South Australian Government Submission

to the

"Commonwealth House of Representatives Inquiry into the Development of High Technology Industries in Regional Australia based on Bioprospecting"

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Overview of Bioprospecting

Of the estimated 250,000 plant species in the world today, perhaps 5,000 have been screened for their medicinal potential. Consumers in the United States spend more than $6 billion annually on medicines derived from tropical plants.

Most regional biota have adapted to their particular evolutionary environments. Species have also evolved diverse defence/survival systems in response to the competitive pressures on them. Plants and animals have developed responses such as chemical signals, venoms, antifouling agents, glues to stick to substrates, biochemical means of protection from harmful habitats and photobiological response. It is recognised that from these there is the potential for discovery of novel and useful compounds and products.

Bioprospecting is not new, just new terminology. It is as old as science and medicine and has yielded many products useful in agriculture, materials science and pharmaceuticals. Virtually all modern medicines are derived from or modelled on chemical compounds found in nature. The Florey/penicillin story reflects this, Box 1.

Box 1
Howard Florey and Alexander Fleming – The Penicillin Story

Penicillin was the first naturally occurring antibiotic discovered. There are now more than 60 antibiotics, which are substances that fight bacteria, fungi and other microbes harmful to humans - the word means against (anti) life (bio).

Three thousand years before penicillin, moulds and fermented materials had been used to cure various skin infections, although without an understanding of how they actually worked. But it wasn't until the late 1800s that scientific studies of antibiotics began. French chemist Louis Pasteur, after discovering that infectious diseases are spread by bacteria, observed that mould inhibited the growth of anthrax (an infectious disease spread from animals to humans). British surgeon Joseph Lister noted that samples of urine contaminated with mould didn't allow bacteria to grow, but he was unable to identify the substance in the mould. French medical student Ernest Duchesne successfully tested a substance from mould that inhibited bacterial growth in animals.

After World War I, Alexander Fleming was conducting an experiment with bacteria when a tear fell from his eye into a culture plate. He later noticed that a substance in his tear (which he named lysozyme) killed the bacteria, but was harmless to the body's white blood cells. Years later, Fleming was doing research on the flu when a similar coincidence occurred. While he was on holidays, a bit of mould had fallen into a discarded culture plate containing bacteria, forming a clear patch. When he returned he recognised this pattern from his

[1] In this submission South Australia applies the following definition of bioprospecting:
The search for and sustainable commercialisation of valuable chemical compounds and genetic material found in plants, animals and microorganisms.

previous experience with lysozyme. He concluded that the mould was producing an antibiotic substance and named the antibiotic penicillin, after the Penicillium mould that produced it.

But Fleming couldn't extract the bacteria-killing substance, so he couldn't try it as a treatment for general infections. He moved on to other research - leaving Howard Florey and his team to pave the way for penicillin's use as a lifesaver more than a decade later.

Florey and his colleague, Dr Ernest Chain, noticed the properties and potential of Penicillium. Their Oxford research team discovered how to produce an effective and safe antibacterial agent from the raw mould juice and designed mass production methods - painstaking and extremely difficult work. Fleming, Chain and Florey were jointly awarded the Nobel Prize in Physiology or Medicine 1945 for this work.

Science, industry, regional communities and governments have come to recognise that wildlife and its habitats (biodiversity) are valuable reservoirs of products yet to be discovered and developed for wider social and economic use.

Australian Biota

The uniqueness of much of Australia's biota is well recognised, most transparently reflected in Australia's marsupial fauna. Despite the recognition that "with close on half a million of the earth's 10 to 30 million species, Australia is one of only 12 mega diverse countries and is the sole developed country among them" (Invest Australia: Biotechnology in Australia, an investment in the future), less known is the uniqueness of much of Australia's other biota. Of particular example is southern Australia's marine biota. (see Box 2)

Box 2

Biodiversity and Evolution of Australia's Marine Biota

The extent and diversity of Australia's marine and coastal environments has resulted in unique and spectacular marine life supporting some of the greatest diversity of marine species in the world. Australia has the world's largest areas and highest species diversity of tropical and temperate seagrasses, the highest diversity of marine macroalgae, the largest area of coral reefs, the highest mangrove species diversity and global levels of biodiversity for many marine invertebrates (eg. bryozoans, ascidians, nudibranchs). Approximately 4,000 species of fish, 43 species of whales and dolphins, and 6 of the 7 world species of marine turtles are recorded from Australia.

Many factors which have made Australia's terrestrial fauna and flora unique and biologically diverse have also produced the high global levels of biodiversity and endemism (uniqueness) in the marine biota. These factors include the long period of geological isolation, large continental landmass, including the extensive continental shelf and the longest east-west ice-free southern coastline in the Southern Hemisphere. The characteristic low nutrient status of Australia's coastal waters has also been attributed as contributing significantly to Australia's temperate marine biological diversity as low nutrient regimes generally promote co-evolutionary strategies to rapidly harvest, utilise and recycle limited nutrient resources.

Marine Biogeography of Southern Australia

South Australia's marine biota is at the geographical centre of the temperate "Unique South".

Temperate southern Australian waters have been geographically and climatically isolated for around 65 million years. Approximately 85% of the known fish, 95% of mollusc and 90% of echinoderm species are endemic. In contrast, approximately 13%, 10% and 13% of the known fish, mollusc and echinoderms respectively, are endemic in the tropical regions of Australia. The richness of the temperate macroalgal flora (ie. 1,155 species) is 50-80% greater than in other comparable global regions, with approximately 800 species and over 75% endemism recorded in the red algae alone. The diversity of temperate species of macroalgae is approximately three times the level recorded in the tropical regions of Australia.

Australia's waters also contain the highest species diversity and endemism for seagrasses in the world. Like the macroalgae, diversity and endemism of seagrasses is highest in temperate waters, where 22 species have been recorded compared with 15 in tropical waters.

Legal Instruments of Bioprospecting Operation

Patent law is the legal instrument most commonly used to protect the right to benefit financially from innovations. However as practiced in many countries it is frequently seen as an inadequate tool. Patentable inventions and discoveries must be novel, non obvious and useful. As a result of these requirements and others patent law is generally unable to recognise stewardship of biodiversity by nations and states or maintenance of traditional knowledge of the use of biodiversity

Contractual arrangements among bioprospecting partnerships are increasingly becoming widely considered. Contracts have the flexibility to "fit" the particular situation and relationship between the various collaborators. They can be used to define the nature and magnitude of benefit attribution, including non direct fiscal "dividends".

Highlighting the need for Australia as a whole to rapidly come to grips with this issue, an increasing number of "target" nations around the world have already developed bioprospecting policies and legislation that enables them to effectively negotiate and benefit from the international bioprospecting activities. These countries include Madagascar, Indonesia, Guyana, Cameroon, Suriname and Peru.

An example of the nationally organised contractual arrangement approach is seen in the activities of the United States of America based International Cooperative Biodiversity Groups (ICBG) (Box 3).

Box 3
International Cooperative Biodiversity Groups (ICBG) Program - United States of America

The International Co-operative Biodiversity Groups (ICBG) Program is funded and guided co-operatively by three agencies of the United States Government -- the National Institutes of Health, the National Science Foundation, and the US Agency for International Development. It was designed to stimulate the field of

bioprospecting, to provide models for the development of sustainable use of biodiversity, and to gather evidence on the feasibility of bioprospecting as a means to:

1. improve human health through discovery of natural products with medicinal properties;

2. conserve biodiversity through valuation of natural resources, training and infrastructure building to aid in management;

3. promote sustainable economic activity of communities, primarily in less developed countries in which much of the world's biodiversity is found.

Each of the International Co-operative Biodiversity Groups is run by an academic principal investigator, who directs his or her own research program in natural products chemistry, drug development or ethnobotany, and co-ordinates the activities of several associate programs. The associate programs generally include other academic research institutions, local and international NGOs that are working in the host countries, and in most cases, a commercial pharmaceutical partner. While each of the groups is unique, generally each associate program is charged with one or more of the basic missions of the ICBG -- biodiversity inventory, collection and conservation, screening and chemistry, drug development, or economic development. The awards are in the form of co-operative agreements, rather than grants. This means that the US Government has continued involvement in the projects through scientific advisory committees that comprise representatives from each agency, as well as general facilitation and policy advice from the Fogarty International Centre of the NIH, which handles program management for the ICBG awards.

The basic philosophy of this integrated conservation and development program (ICDP) is that appropriately designed natural products research and development can bring both short and long-term benefits to the countries and communities that are the stewards of the genetic resources (Schweitzer et al. 1991, Grifo in press). Sharing benefits from both the research process and from any drug discoveries that are made down the road creates incentives for conservation and provides alternatives to destructive use.

In the context of the ICBG program, appropriate design includes: 1) active participation of host country individuals and organisations from the planning stage onward, 2) multi-disciplinary research on diseases of both local and international significance, 3) local training and infrastructure development in both drug discovery and biodiversity management, 4) biodiversity inventory and monitoring, and 5) equitable intellectual property and benefit-sharing arrangements.

Applicants for the ICBG awards were given a description of program goals and intellectual property principles to use in the design of their research proposals and contractual agreements. Formal written agreements that govern treatment of intellectual property and benefit-sharing were required of all applicants prior to making an award. Because the funding agencies are not parties to the research and benefit-sharing agreements, they are prohibited by US Federal law from stipulating specific contractual terms, but rather encourage the parties to develop innovative agreements that fit the nature of the organisations, countries, communities and resources involved, within the general framework of the program's principles.

Bioprospecting vs biopiracy

The converse of bioprospecting is biopiracy.

The International Code of Conduct for Plant Germplasm Collecting and Transfer (adopted by the FAO in 1993 as a voluntary code) emphasises the importance of the exchange of plant biological resources, with the involvement of source communities with the suggested safeguards:

- Appropriate standards of conduct to define obligations of collectors;
- The sharing of benefits between the donors and users of germplasm;

There are ample examples to illustrate the wider recognition of the inherent scientific and commercial value of biodiversity and increasing desire by nations and communities to both capitalise on this awareness and protect their intellectual and commercial rights.

South Australia recognises that bioprospecting internationally should operate in a policy framework that includes agreement from an appropriate government agency in the country concerned. Evidence of this is best seen in the recent history of genetic accessions for agricultural related breeding programs in Australia. Southern Australia, having a mainly temperate "Mediterranean" type climatic regime, means almost all our traditional agricultural crops (germplasm) have been derived from Mediterranean or near countries. Whilst accessions and genetic material exchanges have generally occurred with good intent and acknowledgment, more recent scrutiny by a number of international "public good interest" groups have resulted in an increased awareness of the threat of bio-piracy and the need for an internationally/universal and national legislative and operating framework.

The concept of a viable market driven by bioprospecting is premised on protection of property rights for specific biological resources and the products derived from them. It presupposes the creation of a legal system along the lines of patent law and the legislation governing intellectual property in the high tech industry. Whilst there are many historic examples worldwide that illustrate the need to develop such an approach, the experience of Yellowstone National Park in the United States of America is relevant (Box 4).

Box 4

Yellowstone National Park – Bioprospecting Experience

Enzymes are protein molecules that carry out functions within cells. Enzymes can be destroyed by changes in conditions such as temperature and pH. Organisms thriving (thermphiles) in Yellowstone National Park's thermal springs contain "environmentally" friendly enzymes that are stable under high temperatures.

One of the most widely used processes in bioscience research and industry is the multiplication of small amounts of DNA through the PCR (polymerase chain reaction) process using a heat stable enzyme derived from an organism (the cyanobacterium *Thermus aquaticus* (*Taq* YT–1)) discovered in Yellowstone's thermal springs. PCR has become the cornerstone of modern medical and genetic based diagnostics with annual sales of the Taq polymerse of the order of hundreds of millions of US$. None of these revenues benefit Yellowstone National Park and its resources.

In response Yellowstone sought to capitalise on its unique biota to enable it to be better able to address its conservation objectives. In August 1997 Yellowstone entered into agreement with Diversa Corporation, a company specialising in the industrial application of biocatalysts. Diversa agreed to pay Yellowstone $25,000 a year for five years for permission to collect microbes in the park. If Diversa develops a profitable product based on the Yellowstone microbes, the park will receive a royalty based on profits.

In March 1998 a number of conservation and public good technology interest groups initiated litigation to stop the Yellowstone-Diversa deal. In March 1999 a US Federal Judge ruled that the National Parks Service must complete an environmental review before it can proceed with the arrangement.

Bioscience Industry in South Australia

South Australia recognises bioprospecting as an element of its overall bioscience industry development strategies. The South Australian government is addressing this through the formation of BioInnovation SA.

The South Australian Government approved establishment of BioInnovation SA in December 2000 to create a world class bioscience industry in South Australia. It aims to foster research and development, facilitate commercialisation and encourage global investment to enhance the State's economic and social future. Areas of opportunity include agriculture, aquaculture, cosmetics, biotechnology development, flavours, fragrances, food products including nutraceuticals, fibre, fuels, industrial processes and pharmaceuticals.

South Australia and BioInnovation SA's vision are to facilitate the development of industry and science capability in the biosciences. It also seeks to address issues such as freedom to operate, access to required resources and technologies (whether they be enabling technologies such as access to a particular patented gene from a transnational corporate or access to a compound through bioprospecting activities), and the necessary competence and skill to negotiate and operate successfully in the internationally competitive bioscience industry market place, including in the bioprospecting arena.

The South Australian Government has also begun to consider issues surrounding access. In September 2000 the Government released for public comment a Discussion Paper on "Access to Biological Resources in South Australia" (attached at Appendix 1).

In order to stimulate consideration of the issues associated with bioprospecting the South Australian discussion paper identified six regulatory options for consideration.

- Do nothing beyond the existing arrangements;
- Broaden Statutory controls;
- Establish Access to Biological Resources Committee;
- Require Ministerial Notification;
- Require Ministerial Approval;
- Crown Ownership of Biota.

Bioprospecting and Conservation

The 1992 Convention on Biological Diversity, reaffirmed the sovereign rights of countries over their own biological resources and their responsibility for using their resources in a sustainable manner. It also sought governments to commit themselves to a set of activities related directly to conservation (eg inventory of species, establishment of protected area systems). To date approximately 140 countries have ratified the Convention.

South Australia recognises the potential opportunity bioprospecting provides through linking it (and the related activity of biotourism) to conservation, utilising business success for conservation, ie using the economics of bioprospecting as one tool in the effort to preserve biodiversity.

South Australia has an extensive and ongoing development program for terrestrial based natural system protection. It is also currently committed to developing a Marine Planning

Framework. The framework will allow for the establishment of scientifically determined biogeographic based marine protected areas (MPAs). These will be invaluable in ensuring that any bioprospecting opportunities, policies and programs which address both economic and biodiversity conservation objectives can be pursued.

Indigenous communities

Many bioprospecting "discoveries" capitalise on the knowledge of traditional peoples. Therefore any bioprospecting framework needs to ensure that this input is recognised and rewarded through consultation and agreement. This is analogous to any other "know how" or "access to enabling technology" requirement/process in the wider biosciences and technologies arena.

Benefits flowing to Indigenous communities can include the usual proportion of revenues or royalties as well as more community focussed provisions of technology transfer and training within the community. These are also relevant to benefit considerations flowing to the wider Australian regional community. Benefits can either be in the form of social benefits (ie improvement of infrastructure or services to the local community), process benefits (ie permit fees, research equipment and chemicals, provision of literature, sharing of results, transfer of technology, exchange of staff) or financial benefits (ie cash payments).

In South Australia approximately 27% of the land is owned by Aboriginal land holding authorities. The South Australian Department of State Aboriginal Affairs convenes a coalition of these authorities which represents the Arangu Pitjantjatjara, Maralinga Tjarutja and Aboriginal Lands Trust communities. Aboriginal people's use of their local environment and their cultural knowledge and experiences make their intellectual knowledge a valuable resource in bioprospecting. Complex matters need to be addressed in respect of ensuring Indigenous interests are not compromised through individual agreements with entrepreneurs.

Jurisdictions and Legislation

This submission highlights that bioprospecting is an international issue. For Australia to fully benefit from its own biodiversity, as well as compete internationally in incorporating bioprospecting into its emerging biosciences industry, requires Australia to rapidly "come to grips" with this issue nationally. This needs to incorporate the expectations and obligations of both the states and Commonwealth, as well as ensuring appropriate and coordinated science capability, industry readiness, jurisdictional framework and cultural partnership collaborative arrangements are in place.

The South Australian Government Discussion Paper on "Access to Biological Resources in South Australia" (Appendix 1) complemented the July 2000 report of the Commonwealth Public Inquiry "Access to Biological Resources in Commonwealth Areas". Further discussion on the impacts and implications of the major international conventions and legislative approaches are given full consideration in those reports.

For Australia to benefit there also needs to be reconciliation and agreement on the linkages and complementarity of any State and Commonwealth legislation with regard to bioprospecting. The National Strategy for the Conservation of Biological Diversity states that by the year 2000, Australia will have established legislative and administrative mechanisms for control of access to Australia's genetic resources.

Currently the Commonwealth Environment Protection and Biodiversity Act 1999 addresses access to biological resources.

Each state also has legislation that is relevant to the issue, but which has usually been established for some other purpose such as the management of fish resources or native wildlife. In South Australia such legislation includes:

- Fisheries Act 1982,
- National Parks and Wildlife Act 1972,
- Forestry Act 1950,
- Native Vegetation Act 1981 and
- Local Government Act 1999.

In developing Australian policies and processes on bioprospecting it is essential the role and responsibilities of the States for local land use and ownership (eg Crown lands) are recognised and accommodated.

Summary and Recommendations

Governments are seeking to catch up with both the increasing recognition of and moves to capitalise on the value of a nation's biodiversity, and the increasing number worldwide of bioprospecting ventures. These activities are arguably taking place without a sufficiently rigorous policy framework at the national level. This parallels the situation in addressing the development and application of transgenic technologies.

In both areas the debate is littered with industry and stakeholder groups frustrated with the time taken to negotiate and establish the jurisdictional and legislative framework for the industry.

The key bioprospecting issues for South Australia are the issues of access and benefits. In addition, South Australia seeks the rapid development of a national legislative framework within which states and territories can operate.

Recommendation 1 – Strong and coordinated Bioscience policy

For Australia to be competitive in the international bioscience and bioprospecting market place it needs to ensure it:

- Recognises bioprospecting and its outcomes in the wider bioscience industry as an emerging economic and social development opportunity that Australia should pursue;
- Has an effective and critically focussed science capability in this area;
- Has a bioscience based industry that is both world competitive and recognises the potential from investing in bioscience and bioprospecting (this includes the biotechnology as well as venture finance sectors);
- Has a Commonwealth and State coordinated policy that enables Australian science and industry communities to effectively operate in the competitive international arena as well as ensure Australia can adequately protect and capitalise on its own biodiversity;
- Recognises that access to bioprospecting opportunities includes the need to negotiate access to Australian and international biodiversity and know how with relevant regional jurisdictions and communities (this includes traditional agricultural focussed access to germplasm as well as Indigenous based knowledge leading to novel compounds of economic value).

Recommendation 2 – Innovation strategies

Issues of scientific and industry potential should be addressed and incorporated into appropriate national and state innovation, science and technology strategies and policies such as the Commonwealth Innovation Statement and the Strategy currently being developed by the South Australian Innovation, Science and Technology Council.

Recommendation 3 – Legal instruments

Australia needs to decide on the nature of the bioprospecting legal instrument it wishes to apply.

Whilst recognising the ongoing option of using Patent Law by the bioprospecting industry, Australia should urgently develop a Bioprospecting Policy and Legislative framework based on the negotiation of contractual arrangements and partnerships with relevant jurisdictions and stakeholder groups, with relevant Government oversight.

Any such arrangement needs to provide appropriate monitoring, audit and compliance arrangements to provide for protection of the environment in pursuit of bioprospecting.

Recommendation 4 – Opportunities for rural and indigenous communities

The Commonwealth should further explore the opportunities for Australia's rural and Indigenous communities to benefit from the use of Australia's biodiversity by international and/or national bioprospecting interests, in accordance with the principles outlined in the 1992 Convention on Biological Diversity.

Recommendation 5 – Fostering competitiveness and effectiveness

To facilitate Australia's bioprospecting competitiveness and effectiveness in the international bioscience market, the Commonwealth government should establish an Australian International Cooperative Biodiversity Group (AICBG) involving relevant Commonwealth and State government, research and industry organisations.

Recommendation 6 – Audit of assets and potential

Australia should undertake an audit/inventory (through the proposed Australian International Biodiversity Group and relevant state authorities) of its bioprospecting assets and potential.