to provide information about developments to the resource provider.
- Agreement regarding intellectual property rights.
- Contract takes effect only if Minister issues an access permit.
- Provision anticipating the possibility that further permits may be required, and consequences for the contract if refused.
- Provision regarding effect on the contract if the permit is breached, suspended or revoked etc.
- Successors are bound by the contract.
- Arrangements where third parties are involved, eg where there is a series of contracts, to ensure there is no dilution of benefits, eg royalties.
- Standard clauses, eg variations (including that the contract and any amendments be subject to the Minister's approval), waiver, severability of provisions, governing law, entire agreement, dispute resolution, termination, notices costs, goods and services tax.
- Permit could be included as a Schedule.

Recommendations

14. That the Department of the Environment and Heritage develop a model contract to guide and assist the parties in their negotiations over possible benefit-sharing arrangements.

15. That the model contract be endorsed by stakeholders including Biotechnology Australia, the Australian Biotechnology Association, the Indigenous Advisory Committee, key land councils and peak environment organisations and subsequently submitted for endorsement by the Minister for the Environment and Heritage.

16. That the regulations and model contract be used in discussions with State and Territory Governments as the basis of a proposed nationally consistent scheme.