

Executive Summary

This paper has been prepared by the Commonwealth Government agency Biotechnology Australia (BA)¹ on behalf of the Commonwealth Biotechnology Ministerial Council². BA has an active interest in biotechnology issues, including those related to bioprocessing, bioprospecting and related technologies.

Australia is one of only 17 megadiverse³ countries in the world. It is important for the Commonwealth Government to develop policies that ensure, ‘consistent with safeguarding human health and ensuring environmental protection, that Australia capture the benefits of biotechnology for the Australian community, industry and the environment’. This vision is based on the responsible use of biotechnology to drive economic and community benefit, including in regional and rural areas. It provided the framework around which the Commonwealth Government developed its National Biotechnology Strategy (NBS). The NBS not only addresses many issues relevant to the Inquiry’s terms of reference, but it is also a dynamic strategy, designed to be modified as biotechnologies develop and circumstances change.

The Australian biotechnology sector is an emerging industry and bioprospecting, bioprocessing and related biotechnologies can attract investors with unrealistic expectations of large returns. When the returns are not forthcoming, because of the high-risk nature of such industries and the long development times to market, investors’ confidence can be affected. These are some of the factors that need to be taken into consideration in developing an appropriate policy framework.

International case studies indicate that there are lessons to be learned for Australia, and that Governments should remain vigilant so that policies keep pace with the rapidly changing technologies and opportunities.

1. The contribution towards the development of high technology knowledge industries based on bioprospecting, bioprocessing and related biotechnologies

The Government has established many of the policies necessary to develop high-technology knowledge industries based on bioprospecting, bioprocessing and related biotechnologies. The objectives and strategies to achieve them in the NBS are being implemented by the Government through BA Departments. There are also many funding mechanisms available to assist start-up companies with research and development of products. In the 2000 budget and in *Backing Australia’s Ability—an innovation action plan for the future*, the Government announced

¹ Biotechnology Australia is established in the Industry, Science and Resources portfolio and comprises five departments: Industry, Science and Resources, Environment Australia, Agriculture, Fisheries and Forestry—Australia, Health and Aged Care, and Education, Training and Youth Affairs.

² The members of the Commonwealth Biotechnology Ministerial Council are Senator the Hon. Nick Minchin (Minister for Industry, Science and Resources, and Chair), Senator the Hon. Robert Hill, the Hon. Mr Warren Truss MP, the Hon. Dr Michael Wooldridge MP and the Hon. Dr David Kemp MP.

³ Megadiverse countries are Brazil, Colombia, Australia, Malaysia, Indonesia, China, Mexico, South Africa, Venezuela, Ecuador, Peru, United States of America, Papua New Guinea, India, Madagascar, Philippines, and the Democratic Republic of Congo. Source: www.conservation.org/web/fieldact/megadiv/list.htm, Nov. 2000.

additional funding for the Biotechnology Innovation Fund (BIF), which will provide pre-seed funding for start-up companies, and for biotechnology centres of excellence.

There are not many bioprospecting companies and organisations in Australia and only a small number of Cooperative Research Centres (CRCs) with an interest in bioprospecting. Of particular note however is Cellulose Valley, a project of Southern Cross University in northern NSW, which aims to position itself as a hub for the primary production, manufacturing and research for medicinal plant products and related products.

2. Impediments to growth of these new industries

Appropriate policies will facilitate the development of high knowledge industries such as bioprospecting. The NBS addresses many impediments confronting these industries. Access and benefit sharing issues are complex. Policies should provide companies and organisations with clear terms for access to biological resources, otherwise bioprospecting might not occur. High technology industries require appropriate infrastructure and a highly qualified workforce. These are usually found in larger urban centres but the Cellulose Valley and AIMS examples show that such an infrastructure and workforce can be developed in regional areas.

There are large costs associated with bioprospecting and the subsequent development of bioactive molecules. These can be mitigated by generic government programs designed to assist high-technology companies and through the assistance of biotechnology-specific programs such as BIF.

The NBS provides the framework around which the Government is addressing many of these issues. The BA priorities include a public awareness program on biotechnology issues, improving IP management, and negotiation of a BIF.

3. The capacity to maximise benefit through intellectual property rights and other mechanisms to support development of these industries in Australia

BA has identified significant gaps in the knowledge of many biotechnology researchers about Intellectual Property (IP) matters. Strategies that have been developed, including those under the NBS, include:

- the establishment of the Australian Centre for Intellectual Property in Agriculture;
- the promotion of IP best practice by the National Health and Medical Research Council (NHMRC);
- an Australia-wide seminar series on biotechnology IP held in 2000; and
- a forthcoming biotechnology IP management training course to be held in April 2001 targeted at biotechnology researchers and start-up companies.

4. The impacts on and benefits to the environment

Benefits may include the development of new processes for the bioremediation of hazardous waste material, safeguarding Australia's biodiversity through attaching commercial value to its sustainable use, and the production of biofuels to reduce greenhouse gas emissions. There may be many other benefits that flow to the environment from bioprospecting, bioprocessing and other related biotechnologies. At this stage it is difficult to predict what these might be.

Bioprospecting is essentially an extractive process, and therefore potentially damaging to some sensitive environments. The risks of this damage occurring need to be managed carefully by governments and industry. This is recognised in the NBS.

There are a number of strategies for managing the environmental impacts of these technologies. The NBS states that the Government is developing strategies to enhance access to Australian biological resources. These include working with the States and Territories to achieve nationally consistent regimes on access and working with Commonwealth areas looking at regulations under the *Environment Protection and Biodiversity Conservation Act 1999* (EPBC Act).

BA is available to discuss issues with the Inquiry as required.

Introduction

This paper has been prepared by Biotechnology Australia¹ (BA) as a submission to the Inquiry into the Development of High Technology Industries in Regional Australia based on Bioprospecting by the House of Representatives Standing Committee on Primary Industries and Regional Services.

Biotechnology issues cross portfolio boundaries. The Commonwealth Government established BA in May 1999 specifically to coordinate biotechnology within the Government and undertake non-regulatory activities to best position Australia so that it can benefit from biotechnology. As such BA is the main coordination mechanism for biotechnology issues within the Commonwealth Government. BA reports to the Commonwealth Biotechnology Ministerial Council².

The terms of reference of the Inquiry are to inquire into and report on the following areas with particular emphasis on the opportunities in rural and regional Australia:

1. The contribution towards the development of high technology knowledge industries based on bioprospecting, bioprocessing and related biotechnologies;
2. The impediments to growth of these new industries;
3. The capacity to maximise benefit through intellectual property rights and other mechanisms to support development of these industries in Australia; and
4. The impacts on and benefits to the environment.

The Inquiry's focus on bioprospecting, bioprocessing and related biotechnologies is timely, given bioprospecting's relative immaturity in Australia and its potential for economic and regional development. This paper will discuss 'biotechnology' broadly because the Commonwealth Government has established policies that apply to all biotechnologies—and bioprospecting, bioprocessing and related biotechnologies are also able to benefit from these policies. The Inquiry's interest in high-technology industries in regional Australia highlights a particular challenge given that high technology industries tend to locate in urban areas where academic expertise and a skilled workforce are often more readily available.

This submission discusses many issues relevant to the Inquiry's terms of reference. In addition, two BA departments, Environment Australia (EA) and Agriculture, Fisheries and Forestry - Australia (AFFA), will produce separate submissions complementing this paper. Some portfolio agencies such as CSIRO, the Australian Institute of Marine Science (AIMS), and IP Australia also have interests in the Inquiry's terms of reference. They have indicated that they will also develop submissions. These complementary submissions from BA member departments should be referred to for more detailed portfolio-specific issues.

This paper has been developed with the cooperation of BA Departments, Industry, Science and Resources (ISR), AFFA, EA, Health and Aged Care, and Education, Training and Youth Affairs (DETYA), in addition to CSIRO, and the Department of Foreign Affairs and Trade (DFAT). The paper provides some information on the industry structure and draws on experience gained overseas. The paper considers issues of relevance to the Inquiry. The paper addresses the

programs that the Commonwealth Government has in place to assist all companies (including those involved in bioprospecting, bioprocessing and related biotechnologies) to access finance and assist them in developing into high-technology and high-knowledge industries. It then discusses the impediments to realising optimum growth in these industries, intellectual property issues, and the impacts on and benefits to the environment.

Background

INTERNATIONAL CONTEXT

Bioprospecting is the search for naturally occurring chemical compounds, genes or other parts of organisms that have potential economic value. These naturally found ingredients have the greatest economic benefits when they are used in commercial products such as pharmaceuticals, chemicals and food additives⁴. There is however no standard definition of bioprocessing and there are different views on how far 'bioprospecting' extends down the commercialisation path. Australia's unique biodiversity (it is one of only 17 megadiverse countries in the world³) has the potential to yield a range of useful products. This diversity provides Australia with a natural competitive advantage. It is in Australia's best interest that it should be in a position to benefit from the discovery of potentially useful new compounds.

Any policy dealing with accessing biological resources, as bioprospecting does, must also be consistent with Australia's international treaty obligations, including the Convention on Biological Diversity (CBD). The objectives of the CBD are the 'conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources'.

Australia is also a party, since 1995, to the World Trade Organisation's agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). This agreement recognises the importance of intellectual property rights in encouraging innovation, research and development and establishes minimum standards for intellectual property protection in World Trade Organisation (WTO) member states.

Bioprospecting is a high-risk industry for investors but it has the potential to generate significant returns for a successful company. Molecules derived from natural products can provide novel chemical structures and new pharmaceuticals. Ten of the world's 25 top-selling pharmaceuticals were derived from natural products and accounted for global sales of almost US\$14 billion in 1995. Some potential applications arising from biotechnology are listed in Table 1. Many of these could eventuate from bioprospecting, bioprocessing and related biotechnologies.

Despite significant interest in rational drug design in the 1970s and 1980s and the long odds against finding compounds that may be developed as new drugs from natural sources, there remains a keen interest in bioprospecting for new molecules. In spite of encouraging new

⁴ House of Representatives Standing Committee on Primary Industries and Regional Services Media Release *Our Future can be found in Bioprospecting*, Fran Bailey MP, 10 Nov. 2000.

TABLE 1 SOME CURRENT AND POTENTIAL BIOTECHNOLOGY APPLICATIONS

| <i>Sector</i> | <i>Application</i> |
|--------------------------------------|---|
| Health | More specific therapeutics with minimal side effects, developed through a better understanding of disease New and improved vaccines and diagnostic tests Improved production of pharmaceuticals and novel therapeutics Testing and treatment for genetic diseases |
| Agriculture | Improved pest and disease resistance Selective herbicide tolerance Tolerance of water, temperature and saline extremes Domestication of new wild or non-commercial plants Vaccines and diagnostic tests for animal diseases Production by plants or animals of speciality chemicals and novel products (therapeutics, and ingredients for oils and plastics) Improved animal welfare Higher yields and quality |
| Forestry | Faster tree growth Improved fibre and wood quality Disease resistance and saline tolerance Improved enzymatic treatment of pulp and processing wastes |
| Mining | Leaching of ores Mine site rehabilitation |
| Manufacturing/bioprocessing | Improved production of high value products (eg. pharmaceuticals and flavours) Production of gas, liquid fuels and commodity chemicals |
| Environment | Bioremediation ⁵ of heavy metals, oil and chemicals Conversion of waste to energy Contaminant testing, salinity management and soil protection Revegetation and biodiversity protection |
| Food processing and beverages | Improved quality Improved food storage and nutritional quality Improved maturation and preservation techniques New and novel foods |
| Marine biotechnology and aquaculture | New pharmaceuticals, enzymes and biomolecular materials (eg. bioceramics) Biomonitors (e.g. via bioluminescence) New and improved varieties and management for aquaculture |

developments in combinatorial chemical and genetic artificial evolution procedures, , there is little likelihood that these techniques will replace the need for bioprospecting in the short term.

An international example

Yellowstone National Park provides a US example of how agreements can be developed to support bioprospecting. Yellowstone realised the potential of its resources several years ago, when an enzyme, Taq polymerase, derived from a microbe discovered in Yellowstone's hot springs, was developed for biotechnology application and became widely used in DNA replication work.

The patent on the enzyme was sold in 1991 for \$300 million and now generates an estimated \$100 million per year. However, the Park receives nothing from this discovery, as they did not have a benefit sharing agreement with the researchers who made the discovery. In 1997 Yellowstone entered into an agreement with the Diversa Corporation, giving it non-exclusive access to the Park's resources in exchange for a one-time payment and future royalties. Box 1

⁵ Bioremediation is defined by the American Academy of Microbiology as 'the use of living organisms to reduce or eliminate environmental hazards resulting from accumulations of toxic chemicals and other hazardous wastes'

Box 1.

Yellowstone National Park and Diversa Corporation

In 1997 Yellowstone National Park signed the first bioprospecting agreement in the US with Diversa Corporation. Diversa specialises in the industrial application of biocatalysts and wanted to conduct research on microorganisms sampled at Yellowstone.

Diversa agreed to pay a fee of \$US25 000 a year for five years in return for permission to collect microbes in the park. Yellowstone would also be entitled to royalties on any profits Diversa makes from products using the microbes from the park.

There has however been some controversy over the agreement. The Edmonds Institute, an organisation opposed to many biotechnology industry practices, took the National Park Service to the Federal Court in an attempt to stop bioprospecting at Yellowstone National Park. The Edmonds Institute was successful in temporarily stopping bioprospecting in Yellowstone. The District Court judge who ruled on the case said that rules needed to be established to govern bioprospecting on US Government lands. The judge commented that

'Essentially, the future of bioprospecting on federal lands in the United States appears to be a work in progress, but the government as of yet has not engaged in any public debate on the issue nor made any definitive policy statement through regulations or less formal means'.

Source Yellowstone National Park Website (www.nps.gov/yell/nature/thermophiles/biopro.htm), Puget Sound Business Journal (Seattle), 5 April 1999.

details the bioprospecting agreement between Yellowstone National Park and Diversa Corporation, and some of the problems that have been experienced by Diversa.

This example illustrates some of the different dimensions that may arise in considering the complex issues involving access and benefit sharing.

THE AUSTRALIAN INDUSTRY PERSPECTIVE

Bioprospecting industry structure

There is limited data available on the state of bioprospecting in Australia. There are about 200 organisations involved in the biotechnology industry in Australia, and there could be around 20 with an interest in bioprospecting including pharmaceutical companies, researchers, Commonwealth and State governments, rural landowners, and indigenous communities.

Table 2 lists some Australian companies with bioprospecting as a part of their business, though it is not a comprehensive listing. Box 2 presents the case study for the most recent company listed, BioProspect, which is based in Perth and Box 3 outlines the scenario for Cellulose Valley, a regional bioprospecting initiative based in rural NSW. Some observations about the industry include:

- bioprospecting companies are few and are active mainly in plant product and cancer research;
- smaller, newer companies do not rely on a single site (collection, storage, analysis, production) but on smaller 'satellite' companies, formed through agreements between providers of specialist services, enabling biotechnology companies to spread their expertise across Australia; and
- the establishment of larger centres of excellence like Cellulose Valley is assisted by effective collaboration with both regional and urban universities and centres.

TABLE 2. SOME COMPANIES AND ORGANISATIONS INVOLVED IN BIOPROSPECTING IN AUSTRALIA

| <i>Institution</i> | <i>Partners</i> | <i>Research field</i> |
|--|---|---|
| Australian Institute of Marine Science (AIMS) | AMRAD, Nufarm, NCI | 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 (alliance between BioProspect and 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 Llewellyn, April 2000, Drug discovery from biodiversity in Australia.

Box 2.

Case Study on BioProspect—a new bioprospecting company in Australia

BioProspect Limited was formed in 1998 by a group of Western Australians for the sole purpose of exploring Australia's unique flora for substances of value.

BioProspect has been and is negotiating licences with international sovereign states for access to their natural biological resources for the purposes of drug discovery with the clear intention of adherence to the Convention on Biodiversity (CBD). They currently have a licence with the Government of Western Australia to bioprospect for useful compounds.

This landmark licence makes BioProspect the broker of some of the most diverse, unique and largely unexplored biota in the world. BioProspect intends to systematically bioprospect the Western Australian native flora for new and novel lead compounds for new drug discovery. Currently compounds from approximately 4000 species have been chemically evaluated and are ready for screening.

Similar negotiations are underway with other countries and by next year, BioProspect expects to have over 9000 species available for drug discovery. In addition, its collections program will be expanding this extensive library by around 2000 new species every year. This will make BioProspect probably the largest source of extracts of novel plant species in the world today.

Its existing library is mainly extracts ready for pre-processing prior to screening. However, BioProspect is able to offer customised plant material extraction to clients' specifications. Its policies regarding collections and processing ensure continuity of supply and repeatability of processing.

Source Paraphrased from the BioProspect Ltd Company prospectus: Corporate profile (www.bioprospect.com).

Box 3.

Case Study on Cellulose Valley — Developing Rural Northern Rivers Region of NSW

Cellulose Valley is a project of Southern Cross University. It is the result of the recent interest in medicinal plant research activity being undertaken by Southern Cross University, representatives of the medicinal plants industry, and growers of medicinal plants.

Cellulose Valley represents the northern New South Wales region of Australia, and is fast becoming an important centre of research and development, primary production and manufacturing of medicinal plants. Cellulose Valley will position the Northern NSW region and Australia as the possible focus of primary production, manufacturing and research for medicinal plant products and related products.

Cellulose Valley is focused on using modern technology to develop quality assured, value-added natural plant product for the national and international markets, and establishing of industry standards for those products. Value-adding is to occur through the full chain of activities, from plant production at farm level, through to handling, processing, manufacturing, research and marketing. This will occur by creating synergies between growers, manufacturers and researchers.

The vision of Cellulose Valley is 'that Southern Cross University and the Northern Rivers region will become an international centre for research, development and commercial production of natural plant products'. Southern Cross University hosts a rapidly growing range of sophisticated research services and affiliations that provide the basis for the R&D component of the Cellulose Valley project.

These include:

- Centre for Phytochemistry;
- School of Natural and Complementary Medicine;
- Centre for Plant Conservation Genetics;
- College of Indigenous Australian Peoples;
- Australian Phytochemistry Research Institute Incorporated; and
- Environmental Analysis Laboratory

The University provides world class research facilities and, in addition to the research services and equipment available at Southern Cross University's Lismore campus, Cellulose Valley offers a wide range of other services related to research, business development and services, networking, investment and innovation.

Source Innovation Event Report, April 2000 (www.cellulosevalley.com.au).

Boxes 2 and 3 provide an interesting contrast. BioProspect has an urban base in with the advantages of existing infrastructure and facilities. The Company's agreement with the State Department of Conservation and Land Management (CALM) allows its people access to rural Western Australia for sampling, but they have to travel to those sites irrespective of whether they are based in Perth or in regional areas⁶. The key to making BioProspect work will be to maintain effective collaboration with its analytical facilities in eastern Australia (Southern Cross University) and other business partners. In that sense there is no incentive for the company to base itself in a rural community.

The Cellulose Valley project is located not only in a rural area, but also in a centre of excellence in plant product research. Its advantage, however, is that because of its location in a rural area it can also grow medicinal plants and manufacture products from them. This creates local opportunities downstream; an advantage not available to companies like BioProspect.

In a similar fashion, the Cellulose Valley model shares much with the vision outlined for a rural bioindustry based on marine biotechnology, at the AIMS in Townsville.

⁶ Dr Matt Keeley, Senior Scientist, BioProspect Ltd.

While bioprospecting companies are appearing on the Australian scene, it is not the bioprospecting boom predicted by some in the early 1990s. The reasons are numerous but the uncertainties facing investors and companies regarding the likelihood of a some return, even in the long-term, and the cost of supporting the project while waiting for a commercial return, are evidently significant barriers to many organisations undertaking bioprospecting.

In the light of the investor uncertainty and the early stage of development of the Australian bioprospecting industry, it is therefore not surprising that many of the companies involved internationally are large multinational pharmaceutical companies. Table 2 shows that of the 13 institutions listed, 6 major multinational companies were involved as project partners.

BIOPROCESSING AND RELATED BIOTECHNOLOGIES

Bioprocessing

Bioprocessing includes fermentation processes, downstream processing of waste products and biotransformations using enzymes or microbial cells. As bioprocessing can be an on-site application of biotechnology, there is potential for small industries to be created in rural and regional areas that have mines, are large producers of waste materials or are crop-growing enterprises.

As an example, CSIRO has discovered that some species of *Thiobacillus* and *Halomonas* are capable of digesting toxic effluent from gold extraction. When tested, the microbe reduces the amount of toxins in the water fifteen-fold. CSIRO is hoping to refine the process to sufficiently purify the water so that it can be reused in the mine. This has the potential to greatly benefit both the mining industry, by decreasing the costs involved in gold extraction, and the environment, by reducing ground water contamination.

Another bioprocess is bioleaching of metal ores. Bioleaching uses naturally occurring bacteria to break down metal sulphides and is more environmentally friendly than traditional smelting techniques. The natural ores, including those of copper, zinc, nickel, gold, silver and cobalt, are dissolved into solution and metals can be recovered using solvent extraction techniques. Bioleaching is carried out in situ.

Companies that use bioleaching report a significant rise in the amount of metal recovered. Also, bioleaching is cheaper than traditional methods making it an attractive proposition for large mining enterprises. However, because the bacterial oxidation of ore requires low salinity water, the availability of suitable water at some mines has been a factor that has restricted use of bioleaching in Australia. Also, the microbes used in the CSIRO procedure are site specific and so each mine would need to find specific microbes for its area, adding to the expense of the mining operation.

Biofuels

Fuel made from biomass⁷ is called biofuel. Biomass energy can be derived from a range of different materials including wood, corn, soy beans, bagasse (sugar cane waste), human and

⁷ 'Biomass: Organic matter available on a renewable basis. 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.' (Defined by the National Renewable Energy Laboratory, redec.nrel.gov/biomass).

animal wastes, residues from agricultural and forestry processes and some other waste products. Waste products are largely used to produce methane gas, which is tapped and used for heating and electricity generation. The main sources of gas from waste products are landfill sites and sewage treatment.

Manildra Energy Australia Pty Ltd is researching technologies to assist with the development of a commercial scale advanced technology ethanol fuel plant using wheat starch as a feed stock. The ethanol is sold as a 10% blend with petrol through selected service stations. The economics of ethanol use and production in Australia are largely dependent on its excise exempt status, which currently represents a 39.6 cents per litre cost advantage over petrol, *although even with this advantage, large-scale ethanol production is not a cost-effective procedure.*

The food industry produces a large number of residues and by-products that are possible biomass energy sources. These wastes are usually disposed in landfill dumps with the food company responsible for the cost of their disposal. There is potential for these industrial wastes to be anaerobically digested to produce biogas or fermented to produce ethanol, and several commercial examples of waste-to-energy conversion already exist. The authors of a report commissioned by the Australian Greenhouse Office estimate that the upper limit of electricity generation from agricultural and food processing wet wastes to be about 1500 GWh/y.

Black liquor is a waste product generated by the paper and pulp making industry. Black liquor can be pyrolysed or gasified as a biomass energy source. The University of Melbourne has developed a fluidised bed fast pyrolysis process that can convert black liquor into a 'bio-oil'. The bio-oil can be processed into transport fuel substitutes such as biodiesel. As with ethanol, costs of production render this fuel currently uneconomic compared to fossil fuels.

On 25 September 2000, Mr Truss, the Minister for Agriculture, Fisheries and Forestry, announced the Government would fund a study into the commercial viability of increasing ethanol production by the Australian sugar industry. The study, coordinated by the Australian Bureau of Agriculture and Resource Economics (ABARE), will review previous research into large-scale ethanol production and examine other factors affecting the economic viability of ethanol production, including:

- new developments in technology;
- different ways of using and disposing of major waste products;
- market demand; and
- other options when waste cane is not available.

Further, the study will examine whether Government programs such as the Greenhouse Gas Abatement Program and Renewable Energy Commercialisation Program can assist.

Under the Diesel and Alternative Fuels Grants Scheme, which commenced on 1 July 2000, grants are provided to encourage the use of alternative fuels including ethanol. The Scheme offers a 23 cents per litre grant to eligible transport operators for the on-road use of ethanol. The Government is supporting research into ethanol fuel manufacturing methods, with \$2 million going towards the construction of a pilot plant to use woody material such as pine plantation thinnings as the feedstock. A \$1 million grant has also been offered for the development of a commercial scale advanced technology fuel ethanol plant using wheat starch as feedstock. The plant has sourced wheat from farms in Western NSW.

Regional and rural implications

The discussion paper on renewable energy *New Era-New Energy: Emerging and Renewable Energy Action Agenda*⁸ made recommendations regarding the production of biofuels in Australia. As the transportation of biomass for conversion into fuel would add further costs to the already high production costs of biofuel production, the discussion paper recommends that the processing plant be situated close to the biomass sources. This would mean that in many cases, *the fuel processing plants would be located in regional or rural areas in order to be able to use the waste products generated from agriculture and forestry*. There is also the possibility of farming for production of biofuels, for example quick growing trees, soybeans or corn for use in biofuel production.

Environmental impacts

With increasing concerns regarding greenhouse gases, the use of biofuels is becoming increasingly attractive because they are a cleaner fuel and release fewer greenhouse gases than fossil fuels. Ethanol is already being used as a fuel additive in the US for the sole purpose of reducing pollutants from vehicles. The processing of waste products into biofuels will also have a positive impact on waste dumping and waste management. The waste will now have economic value and so is more likely to be put to good use rather than dumped as landfill.

Term of Reference 1

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

The Commonwealth Government's biotechnology initiatives

The Commonwealth Biotechnology Ministerial Council recognises that biotechnology is a key technology of the future and that it presents both opportunities and challenges. In particular, 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. This has, however, been from a low base. To take greater advantage of the opportunities created by biotechnology, the Commonwealth Government developed a National Biotechnology Strategy, which was launched by Senator Minchin in July 2000.

The Commonwealth Government's biotechnology vision, as stated in the National Biotechnology Strategy, is:

⁸ Department of Industry, Science and Resources (2000), Commonwealth Government.

Consistent with safeguarding human health and ensuring environmental protection, that Australia capture the benefits of biotechnology for the Australian community, industry and the environment.

This National Biotechnology Strategy provides a comprehensive framework for biotechnology development including policies to ensure that bioprospecting, bioprocessing and related biotechnologies can develop to their potential. The Government's strategy includes raising public awareness on key biotechnology issues, ensuring that an effective regulatory system exists, addressing impediments to successful commercialisation of biotechnology products, marketing biotechnology internationally, and ensuring that management skills in the biotechnology sector and access to biological resources are enhanced.

The Commonwealth Government's biotechnology vision outlines the Government's commitment to biotechnology. In particular, BA was established in 1999 with a 2-year budget of \$10 million at the same time as the Interim Office of the Gene Technology Regulator (IOGTR) was established to develop a nationally consistent gene technology regulatory system. The 2000 budget allocated a further \$30.5 million to biotechnology, \$20 million of which was earmarked for the Biotechnology Innovation Fund (BIF). BIF is a program that is being designed to address the gap between biotechnology research and commercialisation.

The Prime Minister's announcement in *Backing Australia's Ability*⁹ on 29 January 2001 added a further \$66.5 million to fund biotechnology initiatives, including \$46.5 million for a Biotechnology Centre of Excellence and an additional \$20 million for BIF. This is in addition to the Government's annual expenditure of over \$250 million on biotechnology R&D (excluding infrastructure).

In addition, the Australian biotechnology industry (including companies and organisations involved in bioprospecting, bioprocessing and related industries) will be able to benefit from the more generic, non-biotechnology specific schemes that have been enhanced under the new initiative. Some of these are outlined below⁹.

- Australian Research Council (ARC)—grants doubled over five years to around \$550 million a year by 2006;
- The Government has allocated \$337 million over five years to maintain the Research Infrastructure Block Grants (RIBG) scheme for universities;
- Cooperative Research Centres (CRCs)—funding was increased by \$227 million.
- Innovation Access Program (IAP)—\$100 million over five years has been allocated to link Australian companies with overseas markets through a variety of mechanisms including bilateral Science & Technology Agreements;
- Pre-seed fund—\$78.7 million over five years. Universities and public sector research institutions are eligible for funding;
- An extra \$40 million for the Commercialising Emerging Technologies (COMET) program; and
- Ongoing commitment to the R&D Start program (\$535 million over five years).

This range of programs and initiatives, put in place by the Commonwealth Government in *Backing Australia's Ability* and amounting to \$2.9 billion in total, demonstrates the Commonwealth Government's commitment to its science base and commercialisation arising from Australian research. Bioprospecting can also benefit from these Government initiatives.

⁹ 'Backing Australia's Ability: an innovation action plan for the future', 29 January 2001. www.innovation.gov.au/iap/Info_Pack/info_pack.html.

Education and Training

In December 1999 the Government announced the Higher Education White Paper *Knowledge and Innovation: A policy statement on research and research training*. The White Paper puts in place a new policy framework to support and reward research excellence, build critical mass in areas of opportunity and strength, capitalise on the returns on Australia's investment in research and promote the role of universities in regional economic, social and cultural development. Through an emphasis on performance based research funding, an invigorated national competitive grants scheme and a broad quality verification framework, the White Paper reforms will encourage universities to respond strategically and flexibly to emerging industries such as biotechnology. The White Paper reforms will enhance the development of a more entrepreneurial culture within the higher education sector and improve stronger linkages with industry.

The Strategic Partnership with Industry - Research and Training (SPIRT) Scheme, for example, supports high quality research that will encourage research collaboration between higher education institutions and industry. Proposals funded under SPIRT contain an industry contribution, in cash or in kind, with Commonwealth funding matched on a dollar-for-dollar basis with industry.

Other funding schemes build the research infrastructure of higher education institutions. They include various grant schemes to fund quality pure and applied research in different discipline areas, scholarships for research training, and project infrastructure.

*Backing Australia's Ability*⁹ will further boost funding for quality research and university research infrastructure which will contribute to innovations in high technology industries.

Other Government assistance programs

The Government currently has a number of different programs to assist industry, research and development, and commercialisation, and these are available to all industry sectors, not just biotechnology. These programs are managed through the Government's AusIndustry program. The most significant funds for companies and organisations involved in bioprospecting include the Pooled Development Funds, Commercialising Emerging Technologies, Innovation Investment Fund, Technology Diffusion Program, R&D Start Grants and Loans and the new 175% tax concession for additional research (see Appendix 1). While these funding mechanisms are valuable to all technologies and developing industries, BIF is a fund targeted specifically at biotechnology. By addressing the proof-of-concept commercialisation gap, BIF's objective is to fund pre-seed companies to the stage where they will be able to attract venture capital funding. These funding mechanisms, and funding provided through the ARC and the NHMRC, indicate the level of Government support for research and the development of high-technology industries in general. Funding through BIF and the biotechnology centres of excellence show support to biotechnologies more specifically.

The Commonwealth Government announced that it would develop an NBS in March 1999. At that time it envisaged that Australia could benefit from the advances in biotechnology, based on our R&D expertise in medical and agricultural fields. The Government has, through the NBS budget allocations and *Backing Australia's Ability*, directed substantial new funding to biotechnology to address priorities for biotechnology development.

Further opportunities for Australia

‘Biotechnology is a powerful enabling technology, with applications that have the potential to revolutionise many industry sectors including agriculture, forestry, fishing, pharmaceuticals and health, chemicals, textiles, food processing, environmental industries, and energy and mining.’¹⁰ As noted earlier, Australia is also in the fortunate position of being one of the few truly megadiverse countries. However, in order to make use of Australia’s megadiversity we must make use of its genetic resources in a sustainable manner. The Commonwealth Government’s continual involvement will help to ensure that this occurs.

When there is a risk of a project not being commercialised in Australia, then it might be beneficial to seek commercialisation overseas and realise the benefits of royalties from that commercialisation. This is the basic thrust of the national benefit principles, endorsed in 1999 by the Industry, Research and Development Board. Such international commercialisation usually provides additional ‘spillover’ benefits to the Australian economy, such as access to market knowledge and linkages with international research and business partners. The national benefit framework has been developed to better reflect the realities of competing in a global market place, and to ensure that Australia receives the maximum benefit from its public investment in R&D. It seeks to maintain Australia’s benefits from commercialisation by ensuring that Australian companies that commercialise overseas using funds from AusIndustry’s R&D fund, retain Australia as a home base for R&D activities.

National benefits are not necessarily monetary, but can take the form of increased knowledge and knowledge transfer between research institutions, the formation of strategic alliances with international companies by both Australian companies and tertiary institutions, consumer benefits through cheaper and safer products and technologies, and community benefits through increased employment and prosperity.

Significant funding, available through BIF and other funding mechanisms, will be available to support the growth of the biotechnology industry. Bioprospecting, bioprocessing and related biotechnologies will be able to benefit from these funds, as might companies based in rural and regional areas.

Term of Reference 2 Impediments to growth of these new industries.

Infrastructure and skills

In order to be able to process the large number of compounds involved in bioprospecting, researchers must have access to technologically sophisticated facilities and a well qualified workforce, including many scientists. These facilities are normally located with larger universities and research organisations. The lack of such facilities in regional areas is a disadvantage to the establishment of laboratories in some areas for processing compounds

¹⁰ Biotechnology Australia (2000) *National Biotechnology Strategy*, Commonwealth of Australia, p. 8.

collected through bioprocessing. In addition, freight and relocation costs for companies may also pose an impediment to companies establishing operations in rural areas.

Australian biotechnology may also need to improve the management skills and market expertise needed to take a product from innovation to market. The Commonwealth Government is aware of this and the National Biotechnology Strategy includes strategies to improve the researcher–entrepreneur interface. The Government’s recent announcement of biotechnology centres of excellence highlights another initiative designed to contribute directly to enterprise creation, skill development and the creation of wealth and high-value jobs.

Despite the obstacles noted above, Cellulose Valley, as described in Box 3 (page 10) shows that there are opportunities for development in rural and regional areas. Aside from northern NSW, it is possible that bioprospecting could develop around existing regional centres in areas such as Townsville, in relation to the unique resources of the Great Barrier Reef and AIMS, and Tasmania, in relation to field growing material for the pharmaceutical industry such as the Tasmanian poppy.

Return on investment

The successful commercialisation of biotechnology demands high-quality research and analysis. Typically, numerous compounds would be analysed before one with a commercial application might be found. The time to commercialisation is thus very long. The cost of financing a bioprospecting operation is equally taxing on investors’ capital and patience, and the size of a commercial return and when it might be forthcoming are perhaps less predictable than many other investment projects.

A recent workshop on Bioprospecting and Benefit-Sharing in April 1999 was conducted by United Nations Environment Development – United Kingdom (UNED–UK)/ Novartis. The study revealed that it is becoming increasingly clear from experiences overseas that the potential contribution of bioprospecting to the biotechnology industry and the communities involved may not be as substantial, and certainly not as immediate, as was previously believed. This perception may have resulted in changed expectations of profitability in the industry.

The Commonwealth Government and some State Governments are investing in biotechnology to assist products to commercialisation—the Commonwealth funds available to biotechnologists are described under Term of Reference 1. Ultimately however, as companies are floated on the stock exchange, they rely on investor confidence in their ability to produce dividends and capital growth. Investors realise that the cost structure of bioprospecting companies involves long lead times and large costs until products are commercialised. This is an impediment to a bioprospecting industry, and one that will be substantial for bioprospecting companies in regional and rural areas.

Term of Reference 3

The capacity to maximise benefit through intellectual property rights and other mechanisms to support development of these industries in Australia

The protection, commercialisation and strategic management of IP are significant issues for the biotechnology industry in Australia. Through its research and awareness activities, BA has found that there are significant gaps in the knowledge of many biotechnology practitioners about IP matters. Many practitioners were unaware of the importance of properly protecting the IP or how to best manage and commercialise that IP. The reasons for this include a lack of understanding of IP issues, when IP protection is relevant, what form of IP is most appropriate, the cost involved in using what expertise is available (in the form of IP lawyers), and how to manage the IP effectively.

The NBS proposes a number of strategies for dealing with impediments to the biotechnology industry, including strengthening capabilities for the commercial and strategic management of biotechnology intellectual property (IP).

The issues arising from commercialising research to benefit Australia are not only related to the development of high technology industries based on bioprospecting but a range of fundamental and applied research with commercial potential. Australia has 'suffered from a serious shortage of skills in identifying, establishing and utilising IP rights, and in negotiating a way through the IP rights of others'¹¹. To combat this problem, the Australian Centre for Intellectual Property in Agriculture (ACIPA), partly funded through BA, was established in the Australian National University's Faculty of Law in February 2000. ACIPA provides education and training and engages in research and policy development. ACIPA will focus on IP issues as they apply to agriculture and agricultural biotechnology. The law faculty will be joined by ANU's Research School of Biological Sciences to develop education and training programs based on contemporary case studies. ACIPA also intends to form partnerships with other centres of excellence to develop a national network in intellectual property law and policy. The Centre's work is intended to enable Australia to compete internationally by helping industry and researchers to safeguard their IP.

The NHMRC, as a primary funder of health and medical related research, believes that Government support at the 'proof of concept' stage is vital to assist researchers to further develop their discoveries; to ensure any IP is properly protected; and to develop local industry to benefit Australia. To this end, the NHMRC is currently working on:

- promoting best practice of intellectual property (IP) management in the research sector including the development of guidelines for IP management and commercialisation;
- supporting commercial development of research findings through the NHMRC Development Grants; and
- establishing Industry Research Fellowships to enable researchers to gain experience in the commercial aspects of R&D and foster closer interaction between researchers and high technology industries.

In 2000, BA conducted a national series of well-received Australia-wide seminars on Biotechnology IP Management. In April 2001, BA will be implementing the next stage of its

¹¹ Professor John Lovett, ANU Public Affairs Division Media Release, 6 Mar. 2000.

Biotechnology IP Management Strategy, the key element of which is a series of 1-day biotechnology IP training courses being conducted in capital cities aimed at researchers and start-up companies. A biotechnology IP manual will be produced for stakeholders' ready reference. This program, funded under the NBS, will be a valuable public education program not only to existing industry members but also to emerging bioprospecting companies.

Term of Reference 4

The impacts on and benefits to the environment

Bioprospecting involves extracting material from a range of sources, including the environment, for commercial purposes. The Commonwealth Government is aware, as clearly indicated in its biotechnology vision, that policies must be established consistent with safeguarding human health and ensuring environmental protection, so that Australia captures the benefits of biotechnology for the Australian community, industry and the environment.

Environmental benefits

Australia is in a unique position to take advantage of bioprospecting activity through accessing its rich biodiversity and skills base in biotechnology. As an example of the discoveries that could be to Australia's advantage, recent research has shown that some biologically active compounds are present in unrelated species. The source compounds for paclitaxel (Taxol), the anti-cancer drug derived from the Yew tree (*Taxus brevifolia*), have now been identified in tropical waters with the discovery of similar antimetabolic agents, such as discodermolide, isolated from a Caribbean sponge (*Discodermia dissoluta*). Being the country of first discovery might confer significant commercial advantage, which raises possibilities of extensive opportunity for prospecting Australia's coastlines, particularly the Great Barrier Reef. In some instances where biological resources are not well managed, the commercial value of a biological resource could result in the harvesting of that resource to its extinction. On the other hand, if policies are in place to sustainably manage Australia's unique and diverse biological resources, then a biological resource's commercial value could ensure the resource's protection.

While activities such as bioprospecting are likely to have a greater impact in the near future through the increased production of new pharmaceuticals, there could also be significant benefits to the environment from new biotechnologies through waste and waste water management, bioremediation and the use of new products such as biofuels, or plants resistant to disease, salinity or climatic extremes.

Bioprospecting has the potential to significantly enhance the discovery and documentation of Australia's biodiversity. The ARC has emphasised that there is a need for increased rate of species identification and description, a need that could be met by increased funding to agencies engaged in taxonomic work.

Industrial bioprocessing methods can also be used to mitigate problems that are already causing Australia environmental concern and for bioremediation purposes. As one example, CSIRO and BacTech Pty Ltd have discovered an indigenous microbe capable of removing toxic effluent

from gold extraction. Bioprocessing can be used to more efficiently extract metals from mineral ores, and reduce the use of chemicals for this purpose.

The increased use of biofuels will reduce harmful gaseous emissions into the environment and reduce the dependence on use of greenhouse gas-producing fossil fuels. There would seem to be a great potential for biotechnologies to conserve, protect and offer benefit to the environment. As costs of some of these biotechnologies decrease, they are likely to be more widely used.

Managing environmental impacts

While there are considerable benefits flowing from these biotechnologies, as with any technology, there are accompanying risks that must be managed. The NBS recognises this fact. As bioprospecting is an extractive process the potential for environmental damage must be addressed. While modern bio-assaying techniques require only small amounts of tissue, care must be taken if rare, endangered, or sensitive species, or sensitive biological communities, are involved. The downstream effects of utilisation also need to be considered. Consequently, policies need to be in place to ensure that, for example, large-scale damage of the marine or terrestrial environment, or imbalances in ecosystems particularly sensitive to external forces, do not occur. For example, only small quantities of a resource may be required to test for useful compounds, however large amounts of the same resource may be required for further testing or for synthesis of the useful compound. Without the ability to propagate however, such as was the case with the Pacific Yew tree and the anti-cancer drug Taxol, the sustainability of continued collection would need to be assessed.

Bioprospecting for active molecules, therefore, may not necessarily have to adversely impact the natural environment if the plants can be propagated. A good example of this situation is the Madagascar rosy periwinkle, *Catharanthus roseus*. This seed-propagated annual is the natural source of the anti-cancer drug vincristine, which has notably decreased mortality rates for patients suffering from leukemia and certain solid tumour malignancies. This molecule is too complicated for chemists to currently synthesise economically and so vincristine is still extracted directly from plants grown on huge plantations.

In recognition of the importance of developing workable access regimes, in 1994, the Commonwealth Government formed a Working Group to address policy and management matters relating to access to biological resources. The Commonwealth State Working Group (CSWG) on access to biological resources, was asked to¹²:

- investigate and report on action required to develop a national approach to access to Australia's biological resources;
- identify benefits from a national approach;
- develop principles to underpin access management; and
- suggest mechanisms that could be used to govern access, collection, processing, development and export of Australia's indigenous biological resources.

The CSWG report was supportive of a nationally consistent approach to access issues, 'that there are significant benefits to be gained from a nationally consistent approach, but that these need to be weighed up against the cost of changes to regulations in each jurisdiction'.¹³ The report additionally indicated that fundamental to the development of a nationally consistent approach

¹² 'Managing Access to Australia's Biological Resources: Developing a Nationally Consistent Approach', CSWG Discussion paper, Oct. 1996.

¹³ 'Managing Access to Australia's Biological Resources: Developing a Nationally Consistent Approach'. CSWG Discussion paper, Oct. 1996, s. 19, p. 34.

would be the adoption by jurisdictions of a common set of principles to underpin access. The CSWG proposed such a common set of principles.¹⁴

More recently, the National Biotechnology Strategy¹⁵ states that one of the Commonwealth Government's objectives is to develop measures to enhance access to Australian biological resources. If biological resources cannot be accessed, then bioprospecting cannot occur. The NBS has a number of strategies for achieving the NBS objective. These include:

- resolving legal issues on the ownership of Australian biological resources;
- working with sectoral interests to identify their biotechnology resource needs;
- working with the States and Territories to achieve nationally consistent regimes on access;
- developing appropriate documentation management and access protocols;
- addressing matters involving indigenous people and their ownership of biological resources; and
- addressing access issues as they apply in Commonwealth areas, including through regulations under the EPBC Act.

In pursuing these strategies Senator Hill, Minister for the Environment and Heritage, initiated an Inquiry into Access to Biological Resources in Commonwealth Areas, chaired by Mr John Voumard, in December 1999. Senator Hill stated at the release of the Inquiry's Report on 6 September 2000, that 'Access to biological and genetic resources is of strategic importance to Australia's ability to develop a prosperous biotechnology industry'. The Voumard Report on Access to Biological Resources in Commonwealth Areas examined many issues relating to bioprospecting in Australia. Senator Hill said that 'as a result of the work of the Inquiry, Australia now has a chance to lead the world in addressing some of these contemporary challenges including those raised by 'bioprospecting''.

The Inquiry considered issues covering:

- the proposed scheme under s.301 of the EPBC Act¹⁶;
- an outline of the proposed regulations, access permits and benefit sharing contracts;
- ownership of biological resources in Commonwealth areas;
- environmental, indigenous and industry issues; and
- moves towards a nationally consistent approach to access to biological resources.

When releasing the report, Senator Hill indicated that the Government would consider the recommendations, make proposed regulations under the EPBC Act and that these draft regulations would be released for public comment.

¹⁴ 'Managing Access to Australia's Biological Resources: Developing a Nationally Consistent Approach', CSWG Discussion paper, Oct. 1996 s. 9, p. 19.

¹⁵ Biotechnology Australia (2000), *National Biotechnology Strategy*, Commonwealth of Australia, p. 26.

¹⁶ 'Access to Biological Resources' Ministerial Press Release, 6 Sep. 2000 (www.environment.gov.au/minister/env/2000/mr6sept00.html).

Appendix 1

Government assistance programs

The Government has a number of funds to support high technology industry, including biotechnology. These are managed through AusIndustry, a division within the Federal Department of Industry, Science and Resources.

A Pooled Development Fund (PDF) raises capital from investors, then pools the funds and invests in individual companies based on assessment of a company's future potential. The development funds provide tax-exempt dividends for shareholders, capital gains tax exemption and a reduced corporate tax rate of registered investment companies. The number of PDFs specifically for biotechnology is relatively low but increasing; it is currently about 10 out of a total of 119 funds Australia-wide.

The Export Market Development Grants scheme aims to support Australian exports. The Australian Biotechnology Report 1999 estimated total biotechnology and related revenue of A\$965 million, of which \$801 million was product sales and \$31 million contract research. About 76% (\$737 million) of total revenue was based on biotechnology only. Approximately 50% of all revenue was from exports. These data were taken from the 20 listed Stock exchange companies, who earned 76% of the total revenue.¹⁷ There would seem to be potential therefore for biotechnology export growth through a greater use of the Export Market Development Grants. Before this occurs, the biotechnology and bioprospecting companies must grow to the stage where they can compete internationally.

The Commercialising Emerging Technologies (COMET) program was given additional support in *Backing Australia's Ability*. COMET caters for individuals, early stage companies and spin-off companies from research organisations that are looking to commercialise an innovative product, service or process with commercial potential. The applicant must have a demonstrated need for COMET assistance, control of the Intellectual Property relating to the product etc, and some knowledge of the relevant market. In addition, the majority of current business activity must be in Australia. COMET funding can be used to implement an intellectual property strategy, establish a management team, conduct market research, undertake strategic business planning, or make a working prototype.

The Innovation Investment Fund (IIF) program is designed to bring together small companies seeking venture capital and venture capitalists. The companies must be small Australian companies which are investment-ready and commercialising research and development.

The Technology Diffusion Program (TDP) is designed to help industry and researchers adopt new and leading edge technologies which have been developed either in Australia or overseas.

¹⁷ Fayle, D. et al. (2000) Australian Biotechnology and Bioscience Based Industry. *Australasian Biotechnology* 10(3), pp. 33–43.

This fund enables small companies to update their equipment and skills to take advantage of the latest technology so that they can compete in a highly technological market place.

The R&D Start Program is a competitive, merit-based program that will provide \$739 million up to June 2002 and a further \$338 million to June 2006 to assist companies undertake industry R&D and related activities. The R&D Start program has five separate elements of funding:

- Core Start provides grants of up to 50% of the project costs of smaller Australian companies (turnover of up to \$50 million over the previous 3 years) for the early commercialisation of technological innovation;
- Start Plus provides grants of up to 20% of eligible project costs to Australian companies with a group turnover of \$50 million to undertake R&D projects;
- Additional assistance is available to industry for high quality projects through Start Premium. This program offers all companies an additional repayable amount which ‘tops up’ either Core Start or Start Plus to a maximum of 56.25% of eligible project costs;
- Start Graduate grants are available, on a competitive basis, for companies with turnover of less than \$50 million to engage a graduate on a specific R&D-related project that is undertaken in collaboration with a research institution. Projects can extend for up to a 2-year period. The maximum grant is \$100 000 or 50% of eligible project costs; and
- Concessional loans are also available to organisations employing fewer than 100 persons for the commercialisation of technological innovation. Projects must be completed within three years and the loan repaid in the following three years. Loans are for 50% of eligible project costs, with interest waived during the first three years of the project and then charged at 40% of the Commonwealth Bank Index Rate.

The grants and loans available under the R&D Start program would allow biotechnology companies to undertake significantly more research and development. This would mean that Australia could accrue benefits from increased levels of employment and knowledge, well before any commercial return was realised.

The Prime Minister announced on 29 January a 175% tax concession rate to companies that increase their level of non-plant and equipment R&D significantly above their three-year average level.

The CRC program involves formal strategic agreements between universities, the Commonwealth Government, and industry, and aims to stimulate the generation of commercial products and services. Presently there exist five ongoing plus two newly approved CRCs with possible interests in bioprospecting, as described in Table 3. The addition of the biotechnology centres of excellence, the details of which are still being developed, to the enhanced CRC research effort (from *Backing Australia's Ability*), coupled with the science-industry linkages that these organisations develop, is likely to be beneficial to the development of bioprospecting in Australia.

TABLE 3. CRCs WITH POSSIBLE INTEREST IN BIOPROSPECTING

| <i>CRC name</i> | <i>Research focus</i> |
|--|---|
| CRC for Bioproducts | Developing commercially valuable materials produced by plants and other living organisms such as natural colours, nutraceuticals (including the active components in herbal remedies), pharmaceutical intermediates and biopolymers. It aims to establish new industries based on these novel bioproducts and bioprocesses. |
| CRC for Molecular Plant Breeding | Develop, test and implement effective strategies for cereal and pasture grass breeding programs to use the new technologies of molecular biology. |
| CRC for Waste Management and Pollution Control | Waste management systems; biological wastewater treatment; toxic waste immobilisation; membrane and separation technology; solid waste bioreactors; contaminated site monitoring and remediation. |
| CRC for the Great Barrier Reef World Heritage Area | Research programs will provide information, knowledge and tools to ensure best practice outcomes for reef based industry. The research is multi-disciplinary and is regionally focussed on monitoring and evaluation for such things as fisheries and biodiversity |
| CRC for Biopharmaceutical Research | To discover and manufacture new therapeutic agents, 'biopharmaceuticals', and to improve on existing therapeutics. |
| CRC for Value Added Wheat (newly approved) | Apply new biotechnology science to increase knowledge of wheat quality. |
| CRC for Diagnostics (newly approved) | Develop innovative integrated protein and nucleic acid technologies, processes and products for the rapid diagnosis and monitoring of human diseases and phenotypes. This will be achieved through the exploitation of molecular diversity, molecular interactions, genomics and proteomics. |

Acronyms

| | |
|----------|--|
| ABARE | Australian Bureau of Agriculture and Resource Economics |
| ACIPA | Australian Centre for IP in Agriculture |
| AFFA | Agriculture, Fisheries and Forestry - Australia |
| AIMS | Australian Institute of Marine Science |
| ANU | Australian National University |
| ARC | Australian Research Council |
| BA | Biotechnology Australia |
| BIF | Biotechnology Innovation Fund |
| CBD | Convention on Biological Diversity |
| COMET | Commercialising Emerging Technologies |
| CRC | Cooperative Research Centre |
| CSIRO | Commonwealth Scientific and Industrial Research Organisation |
| CSWG | Commonwealth State Working Group |
| DETYA | Department of Education, Training and Youth Affairs |
| DFAT | Department of Foreign Affairs and Trade |
| DNA | Deoxyribonucleic Acid |
| EA | Environment Australia |
| EPBC Act | <i>Environment Protection and Biodiversity Conservation Act 1999</i> |
| GWh/y | Gigawatt hours per year |
| HIV | Human Immunodeficiency Virus |
| IAP | Innovation Access Program |
| IIF | Innovation Investment Fund |
| IOGTR | Interim Office of the Gene Technology Regulator |
| IP | Intellectual Property |
| ISR | Department of Industry, Science and Resources |
| NBS | National Biotechnology Strategy |
| NHMRC | National Health and Medical Research Council |
| PDF | Pooled Development Fund |
| RAFI | Rural Advancement Foundation International |
| R&D | Research and Development |
| SCUCP | Southern Cross University Phytochemistry Centre |
| SPIRT | Strategic Partnership with Industry - Research and Training |
| TDP | Technology Diffusion Program |
| TRIPS | Trade Related Aspects of Intellectual Property Rights |
| UNED–UK | United Nations Environment and Development – United Kingdom |
| US | United States |
| WTO | World Trade Organisation |

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