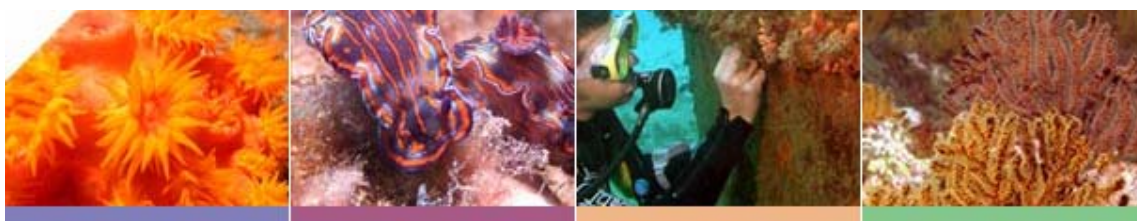




Prime Minister's Science Engineering and Innovation Council



Biodiscovery



Source <http://www.pharmamar.com>.

2 December 2005

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This paper was prepared by an independent working group for the Prime Minister’s Science, Engineering and Innovation Council (PMSEIC). Its views are those of the group, not necessarily those of the Australian Government.

Terms of reference

The PMSEIC working group on biodiscovery will:

1. Examine recent developments in Australian biodiscovery.
 - a. Describe the unique range of Australia's biodiversity and indigenous knowledge and their potential to increase the scientific and economic value of Australia's biodiversity through biodiscovery.
 - b. Outline Australia's current capability in biodiscovery, including taxonomic services, research and legal infrastructure, skills and international collaboration.
2. Provide an overview of Australia's policy and regulatory framework and international developments in biodiscovery including policies and programs which facilitate access to Australia's genetic and biochemical resources, bioinformation and indigenous knowledge, intellectual property (IP) issues, regulatory systems and industry uptake.
3. Identify and address key issues and/or impediments Australia faces on the pathway from biodiscovery to R&D and commercialisation (e.g. IP/legal frameworks, long term conservation of biodiversity).
4. Identify opportunities for Australian biodiscovery, including benefits to Australian science, economy, environment, people and society.

Working group

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Executive summary

Australia stands to gain from an increased investment and legal certainty in biodiscovery – not just economic benefits, but social, environmental and scientific benefits. Australia is well positioned to capture the opportunities presented by our vast and unique biodiversity, but current impediments make this difficult. These relate to legal and regulatory clarity and consistency, the extent and nature of data collections and networks, and taxonomic skill needs.

This report outlines what Australia can do to strengthen its scientific, community, societal and commercial capability in biodiscovery, thereby creating a fertile environment for investment and wealth creation.

Biodiscovery is the examination of biological resources (e.g. plants, animals, micro-organisms) for characteristics that may have wider application and/or commercial value.

Targeted features may include chemical compounds, genes and their products, whole organisms, or in some cases, the physical properties of the material in question. Clues used in searching often encompass biological observations, ecosystem and indigenous knowledge.

Biodiscovery aims to identify new materials or biologically active molecules that can be developed as drugs, insecticides, herbicides or industrial enzymes. Other products may have application to bioremediation, sustainable farming, and materials science. Biodiscovery begins with the collection of samples that are examined for bioactivity, isolating the desired compounds, followed by a lengthy process of developing and testing products for human or industrial use. The manufacturing phase involves gearing up for large scale production, often by synthesising chemicals and compounds to minimise natural harvesting and optimise their utility. The business side of biodiscovery involves protection of intellectual property, patenting of new structures or properties, and the attraction of capital and marketing of the final products.

Australia's plants, animals and microorganisms – of which there are several hundred thousand *known* species – fabricate a huge range of substances within their cells. Some of these are highly specialised chemicals and gene products that help organisms to survive – resisting disease or predation, adapting to harsh environments, or improving their chances of reproduction with enticing colour, flavour, aroma, noise or texture.

Australia is in the top echelon of biodiverse nations from an international perspective. We have a bountiful biodiversity; an astonishingly rich hub of global plant and animal species, both on land and in the sea – a unique national treasure. Australia is one of only nineteen countries classed as “mega-biodiverse”, and among these, one of only two in the developed world. Significantly, more than 80% of our species are found nowhere else on earth - an extraordinarily high level of endemism. More species are being discovered and described almost daily.

This report, through its recommendations, provides an action plan for harnessing of Australia's vast natural resources through support to scientists and researchers investigating natural chemicals and gene products with potential applications in medicine, agriculture, manufacturing and many other industries. It also outlines how indigenous and/or traditional knowledge of the medicinal and other properties of organisms are important sources of wisdom and in many cases represent the catalyst for biodiscovery.

Recommendations

The Working Group has identified two key needs to accelerate biodiscovery in Australia:

- to sustainably manage our existing biodiversity knowledge and acquisitions - identify, describe, understand, conserve and protect the species of our continent; and
- to create certainty for the commercialisation of biodiscovery and thereby improve conditions for investment, benefit sharing and capacity building.

We therefore recommend the following actions to achieve these needs:

National Biodiversity – expanding our understanding

- Develop an ***Atlas of Living Australia*** (a “Biodiversity Google”) by 2015, based on a real time identification and web-based taxonomy system, and incorporating Australian engagement in the International ***Barcode of Life*** Program and linked to a National Network of Collections.

Biodiscovery – unlocking the knowledge

- Establish a ***National Screening Network***, incorporating a compound library facility and Australia’s national collections including centres of indigenous and traditional knowledge.

Commercialisation – seizing the opportunities

- Achieve ***National Harmonisation*** of access and benefit-sharing legislative frameworks, to provide legal certainty for biodiscovery and ensuring swift access (lower cost transactions) for commercialisation.

Further detail on these recommendations is provided in Chapter 4 – Action Plan.

Chapter 1 – Wealth creation from biodiscovery

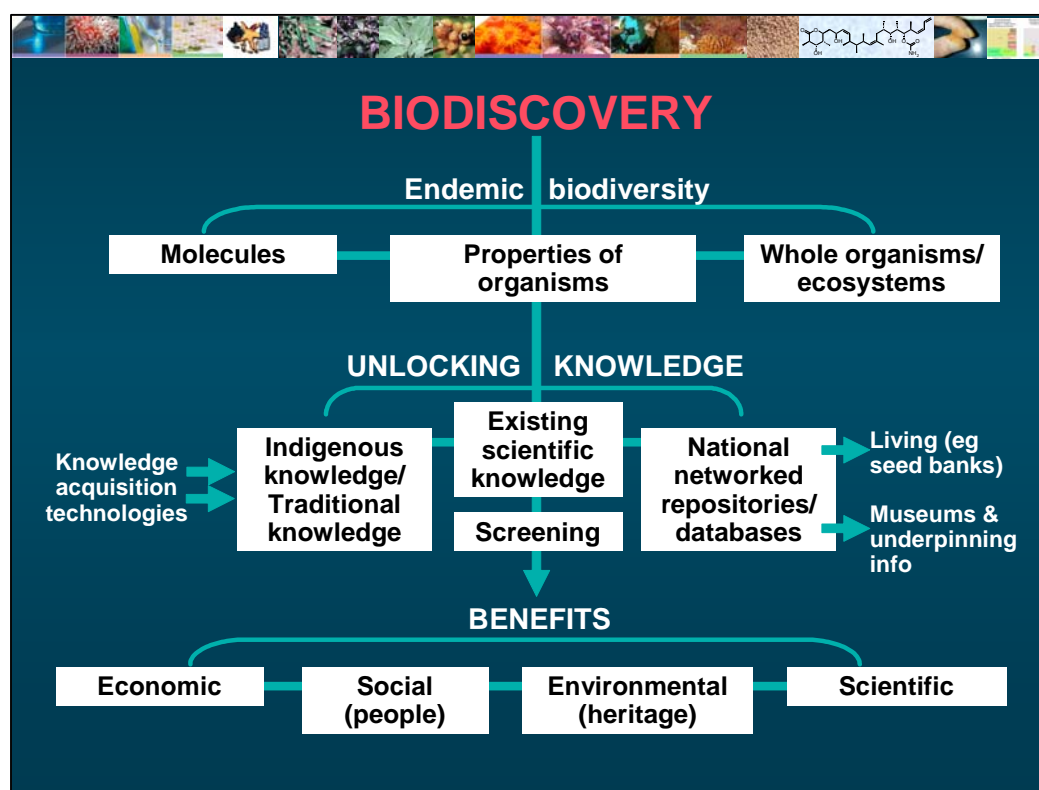
“Every country has three forms of wealth – material, cultural and biological. The first two we understand well because they are the substance of our everyday lives. The essence of the biodiversity problem is that biological wealth is taken much less seriously. This is a major strategic error, one that will be increasingly regretted as time passes”

(EO Wilson 1992 p. 311. The diversity of life, Harvard University Press, Cambridge MA)

Biodiscovery

Biodiscovery is the examination of biological resources (e.g. plants, animals, micro-organisms) for characteristics that may have wider application and/or commercial value. Targeted features may include chemical compounds, genes and their products, whole organisms, or in some cases, the physical properties of the material in question. Clues used in searching often encompass biological observations, ecosystem and indigenous knowledge.

New materials or biologically active molecules can be developed as drugs, insecticides, herbicides or industrial enzymes. Other products may have application to bioremediation, sustainable farming, and materials science.



Delivering benefits

Australia is well positioned with huge potential to reap genuine benefits through biodiscovery of its bioresources. The opportunities provided by Australia's endemic biodiversity, from its genes to whole organisms, places us in a privileged position. The challenge is to identify and develop innovative technologies and strategies to unlock the value inherent in living species, national repositories and our indigenous knowledge. Australia's relatively strong scientific

base means our existing biological and chemical knowledge gives us an important starting point for new discovery efforts.

Investments in biodiscovery activities carry a wide range of potential benefits:

- economic – wealth creation through the chain of development;
- social – benefit to local communities;
- environmental – increased capability in addressing current and future impact on our land and oceans; and
- scientific – increased scientific knowledge of biology and ecology.

Parenthetically, Australia's ability to capture these potential benefits depends on conservation and protection of our biodiverse ecosystem and on maintaining a competitive edge in understanding it.

Creating wealth through the chain of development

Discovery and development of commercial material through to manufacturing and marketing of the final product is complex, has inherent risk and usually takes place over a long period. Australia would accrue appreciable benefit by adding as much value as possible throughout the chain of testing and development. Rather than focusing only on end points of commercialisation, organisations involve themselves in earlier steps, such as preliminary screening. This creates direct financial benefits, for example, through the sale of valuable knowledge. It also creates flow-on effects in employment and capacity-building in local biotechnology industries. Even if the final commercialisation takes place offshore, Australia will benefit from the discovery of the compound.

As an example, a typical pharmaceutical biodiscovery research project would involve the following steps:

- discovery: collecting material, screening for useful properties or "bio-activities", isolating and purifying new and active chemicals, describing new chemical structures;
- protection of intellectual property: largely the patenting of new structures and/or specific types of bioactivity (e.g. antibiotic, insecticidal or anti-tumour properties);
- product development: modifying chemical structures to improve their efficacy, safety and bioavailability, conducting clinical and/or field trials to demonstrate and compare the effectiveness and safety of the product with others currently on the market to obtain product approval;
- manufacturing: developing techniques for larger scale sustainable and reliable industrial production of the chemicals (e.g. by total laboratory synthesis or by purification from cultivated biological material); and
- marketing the final product.

Each of these steps offer a opportunities to gain value for Australia.

In addition to building Australia's scientific capacity and generating employment, it is vital that Australia benefits more from ownership of inventions. This requires a strong proof of concept, such as efficacy in man or in an animal model, or for non-pharmaceuticals a proof of concept in a field, factory or other practical setting, and a strong patent position, owned locally, allowing for leverage in licensing including national benefit provisions, such as product manufacture.

Of note is the range of important, profitable and growing industries that commercialise the fruits of biodiscovery. Global pharmaceutical sales were worth US\$550 billion in 2004. Approximately 50% of all pharmaceuticals are made from, based upon or inspired by chemicals originally isolated from nature. Veterinary pharmaceuticals currently account for sales of US\$12 billion per annum. Biomaterials, medical diagnostics, laboratory reagents and many other types of product also derive significant innovation from biodiscovery, and agriculture is adopting biodiscovery-like processes to identify new crop species and new traits. The global markets for fragrances, flavours and enzymes for food and cosmetics production also benefit from biodiscovery.

Benefit to local communities

Biodiscovery activities can benefit local communities through training and employment of local people to collect biological samples. In Australia, there are opportunities for benefit-sharing arrangements with local communities in general and indigenous communities in particular, should there be a connection between indigenous knowledge and the biological material in question.

Farms of golden sponge

A collaboration between the Australian Institute of Marine Science (AIMS) and the Coolgaree Aboriginal Corporation of Palm Island is establishing Australia's first commercial sea sponge farm venture owned by Coolgaree in agreement with the Manbarra traditional owners. The aim is to produce "golden sponges" for a grossly undersupplied international commercial sponge market.

This venture brings together an institution providing scientific advice on culture methods, farm design, engineering, environmental impact and sustainability, together with indigenous owners developing an aquaculture model that incorporates training of the community in transferable skills. This represents creation of a new economic venture and employment in a severely disadvantaged regional community.

Increased capacity of Australia's scientific sector

Involvement in biodiscovery projects enhances the skills and knowledge of Australian researchers. Employment in biodiscovery makes Australian researchers more attractive to the broader biotechnology industry. This also improves the downstream opportunities for Australia to add value through the development chain of a product. Research can therefore contribute to the economic development through education and training of new PhD-level researchers with valuable skills providing input to the Australian economy.

Additionally, investment in biodiscovery forces the development of national facilities such as genomic centres, biological collections, research vessels, dedicated analytical and physical containment facilities, all of which are essential to underpin Australia's scientific capacity.

Novel glue from native frog

Scientists at CSIRO and the University of Adelaide are hoping to develop new surgical adhesives by studying a natural glue that comes from frogs.

Australian frogs of the genus *Notaden* secrete a sticky exudate when provoked. This sets rapidly into a tacky elastic solid that adheres tightly to a wide range of materials, even in wet conditions. Scientists are aiming to mimic the design of this natural material to produce surgical adhesives to bond cartilage, tendons and bone, repair damaged tissues and to close up wounds. Source: <http://www.news.com.au/story/0,10117,15896240-13762,00.html>



Increased scientific knowledge of biology and ecology

Biodiscovery increases the understanding of our natural systems, regardless of any commercial value. This has intrinsic worth and may contribute to conservation and environmental management practices. The AstraZeneca/Griffith University partnership initiated in 1993 has led to the discovery of 37 new plant species and nearly 1500 new marine organisms. New populations of threatened plant species in remote areas have been located, providing genetic material which can be used to propagate and conserve species. Records of weed encroachment in native forests provide useful information for sustainable forest management. In the marine environment the project has provided knowledge to accurately define distribution of marine sponges, thus contributing invaluable data to further understanding of Australia's marine biota.

Knowledge of Australia's sponge diversity has increased from around 1,000 species in 1978 to over 5,000 today. This quantum increase in knowledge was primarily due to three major biodiscovery collection efforts, undertaken by Roche Research Institute of Pharmacology (1974-1981), AIMS (1987-present), and the Queensland Museum (1993-present).

Downstream production related to scientific discoveries

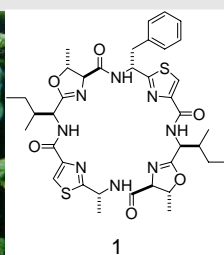
Biodiscovery also has the potential to lead to industries focussed on production of valuable substances or products. This can involve the production of the raw biological material - 'bioprocessing'. For example, there is increased world-wide scientific interest in the biochemical properties of sedentary marine organisms such as sea sponges and Australia has identified several promising species (e.g. as anti-cancer agents). However the most reliable and effective method for obtaining large quantities of particular species of sponge biomass for drug development and production is sea rearing. This in turn creates demand for skills in aquaculture and opens the door to the creation of future bioprocessing industry. Consequently, Australia will need to develop the necessary skills to support such industries.

Marine microbes in novel bioproduction opportunity

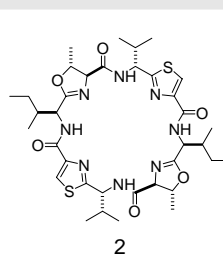
Marine "seasquirt" DNA has been cloned into the easy-to-culture bacterium *E. coli*, in a bid to obtain a sustainable supply of exciting new drug leads from the sea. This world-first achievement is designed to eliminate the supply obstacle that has stalled the development of many promising marine-derived pharmaceuticals due to concerns over ecological sustainability. The methodology, developed by an international team of scientists from AIMS, University of Aberdeen and London School of Pharmacy, has the potential to remove a huge hurdle to the development of new drugs from the sea.



Lissoclinum patella



Patellamide D



Ascidiacyclamide

Royalties from eventual commercial development

It is possible to secure royalty streams for Australian researchers, agencies, companies or resource stakeholders, through the retention of intellectual property in a downstream commercial product. However, only a small proportion of bioactive substances reach the stage of commercial production and the complexity of biodiscovery projects can mean that there are many contributors to the intellectual property. Thus, royalty returns are advantaged by adding as much value as possible in Australia, thereby maintaining the relative contribution to the end product. Nevertheless, the creation of a high value, widely sold product such as a pharmaceutical may produce significant income streams.

Chapter 2 - Australia's competitive edge

Australia as a mega-biodiverse region

As one of the 19 mega-biodiverse countries on earth Australia is an astonishingly rich centre of global plant, fungal and animal biodiversity both on land and sea. In the 65 million years since the Gondwanan break-up, Australia, the island continent, has evolved a biological diversity that rivals the most biologically prodigious of countries equating with the top biodiverse countries on Earth.

Millennia of isolation and geological stability have made Australia the oldest, flattest and, excluding Antarctica, the driest continent. These factors have driven evolution and selected species keenly attuned to the extreme climate and soils of the continent.

No other continent has evolved a terrestrial flora and fauna that can survive and thrive on some of the world's most impoverished soils and under extremes of heat and drought.

The oldest record of life on earth, the 3.45 billion year old cyanobacteria found in the northwest of Western Australia, is evidence of the extraordinary wealth of biology of the nation.



Ancient stromatolites formed by cyanobacteria

About Australia's biodiversity

Biodiversity is the basis for healthy, functioning ecosystems that are necessary to maintain essential ecosystem services including those upon which human survival depends. These include soil formation, nutrient storage and recycling, water purification, waste disposal, plant pollination and pollution breakdown and absorption. Biodiversity provides the critical processes that make life possible.

Australia is one of the most diverse countries on the planet. It is home to hundreds of thousands of species of plants and animals, many of which are found nowhere else in the world. About 85% of insects and flowering plants, 84% of mammals, more than 45% of birds, and 89% of inshore and freshwater fish are unique to Australia.

Including the complexity of diversity within species, between species and of ecosystems, biodiversity is usually considered at 3 levels:

1. Genetic diversity - the variety of genetic information contained in all individual plants, animals and microorganisms.
2. Species diversity - the variety of species on earth. Species diversity is usually regarded as a measure of the number of species (richness) and their relative abundances for a given area or habitat at a given point in time.
3. Ecosystem diversity - the variety of habitats, biotic communities and ecological processes. An ecosystem is a community of plants, animals, fungi and microorganisms and their physical non-living environment interacting together as an ecological unit.

International perspectives on the biodiversity of Australia place the country as more diverse than 98% of other countries. With species level endemism at more than 80%, endemism in Australia is among the highest on earth. Seven families of mammals, four of birds and twelve of flowering plants are endemic to Australia. No other country has as many endemic flowering plant families as Australia thereby providing the unique landscapes, animals and iconic plants that typify Australia.

With twice the number of species as Europe and North America combined, Australia hosts an estimated 25,000 flowering plant species or one in ten of all flowering plants on earth, 253,000 terrestrial arthropods and a bewildering array of micro-organisms. Australia hosts the two largest genera of woody plants on earth, *Acacia* (ca 1200 species) and *Eucalyptus* (ca 850 species), testimony to the unique geological and evolutionary history of the continent.

Australia's oceanic island territories, sub-Antarctic islands and Antarctica itself all support extraordinary biodiversity evolved to survive in extreme conditions. These territories support evolutionary links to ancient lineages and provide information on origins of our biota.

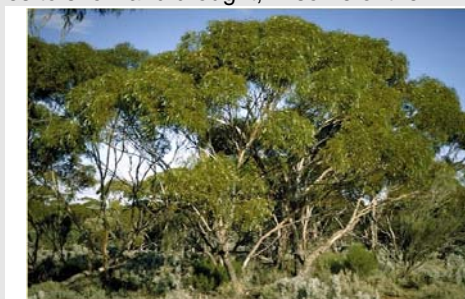
Australia remains one of the world's biodiversity hotspots for new species discoveries - a feature that provides the fundamental fuel for biodiscovery. Recent recognition of Western Australia as home to one of the world's 25 biodiversity hotspots also highlights the fragile nature of the landscapes and species that depend upon them.



Source <http://www.biodiversityhotspots.org/xp/Hotspots/>

Ubiquitous eucalypts and biofuels

With over 850 species of these icons of Australia, eucalypts have evolved features which enable them to tolerate a wide range of environmental conditions from bushfires to snow and drought, in some of the world's poorest soils. Their tough, evergreen leaves, abundance of oils and advanced physiology have enabled species to grow in almost all terrestrial habitats. Forms range from the mallee with multiple stems growing from a swollen basal lignotuber, to the tall forest mountain ash (*Eucalyptus regnans*), the latter giving Australia the record for the tallest tree on earth.



Biofuels are being developed from oil mallee plantations in Western Australia with first oil production from a pilot refinery expected in 2005. These high oil-yielding eucalypts also combat salinisation and soil degradation with their deep, perennial root systems and have potential to benefit rural economies across the nation.

Source: CSIRO

Australia's natural biodiversity is represented at the gene, species and ecosystem level, with each level providing unique opportunities for biodiscovery. Each species has its own particular genetic blueprint that underpins and expresses the adaptive qualities of the species. Since genes are the basic units of life, and Australian organisms represent a unique genetic resource, gene-mining for new and novel traits, from pharmaceuticals to crop development, holds many exciting commercial possibilities.

Firm-footed native grasses

The natural biodiversity of Australia has played a role in all aspects of indigenous life and was pivotal in Australia's economic development. In 1794, John Macarthur, the 'father of the Australian wool industry' depended on the deep rooted perennial native grasses in the 2 million hectares of lowland native grasslands in NSW for establishment of his wool business. Today, Australian scientists are rediscovering Australia's rich native perennial grass biodiversity and working with farmers to establish more sustainable pastures that support year round grazing and reverse or halt salinisation and land degradation.

Salt tolerant genes

Lachnagrostis adamsonii is a rare, highly salt-tolerant native grass being able to survive in levels of salt higher than that of seawater. It was first described in 1853, and then was thought to be extinct until it was discovered 134 years later in 1987. Australian scientists are now examining the genome of *Lachnagrostis adamsonii* to investigate the basis of its salt tolerance, with the aim of applying those findings to enhance salt tolerance in cereals and other crop and pasture plants.

The potential wealth from Australia's marine environment

The marine environment supports over 90% of the globe's phyla. Marine microbial biodiversity (accounting for over 98% of the world's biomass) is vast. The range of metabolites produced by such organisms means that there is an enormous number of compounds available from the existing store of biodiversity. Australia supports a significant proportion of this biodiversity and levels of endemism in Australia are exceptionally high.

Biodiversity – Australia's living wealth

Biodiscovery is dependent on biodiversity

Australia has a well developed economy which includes a burgeoning biotechnology industry, a large agricultural sector, and extensive biomedical, agricultural and environmental research communities. These sectors are clearly reliant on access to biological and genetic resources.

Investment in biodiscovery will increase knowledge of biodiversity. Understanding what biological resources exist, where they are and how they function is crucial knowledge for biodiscovery. It is now clear that nature provides the most diverse source of molecular targets contributing about \$90 billion per year to the global economy.

Nature's deep sleep

Australian biodiscovery research has brought scientists a lot closer to unlocking the mystery of deep dormancy in the world's seeds. Recently, researchers from Kings Park and Botanic Garden, University of Western Australia and Murdoch University discovered a potent chemical in bushfire smoke that has been shown to cause even the mostly deeply dormant seeds to sprout forth.

An artificial version of the chemical could speed up the recovery of damaged vegetation. It could also help farmers to clear weeds from the soil before they sow a crop. Gardeners are also set to benefit. Testing of this remarkable chemical is underway through the agrochemical giant DuPont, The Royal Botanic Gardens Kew and the Millennium Seedbank and via a national link-up of seed researchers from Australia's botanic gardens, herbaria and universities.



Source: Kings Park and Botanic Garden

Germination (right) in response to application of the novel chemical found in bushfire smoke applied at the equivalent rate of 1g per hectare.

Putting a value on biodiversity

There is explicit recognition that economic goods are derived from the diversity of species that exist on earth. Future economic prosperity depends on recognising that biodiversity and ecosystems are living capital.

Agriculture – adapting plants to suit certain widespread and changing conditions has considerable value with transfer of genetic features from wild species accounting for about 50% of annual increases in crop productivity.

Fisheries – Australia's fishing zone is the third largest in the world, and fishing and aquaculture is the fifth most valuable Australian primary industry. Australia's fisheries resources were worth an estimated \$2.41 billion in 2001–02.

Forest goods – products from natural and managed forests include timber, fuel wood, fruits, nuts, mushrooms, honey, other foods and spices, and diverse natural products (e.g. gums and exudates, resins, dyes, waxes, insecticides). These serve as inputs to a wide array of chemical and biochemical industries and contribute about \$90 billion per year globally.

Pharmaceuticals – Substances derived from animals, plants and microbes are used to treat human diseases. Of the 877 small-molecule new chemical entities introduced between 1981 and 2002, roughly half (49%) were derived from natural products. In the US, the commercial value of pharmaceuticals exceeds US\$248 billion annually. Traditional medicinal use of plant extracts is also increasing with over-the-counter plant-based drugs having an estimated market value of US\$84 billion worldwide.

Wollemi Pine may contain anti-cancer agent

The Wollemi pine (*Wollemia nobilis*), Australia's living fossil tree discovered in 1994 near Sydney, is a close relative of the Pacific yew (*Taxus brevifolia*) and may contain taxol-like properties that could one day help in the battle with cancer.

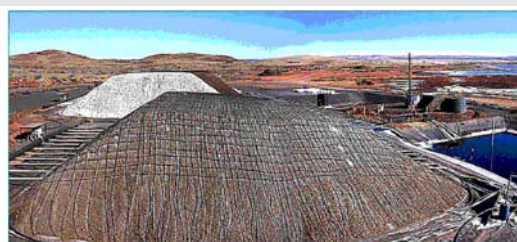
The Pacific yew has been used by humans for thousands of years, for building material and for its healing powers. In the 1960s researchers at the National Cancer Institute demonstrated that a bark extract of Pacific yew showed activity against certain cancer-cell tissue cultures. In the late 1980s and early 1990s the active ingredient, Taxol, was used in association with chemotherapy of ovarian cancer, with significantly promising results.

Medical research tools – research on natural products also enables basic scientific breakthroughs that may not lead directly to a pharmaceutical product, but may nonetheless have profound importance in biomedicine. For example, luciferase enzymes originally isolated from insects and marine organisms are used widely as a tool in biomedical research, drug-screening and hygiene-monitoring. The value of this one class of enzymes is documented to be well over \$100 million per annum.

Manufacturing and environmental applications of biodiscovery – enzymes and other proteins are used extensively for industrial purposes in chemical transformations, food and raw material processing and product formulation. The current market size for industrial enzymes stands at approximately US\$2 billion per annum in the US alone. For example, Australian researchers are screening insects and microbes for enzymes that will process industrial oils and chemical pollutants in the environment.

Bioextraction – mining with microbes

Microbes have the potential to revolutionise the mineral industry and unlock boundless new wealth for Australia. These microbes inhabit the scalding hydrothermal springs around active volcanic sites and dine on ores of copper, gold, lead, zinc, nickel or silver. Bioprocessing is already used in some mineral operations, to concentrate gold or copper, or to purify waste-streams. In the future microbes may be used underground to extract minerals or energy in ways cheaper and cleaner than any existing process.



Source: <http://www.pacificore.com.au>

Indigenous knowledge and traditional knowledge

Extensive knowledge of Australia's ecosystems is held by our indigenous people. Local knowledge generated and held by indigenous communities can contribute significantly to biodiscovery efforts and commercial industries.

Indigenous knowledge

The fundamental insight on which Indigenous knowledge systems are based is that all existence is connected.

Indigenous knowledge systems are dynamic, and are continually influenced by internal creativity and experimentation as well as by contact with external systems. Indigenous knowledge is developed and adapted continuously to changing environments. It is passed from generation to generation and closely interwoven with people's language and cultural values. The knowledge and cultural practices accumulated over time enables indigenous people to live in balance with their environment. To indigenous peoples it is a complete and familiar knowledge system with various traditions and practices that provides foundational pillars to the ways a society can function.

Indigenous knowledge and traditional practices, including the unique ways indigenous people project themselves in the world, have gained much significance over the years regarding the preservation of the Earth's biodiversity and sustainable development approaches. Bio-discovery researchers have a keen interest in indigenous peoples' knowledge and traditions to help expedite the identification of biological resources and examination of biological organisms for commercial development. There is now acceptance that indigenous knowledge and traditions together with commercial enterprises can assist Australia to compete with the rapid advances being made in other countries.

It is well recognised by the UN that 80% of the world's population depends on indigenous knowledge to meet their medicinal needs, and at least half rely on indigenous knowledge of crops for food supplies. Indigenous knowledge has helped fuel innovation and development in multi-billion dollar industries, ranging from agriculture and pharmaceuticals to chemicals, paper products, energy and others. In 1995, with traditional knowledge-based products, such as handicrafts, medicinal plants, agricultural products and non-wood forest products (NWFPs), the estimated total trade in NWFPs was about US\$11 billion.

Traditional knowledge

Traditional knowledge has been defined as the "cumulative body of knowledge, know-how, innovations, practices and representations maintained and developed by peoples with long histories of interaction with the natural environment." It represents broader practical knowledge and is an attribute of societies with historical continuity in resource use practices.

Aboriginal experience led to Australian drug innovation in World War II

Australian aborigines knew of the paralysing action of leaves from the corkwood tree (*Duboisia myoporoides*). Hyoscine and hyoscyamine are drugs extracted from the plant *Duboisia* which later became key drug ingredients in World War II.

Australia alone supplied the Allies with atropine and hyoscine in 1944 for prevention of seasickness among troops during landings on D day.

Duboisia myoporoides



Source: http://www.anbg.gov.au/images/photo_cd/732131822186/097.html

Scientific capabilities

Australia's scientific capabilities have been exemplary over a long period, and in particular the past 50 years. Australia continues to punch above its weight in science and technology, producing 2.9% of the world's science and ranking 8th in the world in the number of research publications per capita. Our greatest research publication outputs are from medical and health

sciences (which account for approximately one-third of papers published) and the biological sciences (approximately one-fifth of publications).

Australia has excellent health infrastructure to support our innovative science-based industries and was ranked 9th in the world for the quality of its scientific research institutions by the 2004 World Economic Forum. Our present challenge is to translate this high world standing into internationally competitive industrial niches in Australia.

This international standing is well evident in medical research. Among Australia's Nobel Laureates are five who were born and educated in Australia and performed in this country the work for which they were awarded the Nobel Prize for Physiology or Medicine; Sir Frank Macfarlane Burnett (1960), John Eccles (1963), Peter Doherty (1996), Barry Marshall and Robin Warren (2005).

The WHO Smallpox Eradication Team lead by Frank Fenner (John Curtin School of Medical Research) freed the world from this devastating disease. The Program removed smallpox that threatened 60% of the world's population, killed every 4th victim and scarred or blinded most survivors.

Over 3.5 million patients have been treated with the Colony-Stimulating Factors (CSFs) discovered by Don Metcalf and his colleagues at the Walter and Eliza Hall Institute of Medical Research. These naturally occurring proteins accelerate white blood cell regeneration in patients treated for cancer. The strength of Australian medical research continues to grow with the development of neuraminidase inhibitors for influenza infections by Peter Colman, Graham Laver and Mark von Itzstein that will be used against the threat of avian influenza and the recent development by a team led by Ian Frazer of the cervical cancer vaccine that could protect millions of women.

Australian biodiscovery and biotechnology are benefiting from the extensive past investment in the biological sciences, and particularly from Australia's research in the medical, agricultural and environmental sectors over the past 50 years. This has placed us in an advantageous position to carry out the search for potentially useful biologically active molecules and isolating and describing new chemical structures.

To capitalise on Australia's rich biodiversity resources accurate taxonomic information is required. We are facing a major skills shortage, with a decline in Australia's taxonomic capacity, impeding the delivery of required services. While much of Australia's biodiversity is still unknown or not fully documented, our taxonomic capacity is diminishing. Our taxonomists are aging and are not being replaced. Australia requires investment in education, training and mentoring of a new generation of taxonomists whilst the opportunity still exists to secure the value of previous investment in this important area

Commercialisation capabilities

Australia has a burgeoning biotechnology industry with over 400 companies adding to its otherwise broad industrial base. The biotech companies generally operate in the human health, medical devices and agriculture sectors and traditionally lift intellectual property up from universities and dedicated research organisations. The range and detail of industry-support for commercialisation through Government programs (eg *Commercial Ready*, COMET, Pharmaceutical Partnership Program (P3), Biotechnology Innovation Fund, Innovation Investment Funds etc) is warmly recognised and considered beyond the scope of this report.

In biodiscovery, Australia has many advantages, including its natural biodiversity, the quality of biomedical research, a robust and transparent legal framework and a strong business

community. However, there can be no question that successfully commercialising discoveries and inventions is more challenging from Australia than from within the major markets. The reasons for this include the small size of Australia's market, the fact that none of the major capital funds are scarce. Australian research institutes and life science companies operate in global markets that compete for resources, capital and customers.

The last decade has seen a growth in the commercial skills and experience in the Australian community. Nevertheless, early steps in biodiscovery, such as collecting, identifying, screening and separation, for which we clearly have the skills, do not constitute a self-sustaining business in Australia and therefore needs to be better supported from public funds if Australian companies are to commercialise the outcomes.

Australian researchers and companies have been searching for active molecules for some time, and more recently researchers have successfully advanced a diverse range of biodiscovery products into major international markets in cancer, pain, infectious diseases and eyesight loss:

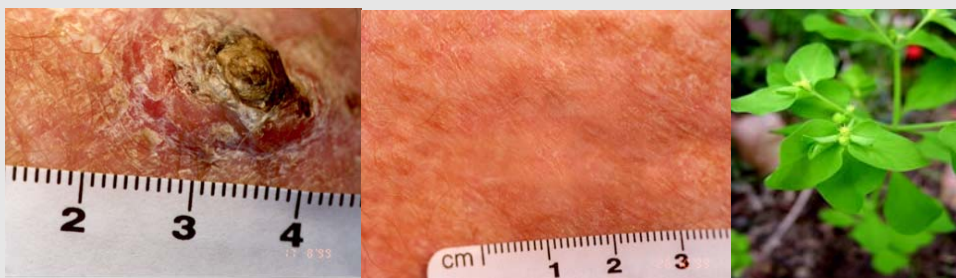
- Xenome Pty Ltd's XEN2014 is a synthetic drug modelled on a peptide isolated from the venom of a Great Barrier Reef cone shell, and is in clinical development for managing severe protracted pain;
- Peplin Ltd has a drug in mid-stage clinical development - a topical gel to treat Australia's most costly cancer indication – non-melanoma skin cancer. This drug, PEP005, is a diterpene isolated in Brisbane from the sap of the *Euphorbia peplus* weed. European clinical trials are also planned for this drug in leukaemia treatment during 2006;



Prospect for skin cancer cure from local plant

Non-melanoma skin cancer is the most common cancer in Australia, and is the most costly cancer burden (>\$AU300m). In the US, costs exceed US\$1Bn annually, and are rising.

A biodiscovery research team at Peplin Ltd in Brisbane isolated and identified the active molecule (PEP005) from the sap of the non-indigenous weed, petty spurge (*Euphorbia peplus*). Development through QIMR, NCI and University of Birmingham now provides the prospect of a new drug for this costly malignancy. Early clinical studies indicate that PEP005 can resolve pre-cancerous skin lesions and the most common forms of non-melanoma skin cancer with one or two daily applications of this compound. European clinical trials using PEP005 against a particularly deadly form of leukaemia, are also planned for 2006.



Before treatment

90 days after '3 day treatment'

Petty spurge (*E. peplus*)

Source: Peplin Limited

- Cerylid Biosciences Ltd of Melbourne is developing its anti-cancer drug CBL316 (isolated from the bark of a Malaysian tree) to treat cancers which are resistant to current treatments;
- Eqitx Ltd is developing a drug for reducing severe pain, based on a molecule isolated from the ginger plant *Zingiber officinale*;
- Small synthetic peptide drugs originally isolated from mammalian organs are under development by BioDiem Ltd of Melbourne (for macular degeneration), Implicit

Bioscience Pty Ltd of Brisbane (for influenza, golden staph infection and cancer) and Metabolic Pharmaceuticals Ltd of Melbourne (for obesity); and

- Solbec Pharmaceuticals Ltd of Perth is developing an anti-cancer treatment based on an extract from *Solanum sodomaeum* (the Devil's apple plant).

While this track record is impressive, and together represents about \$100 million of investment and strong progress through the clinic in at least two cases, it is interesting to note that *only one* of the species from which these discoveries arise is from an indigenous source (Xenome's pain drug from cone shells). Many commercial groups engaged in biodiscovery or commercialisation of natural products have found that the limitations, costs and delays associated with biodiscovery within Australia are not supportable by their business models and narrow capital bases.

The few examples of Australian biotechnology companies or institutes which have made the significant investment required for collecting, screening and maintaining biodiscovery collections including Australian biota have had no notable commercial success of major products on the market. This is due in part to the difficulty of combining in a single business model the demanding skill sets of biodiscovery with product development, and the lack of legal provenance for Australian biota. To date, Queensland is the only Australian state to provide a legal framework, providing explicit evidence of provenance of material collected within its jurisdiction (see Appendix).

The agricultural and environmental science sectors also stand to benefit from the development of products arising from biodiscovery research. In some cases this involves identification of favourable genes for crop or pasture enhancement (see Page 12), while in others recognition of favourable microbial activity may contribute to sustainable farming practices.

Rhizobia in revegetation programs

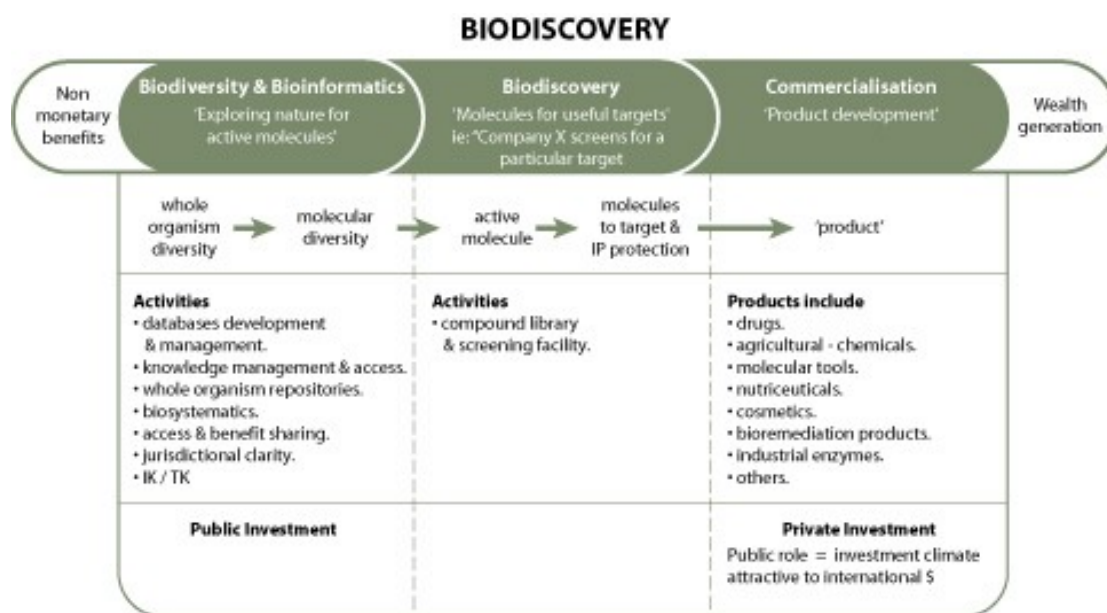
Native vegetation loss occurs. Australia now recognizes the need to rehabilitate many of the areas where native vegetation has been lost. There is a recognized need to strategically replant many areas with native vegetation to restore biodiversity and especially to help combat salinity, which costs Australia \$270 million every year. A key issue for large-scale restoration is the need to increase cost-effectiveness of revegetation practices. In Victoria alone, combined revegetation works planned up to 2025 exceeds 1,000,000 ha and will cost \$600 million.

It is now known that growing wattles with a naturally occurring soil bacterium *Bradyrhizobium* improves their rates of establishment, growth and survival. *Bradyrhizobium* plays a role of helping the wattle 'fix' nitrogen - so that it can take atmospheric nitrogen and turn it into available nitrogen in the soil, which acts as a fertiliser. Increased nitrogen inputs to the soil also benefit other plants.

A joint venture between CSIRO and Bio-Care Technology Pty Ltd has commercialised **Wattle Grow™ Granular Inoculant**. Inoculation of seed of native leguminous species with certain *Bradyrhizobium* strains has led to establishment rates 2 to 5 times better than untreated seed. It has the potential to cut the cost of large-scale revegetation by up to 50%. *Source: CSIRO*

Chapter 3 – Capturing opportunities

Australia has an enormous opportunity to build its scientific, economic and cultural capabilities through embracing biodiversity and biodiscovery as key features for future activity and wealth creation. Biodiscovery has the potential to alter practices and processes in a wide range of industries and community activities adding significant benefit to environmental management, agriculture, medicines and health, mining, fisheries and forest products. Critically, benefit to Australia from biodiscovery depends on maintaining our biodiversity.



2010 biodiversity target

Under the Convention on Biodiversity (CBD) Strategic Plan, Parties to the Convention committed themselves to achieve a significant reduction in the current rate of biodiversity loss at the global, regional and national level by 2010.

The 2010 Biodiversity Target will provide a critical impetus and national focus for Australia to develop its targets, and implement its programs to address Australia's biodiverse resources and their maintenance for future generations.

The National Strategy for the Conservation of Australia's Biological Diversity is to be revised in 2006/07. This strategy is the national implementation mechanism of the CBD and includes articles relevant to biodiscovery, such as access to genetic resources, improving taxonomic skills, indigenous knowledge and technology transfer.

Opportunity: Enhanced national agenda for managing impacts on biodiversity aimed at cutting the current rate of biodiversity loss with alignment to the CBD Strategic Plan

New approaches to biodiversity knowledge and acquisitions

Australia's mega-diverse domain covers a vast continent and attendant marine environment, much of which is undocumented and barely studied. Biodiversity is also constantly changing with the environment under continued climatic influence. This provides an opportunity while requiring our knowledge to be constantly refreshed. Developing Australia's scientific

capabilities and capacity in the fields of taxonomy¹, knowledge acquisition and utilisation will have substantial short and long term benefits. Initiatives in this area would strive to upgrade skills and technology having direct benefits to important issues such as biodiscovery and biosecurity.

Novel approaches to taxonomy and rapid delivery of biodiversity information

New technologies have emerged recently that alter the approaches to taxonomy. Through the development of genomics, new methods have potential to enable identification of all individual species on the planet. This amazing development, the “*Barcode of Life*”² brings cutting edge taxonomy to bear on a multitude of interests and benefits. For example, the economic impact of incorrect identification of insurgent pests could be substantial. Recently, the outbreak of the Red Imported Fire Ant could have been curtailed much earlier if the *Barcode of Life* had been enabled in Australia.

The Consortium for the *Barcode of Life* (CBOL) is an international collaboration of natural history museums, herbaria, biological repositories, and biodiversity inventory sites, together with academic and commercial experts in genomics, taxonomy, electronics, and computer science. The mission of CBOL is to rapidly compile DNA barcodes of known and newly discovered animal and plant species, establish a public library of sequences linked to named specimens, and promote development of portable devices for DNA bar-coding.

A standardized approach to identifying animals and plants by minimal sequences of DNA with public access to the information generated will allow many people to quickly and cheaply recognize known species and retrieve information about them, and will speed discovery of the millions of species yet to be named. Bar-coding will provide vital new tools for appreciating and managing Australia’s immense and changing biodiversity; Australian researchers have this year published the first ever barcode for a fish species.

New information systems can also transform traditional approaches to taxonomy. Remote real-time identification systems and web-based taxonomy approaches will help implement a new paradigm in taxonomic research ensuring rapid electronic delivery of all components of biodiversity information. Web-based initiatives of the Australian Biological Resources Study (ABRS) (<http://www.deh.gov.au/biodiversity/abrs/index.html>) should be supported and expanded. The ABRS research grants scheme drives documentation of Australia’s biodiversity with a rigorous approach to taxonomy, among other priorities.

It is anticipated that enhanced taxonomy and biodiversity information will increase the speed and certainty with which important commercial opportunities will be uncovered while adding to ‘real-time’ information exchanges.

Opportunity: New genomic approaches through the *Barcode of Life*, together with web-based taxonomy and real-time identification systems, should be implemented to drive the documentation of the nation’s biota facilitating biodiscovery and biosecurity.

Indigenous knowledge acquisition and management

For a long time, social scientists of all disciplines have attempted to document traditional knowledge of the Australian indigenous people. Much of this cumulative knowledge is housed in the Australian Institute of Aboriginal and Torres Strait Islander Studies but vast

¹ Taxonomy - the science of classifying plants, animals, and microorganisms into categories based on shared features, including genetics.

² The *Barcode of Life* project (www.barcodinglife.org) uses short DNA sequences that enable discrimination of species. Over 35,000 barcode sequences have been compiled representing 13,000 individual species.

amounts are also stored and preserved in museums, archives, libraries, universities and private collections across the country and internationally.

Current research work confirms much is still being done to identify indigenous knowledge systems. Indigenous people also, through the development of cultural centres and knowledge centres, are engaging in the documentation of their own knowledge. Collectively, they can offer a wealth of knowledge on the natural resources, ecosystems, and sustained use of the nation's biota. There is a lack of any significant network between the collections, the many locations of knowledge materials, the various discipline-based classification, storage and retrieval systems, the current research and documenting activities.

Opportunity: Better understanding of indigenous and traditional knowledge through systematic approach to gathering information, including through indigenous capacity building, so that it is available for current and future generations including for biodiversity management and biodiscovery.

Network of National Collections

Biodiscovery benefits from many inputs of material and knowledge. Numerous collections of materials have been made over a long period of time and by a wide range of national and state authorities and organisations, including national and state museums, herbaria, departments of agriculture, conservation agencies, CSIRO, and universities.

Collections both as living (botanic gardens), nascent (seed banks, microbes), components (DNA banks, chemical extracts) and preserved collections (plants in herbaria and zoological specimens in museums) represent a critically important resource for biodiscovery. In addition, actual specimens in their natural environment can now be re-sampled through the application of GIS, thus giving rise to the concept of a living bio-repository throughout Australia. These collections (often in separate repositories) represent a vital source of material and knowledge that can advance biodiscovery. The Australia's Virtual Herbarium, as an on-line botanical information resource accessible via the web, provides immediate access to the wealth of data associated with the six million scientific plant specimens in Australia's herbaria. See: www.chah.gov.au/avh.html

Biological collections are also costly to maintain, particularly for small companies which must have flexibility of capital. The establishment and maintenance of interlinked national biological collections and libraries would allow streamlined searching, acquisition, and data compilation essential for maximising the benefits from the bioresources. These linked systems would modernise the management and maintenance of such national databases for the national good while allowing an access system for companies, organisations and individuals, to undertake deeper and more productive levels of inquiry for biodiscovery. There is a pressing need to unite these disparate collections and the associated data using compatible platforms.

Development of an interlinked set of biological collections should be supported by a centralised fund allowing an access system for investigators. For example, the Natural Products Branch of the US National Cancer Institute (NIH) operates an open repository system where the extramural community has access to many hundreds of thousands of samples (see <http://dtp.nci.nih.gov/branches/npb/index.html>).

Opportunity: Better understanding of biodiversity and the impact of the changing environment through a national approach to biological collections and their study.

Bringing modern information systems to accelerate knowledge acquisition and appreciation has the potential to elevate endeavours on biodiscovery. One approach is to link the

collections of information and materials into a stimulating format that will inspire new investigations of Australia's mega-diverse biota.

Opportunity: Create an *Atlas of Living Australia* with a “biodiversity google” approach through a national platform of important static and living collections linked with the natural bio-repository to manage the nation's dynamic bioresources and enable their investigation for wealth creation and conservation.

Australia – Part of the World Seed Bank Strategy

The Millennium Seed Bank Project aims to conserve 10% of the world's plant species in multi-sited seed banks around the world by 2010. The project will invest nearly \$5 million in coordinating a national seed bank strategy for Australia to protect nearly 20% of the Australian flora. For the first time, all Australian states have joined in the strategy and are coordinating collections and research programs in seed conservation science.

Sustaining and enhancing these collections beyond 2010 will be critical if Australia is to stem the tide of plant extinctions, among the highest per capita of any country on earth. These collections form a critical component of a national biodiscovery strategy by providing the raw material for pharmaceutical and agricultural and biotechnological research.

Biodiscovery – unlocking the wealth of our bioresources

Biological collections underpin the knowledge of biodiversity: biodiscovery arises from the ability to link and interrogate collections for specific purposes. Wealth can be created by Australia using its enormous scientific excellence to match compounds, extracts and organisms to perform specific tasks and derive economic advantage. A well organised efficient system of national collections will be a major advantage in the future.

National compound library

A key ingredient in biodiscovery is the capability to systematically analyse compounds and extracts from natural plants and marine organisms. Combining current and future compounds into a “centrally-managed” facility will increase the efficiency with which this searching can be performed.

Three key recent technological advances have driven the creation of compound libraries, and assaying via high through-put screening. First, the successful completion of the Human Genome Project has provided an enormous cache of human biology to be studied and potential drug targets to be discovered. Second, developments in chemistry have given researchers the ability to isolate and synthesise large numbers of related compounds. Third, advances in robotic technology and informatics now allow scientists to screen hundreds of thousands of compounds in a single day, many orders of magnitude greater than was available less than a decade ago.

The establishment of a national compound library has the capacity to enhance the commercial development of the nation's bioresources. This initiative will allow compounds to be deposited into a centrally-managed repository and Australian scientists (public and private sectors) to gain important opportunities. These natural (and non-natural) compounds will be maintained in a manner to ensure long-lasting applicability through quality surveillance.

National screening network

Internationally competitive biodiscovery research undertaken in Australia can be enhanced by ensuring that collections, biological and clinical capability is brought together into a national screening network. Linked together, a network of excellence will provide focus and efficiencies of scale and a real competitive advantage for Australia. Identification and development of compounds derived from Australia's rich endemic biodiversity will engage industrial and academic investigations adding greater value and stronger intellectual property.

Opportunity: Advance biodiscovery in both the private and public sector through the establishment of a national compound library and screening network that captures value and efficiency from Australia's proven asset of endemic biodiversity.

Capability and capacity building

Biodiversity knowledge and certain biodiscovery skills are limited in Australia. Whereas some groups such as marine algae, corals, terrestrial vascular plants, and mammals are comparatively well known, the major biota groups including fungi, insects and microorganisms (terrestrial and marine) require significant investment to resolve their national status. Current predictions for even familiar groups such as flowering plants estimate that a quarter of species are yet to be described. It is not an exaggeration to say that this is a significant bottleneck to biodiscovery with instances coming to light where biodiscovery collections have had to be abandoned because of the absence of appropriate taxonomic skills.

There is an urgent need to build the attractiveness of careers in biodiscovery and to train scientists to utilise modern technologies, *viz* genomics, proteomics, bioinformatics, as well as historical standards to support the interest in biodiversity and biodiscovery. Importantly, collecting and maintaining traditional knowledge through building indigenous capacity should be a priority.

Opportunity: Enhance the national agenda for training and career development in key areas of the modern technologies including informatics, taxonomy, and traditional knowledge.

Borderless biodiscovery demands a national approach

The absence of consistent legislative frameworks across Australia for access and use of the genetic and biochemical makeup of our native biodiversity creates legal uncertainty. Where the burden of uncertainty, over-regulation and high transaction costs impact directly on the resources of parties willing to participate in biodiscovery, the process is slowed or stopped and competitive advantage lost. Legal uncertainty arises from the intersection of Commonwealth and State Laws including jurisdictional and territorial accommodations (see Appendix).

The current approach by the Commonwealth is to work with State and Territory governments to develop a nationally consistent approach to biodiscovery. An important first step was signing the National Strategy for the Conservation of Australia's Biological Diversity (1996) by the heads of all Australian Governments. This broad agreement contains a commitment to biodiscovery in accordance with the terms of the Convention on Biological Diversity (CBD). Key elements of biodiscovery were subsequently integrated in the Commonwealth's 2000 National Biotechnology Strategy.

The successful April 2002 passage of CBD Bonn Guidelines (i.e. world's best practice for nation states on genetic resources management or biodiscovery) paved the way for the 2002 development and adoption of Australia's *Nationally Consistent Approach For Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources* (NCA).

The NCA is an intergovernmental agreement to introduce legal certainty for biodiscovery collection, research and development. Its goal is "to position Australia to obtain the maximum economic, social and environmental benefits from the ecologically sustainable use of its genetic and biochemical resources whilst protecting our biodiversity and natural capital". The NCA was endorsed on 11 October 2002 by the Natural Resource Management Ministerial Council. There is an urgent need to progress the NCA and provide a solid framework to achieve the goals established in 2002.

State and Territory action

Following the signing of the NCA agreement in October 2002, Queensland developed its own legislation (Biodiscovery Act 2004) which was brought into operation on 15 November 2004.

The Queensland Biodiscovery Act 2004

The main purposes of this Act are to facilitate access to small quantities of native biological resources on or in Queensland State land or water; to encourage the development of value-added biodiscovery in Queensland; to ensure that the State obtains a fair and equitable share in the benefits of biodiscovery; and to ensure biodiscovery adds to knowledge of Queensland's biodiversity, conservation and sustainable use of native biological resources.

The Act establishes a regulatory framework for taking and using biological resources, a contractual framework for benefit-sharing agreements, a compliance code and collection protocols, and monitoring and enforcement provisions.

The Commonwealth's access to genetic resources regulations is expected to be signed into law shortly. Western Australia, Northern Territory, South Australia, and Tasmania are making progress on their legislation while New South Wales and Victoria are lagging behind significantly.

While some progress has been made in Australia, over 100 countries are in the process of introducing their own implementation of the Bonn Guidelines. For Australia to attract the investment to support its biotechnology industry in biodiscovery it needs to accelerate the introduction of legislation for legal certainty. Delay will see Australia losing investment to other jurisdictions.

Opportunity: Provide a seamless and consistent legislative framework through the NCA allowing Australia's biological resources to be investigated with confidence that all stakeholders are engaged.

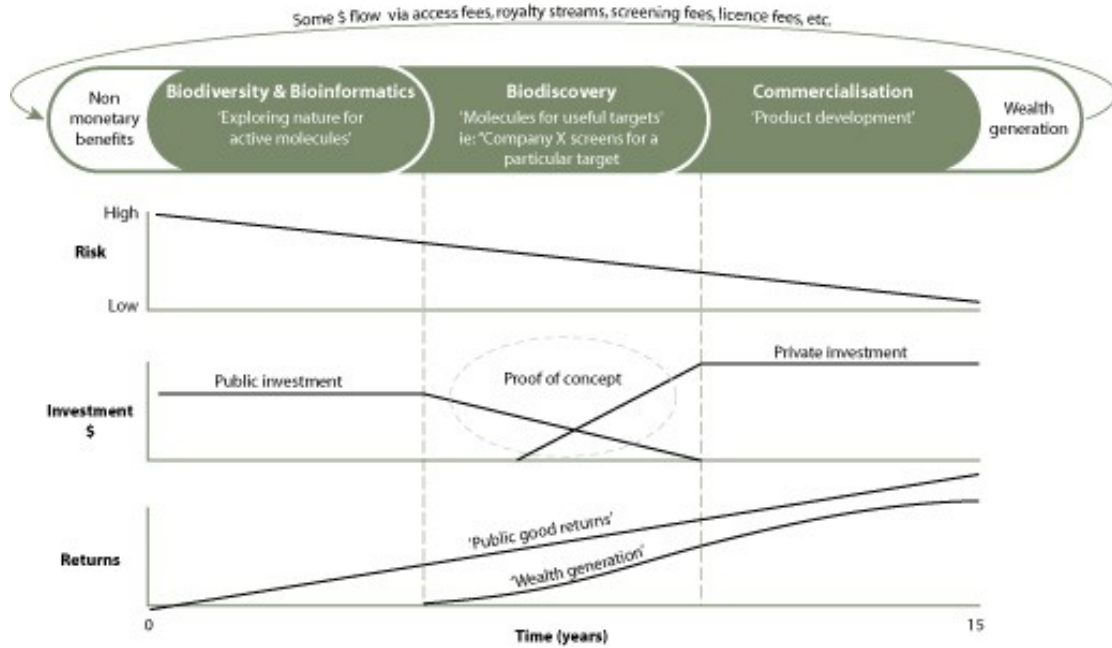
Biodiscovery investment – seizing the opportunities

Biodiscovery has significant future benefits for the Australian economy especially considering the vast array of diverse biota. However, there are also risks in the program of commercialisation.

Increasingly, major producers of high value end products, including pharmaceutical companies, quantify the risk in the investment before taking on the project. Presently, companies evaluate their investments on the project by the potency of the “proof-of-concept” developed by the inventor.

Generally the inventor is in the public sector thereby creating a “gap” between the level of confidence in the project required by the next investor in the chain and the resources available in the discovery process. To bridge this gap, the extent of “public investment” will need to rise in order to meet the requirements of the “private investor”.

BIODISCOVERY



Importantly, the level of return to Australia from biodecovery is predicted to be substantial. This will be manifested through national capability and capacity, infrastructure, employment, knowledge of the biota, conservation initiatives, documenting traditional knowledge, community engagement as well as direct financial returns, such as milestone payments, royalties, licence fees, shares and equities.

To gain future investment in risk-dependent biodecovery projects, the risk must be reduced to a level necessary to facilitate investment. Three key issues are required to be addressed:

- access and benefit-sharing arrangements to be facilitated;
- legal certainty to be realised; and
- minimised transaction costs to the parties.

These are industry-specific matters. The general climate for investment in Australia is healthy, although technology investments are currently drifting in comparison to global trends in commodities, finance and infrastructure sectors. For Australia to realise its potential, more investment is required and this may come from superannuation funds, given appropriate encouragement.

Opportunity: Enhance wealth creation from biodecovery through public sector investment to bridge the gap to private sector engagement and address impediments to investment, including access to longer term investment profiles.

Chapter 4 - Action plan

The Working Group has identified recommendations that derive from two key needs for biodiscovery in Australia. These key needs are:

- to manage our existing biodiversity knowledge and acquisitions – to identify, describe, understand, conserve and protect the species of our continent; and
- to create certainty about the commercialisation of biodiscovery with improved conditions for investment, benefit sharing and capacity building.

The recommendations are:

National Biodiversity – expanding our understanding

Recommendation 1: Develop an **Atlas of Living Australia** (or “Biodiversity Google”) based on a real time identification and web-based taxonomy system, incorporating Australian engagement in the International *Barcode of Life* Program and linked to a National Network of Collections.

Coordinating existing knowledge relating to biodiversity (e.g. taxonomic, geographic, ecosystem and indigenous knowledge) through mechanisms such as National Networked Databases will allow easier access and utilisation of information. This will allow us to effectively benefit from our existing biodiversity and knowledge.

Develop and expand web-based taxonomic approaches

This recommendation aims to document Australia’s natural heritage while at the same time enhancing our capability in taxonomy by rapid identification and web-based publishing of taxonomic, geographic and ecological information, using dynamic biodiversity informatics technology.

Rapid attack is necessary to address the large number of undescribed species many of which have been collected and are already known. Since the infrastructure already exists, it is recommended that this be implemented via specific additional funding to the Australian Biological Resources Study (ABRS). A key management feature will be dedicated, performance-linked, time-critical funding where taxonomic output is tracked and targeted through identification of lead taxonomic nodes across Australia.

This recommendation will address skills shortages in taxonomy by focusing on training the next generation of biological and nomenclatural specialists.

Link to the ‘Barcode of Life’

This recommendation will facilitate a global approach to identification of all species on the planet through genetic signatures. Enabling the *Barcode of Life* in Australia will provide stimulus for rapid, accurate and timely description of endemic species. The *Barcode of Life* will assist the description of invader species that threaten biosecurity.

Establish a national biodiscovery web resource – Atlas of Living Australia (“biodiversity google”)

This recommendation will provide the means to maximise sustainable use of our existing biodiversity knowledge. New information systems will transform traditional approaches to

taxonomy, inspire a new cadre of scientists and interested parties, and underpin unlocking the value inherent in Australia's living national treasure – its unique biota. Remote real-time identification systems and web-based taxonomy approaches will help implement a new paradigm in taxonomic research.

We envisage unlocking the land and sea's knowledge presented in a unique *Atlas of Living Australia* in a "biodiversity google" format with information-dense systems enabling information sharing across many key parameters. This key initiative will unite disparate information sources and link to the national collections. The *Atlas* will contribute taxonomic information to international biodiversity systems such as the Global Biodiversity Information Facility (GBIF) just as specimen-based information is currently provided from Australia.

Promote capacity building in indigenous communities

This recommendation seeks to add value to the ethnobiological knowledge of the land and sea established over thousands of years by the indigenous people. We seek to recognise traditional knowledge and generate benefit for indigenous communities through engagement and support.

Biodiscovery – unlocking the knowledge

Recommendation 2: Establish a **National Screening Network**, incorporating a compound library facility and Australia's National Collections including Centres of indigenous and traditional knowledge.

Link National Collections promoting shared knowledge and access

Coordinating existing physical collections of biodiversity (eg seed banks, extracts of biota, compound collections and traditional knowledge) through mechanisms such as National Repositories and Libraries will allow easier access and utilisation of samples. This will permit us to effectively benefit from our existing biodiversity and knowledge.

Biodiscovery is intended to establish a long-term commercial and social gain to Australia from its outstanding unique biodiversity – a resource that offers much and has been neglected for much of the last two hundred years by the carers of the land.

Biological collections have proven costly to maintain, particularly for small companies and public funded organisations. The current business model is for SMEs to investigate biological activity of compounds and material in a cost-effective manner. They must have flexibility of capital in order to maximise their potential and increase shareholder wealth, which generally means not establishing costly independent collections of material for screening. Therefore, development of an electronically interlinked set of biological/compound collections supported by a centralised fund should allow an access system for all investigators, both private and public.

Establish a national biodiscovery compound library and screening network

A major goal for biodiscovery is for compounds derived from endemic biodiversity to have added value so that translational medical research, industrial applications or academic investigations may be prosecuted. The vision to achieve this involves a streamlined process that utilises state-of-the-art technology to curate, collate and screen extracts/pure compounds. A network of screening capabilities is proposed and can be expected to facilitate wealth creation across a broad range of industrial applications engaging both the chemical and biological research communities in biodiscovery. Commercial organisations will link along

the value-chain of discovery and development and play a key role in commercialising the outcomes.

Identify, coordinate and sustain national organism collections (including national seed banks, tissue banks, microorganisms, DNA banks).

Biodiscovery will be significantly enabled by the establishment and maintenance of National Organism Collections.

National Seed Bank Cluster: to sustain and enhance the existing Millennium Seed Bank national framework that links all Australian states in long-term (>500 year storage) seed banking of Australia's plant biodiversity. Continued guaranteed resourcing for a single national strategy will provide excellent returns for biodiscovery, including farming and agricultural breeding and development programs, and mine site restoration, while protecting the nation's biodiversity for future generations.

National Microbe Bank Cluster: provide protection and support for Australia's existing microbial banks that include fungal and bacterial collections. These collections will need to be linked across a number of organisations and a national framework agreed.

National Biota DNA Bank Cluster: collect, coordinate and resource a national strategy for DNA banking of the Australian biota. Significant and growing collections in DNA banks are emerging in Australia as a result of the molecular revolution and many of these specialise in Australian biota.

Identify, enhance, coordinate and sustain sources, collections and centres of indigenous knowledge and traditional knowledge and link this to the national biodiscovery web resource.

A national repository is recommended to ensure the capability to preserve and gain value from indigenous knowledge. Input to this repository from indigenous communities would only be undertaken with the approval and involvement of the holders of the knowledge. Consequent use or application of the knowledge would be undertaken in accordance with terms under which the knowledge was deposited. Where indigenous knowledge is already in the public realm or where the circumstances of its origin are now uncertain then arrangements should be made, with guidance from indigenous people, so that a share in any benefits derived from its use flows back to indigenous communities.

There exists no single process to link across Australia the different collections of documented materials on Australian indigenous knowledge gathered over the past century, which means only a limited access can be achieved, even for indigenous Australians, to knowledge accumulated over thousands of years.

The development of a virtual network between the range of information sources on indigenous and traditional knowledge is to provide a means:

- to identify the nation's indigenous knowledge resources, their source and the communities they belong to;
- to encourage classification and documentation standards that can be migrated across systems and platforms;
- to promote best practice in biodiscovery which complies with legislative requirements and processes, in engagements with indigenous communities that benefit all; and
- to facilitate national benefit to accrue from the commercialisation of outcomes of biodiscovery enabled by indigenous knowledge.

Commercialisation – seizing the opportunities

Recommendation 3: Achieve **National Harmonisation** of access and benefit-sharing legislative frameworks, to provide legal certainty for biodiscovery and ensuring swift access (lower cost transactions) for commercialisation.

Provide legal certainty for biodiscovery

Achieving commercialisation of biodiscovery is often a long process requiring significant investment from a multitude of sources. To increase the probability of success, investors pay particular attention to any impediments (as well as the market potential) in the acquisition process.

Of particular importance are:

- access and benefit-sharing arrangements in place and in accordance with international conventions and Australian domestic law;
- legal certainty to be realised; and
- minimised transaction costs.

It is recommended that the Commonwealth provide additional incentives to achieve harmonious, consistent, streamlined legislative frameworks across the States and Territories that would remove impediments for biodiscovery.

The creation of certainty of provenance for biodiscovery by ensuring appropriate benefit-sharing agreements are in place will guarantee certainty for commercial operations, increase the potential for investment and reduce the number of opportunities lost.

With these recommendations enacted, all of Australia can rightfully look forward to significant wealth creation derived from its abundant natural resources.

Appendix

Summary and comment on the relevant policy, acts, laws and regulations relevant to Australian biodiscovery

International

Convention on Biological Diversity (CBD)

The 1993 Convention on Biological Diversity (CBD) gives nations sovereignty over their natural resources including genetic resources. The CBD has three primary objectives: the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising from the use of genetic resources. Australia ratified the Convention on Biological Diversity in 1993.

In April 2002 the Conference of the Parties to the CBD adopted guidelines on access to genetic resources and the fair and equitable sharing of the benefits from their utilization (the Bonn Guidelines). These are world's best practice for national legislation.

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The TRIPS Agreement (TRIPS) is part of the World Trade Organization agreement that was signed in Marrakech in April 1994. TRIPS contains minimum standards concerning availability, scope, use and enforcement of intellectual property rights.

TRIPS does not have a direct impact upon biodiscovery law and policy in Australia, it is however relevant in terms of the possible amendments to patent law and plant breeders rights law (particularly in relation to the possibility of introducing a requirement of disclosure of geographic origin or prior informed consent).

National

Australia's Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources (NCA)

On 11 October 2002 the Commonwealth, state and territory Natural Resource Management Ministerial Council endorsed the *Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources (NCA)*. The NCA makes governments' adoption and application of the Bonn Guidelines explicit and sets out general principles for the development or review of legislative, administrative or policy frameworks for access to biological resources in each jurisdiction.

The overarching aim of the NCA is to position Australia to obtain the maximum economic, social and environmental benefits from the ecologically sustainable use of its genetic and biochemical resources whilst protecting our biodiversity and natural capital.

A harmonised regulatory framework under the NCA would:

- enable the fair and equitable sharing of benefits from the use of Australia's genetic and biochemical resources;
- ensure the use of indigenous knowledge is undertaken with the cooperation and approval of the holders of that knowledge and on mutually agreed terms;
- enhance biodiversity conservation and valuing of biodiversity by enabling some of the benefits obtained are used for biodiversity conservation in the area from which the resources were taken; and

- ensure all applicants for access to resources are treated fairly and without prejudice, with all applications judged against transparent criteria and according to law.

The full text of the NCA is at: www.deh.gov.au/biodiversity/science/access/index.html

The *Environment Protection and Biodiversity Conservation Act 1999* and Regulations (Cth)

The *Environment Protection and Biodiversity Conservation Act 1999* (EPBC Act) streamlines national environmental assessment and approvals processes, protects Australian biodiversity and integrates management of important natural and cultural places.

Section 301 of the EPBC Act also provides a regulation-making power to control access to biological resources in Commonwealth areas including:

- equitable sharing of benefits from their use;
- access facilitation;
- right to deny access; and
- terms and conditions under which access is granted.

Amendments to *Environment Protection and Biodiversity Conservation Regulations 2000* (EPBC Regulations) to control access to and utilisation of the genetic resources of native species in Commonwealth areas are expected to be signed into law shortly. They introduce a new Part to the EPBC Regulations and amend the existing permitting provisions in the regulations.

The regulations are aimed at safeguarding the environment, promoting sustainable use of biological resources and providing legal certainty to industry and to researchers. The amendments also introduce simplified arrangements for non-commercial research while safeguarding the Commonwealth's interest. The amendments protect and value indigenous knowledge and are consistent with the Native Title Act 1993.

The Australian Constitution

The Australian Constitution is relevant to biodiscovery because it defines the relationships between the Commonwealth and the States. Generally, States and Territories have authority over their natural resources, however Commonwealth or State/Territory jurisdiction is sometimes unclear.

The Constitution contains an External Affairs Power (section 51 (29)) which enables the Commonwealth to make laws regarding Australia's biological resources. Industry would favour this option as there would be only one regulatory body with which to deal - no matter what part of Australia's biological resources were being sampled. However action to remove existing State and Territory Government control over natural resources would likely lead to substantial litigation and be a serious issue in Commonwealth State relations. This would be particularly so in light of the government's Council of Australian Governments (COAG) Reforms. The prospect of extensive litigation and likely hostility over the issue of biodiscovery would also alienate investors. The Australian jurisdiction would be seen as commercially and legally uncertain.

The Constitution at Section 51(31) provides that any Commonwealth laws that have the effect of acquiring property must provide 'just terms' to those affected. The consequences of this are that any Commonwealth action that results in an acquisition of property must provide just terms at the outset as a matter of good governance, and any debate over whether just terms have been provided can be determined by the High and/or Federal Court. This Constitutional obligation does not bind the states.

An area of developing law is native title and the application of the Native Title Act 1993 (the Act). The obligations under this Act apply to all jurisdictions. In particular, action involving land or waters claimed as native title or for which native title already exists, must take into account the application of obligations under the Act.

Management of Land and Sea

Land management remains primarily a state matter, with the exceptions of the Australian Capital Territory (ACT), a site for a port for that capital (Jervis Bay) and the Northern Territory (NT). Although the ACT and the NT are now self-governing territories they are subject to the 'just terms' provision of the Constitution (i.e. the Territories must compensate for any acquisition of property) and the Commonwealth has the power to override Territory law if it chooses to do so.

Marine Management

The Commonwealth State Offshore Constitutional Settlement (OCS) gives the States and Territories title to offshore areas within three nautical miles of the coast and the power to make laws over those coastal seas. In addition, under the provisions of the *Fisheries Management Act 1991*, States and Territories have been given control over various marine species in Commonwealth waters adjacent to state waters. All jurisdictions have also introduced marine protected areas or Marine National Parks.

Ownership of Genetic Resources

The Commonwealth has not taken action to assert ownership over living marine resources having found that controlling access is sufficient. However some States (including WA and QLD) have provisions in their laws that assert ownership over certain classes of species found on land and waters within the state.

Queensland Biodiscovery Act 2004

In 2004, the Queensland Government passed the Biodiscovery Act. The main purposes of this Act, which complies with Article 15 of CBD, are:

- to facilitate access by biodiscovery entities to minimal quantities of native biological resources on or in State land or Queensland waters for biodiscovery;
- to encourage the development, in the State, of value added biodiscovery;
- to ensure the State, for the benefit of all persons in the State, obtains a fair and equitable share in the benefits of biodiscovery; and
- to ensure biodiscovery enhances knowledge of the State's biological diversity, promoting conservation and sustainable use of native biological resources.

The purposes are achieved by providing for:

- a regulatory framework for taking and the sustainable use of State native biological resources for biodiscovery;
- a contractual framework for benefit sharing agreements to be entered into with biodiscovery entities for the use of State native biological resources for biodiscovery;
- a compliance code and collection protocols for taking native biological material; and
- the monitoring and enforcement of compliance with the Act.

Draft policy for Access to and Use of Biological Resources in the Northern Territory

So that the Northern Territory may capture benefits from access to and use of biological resources through bioprospecting, the NT Government has established a draft policy to ensure that the conditions under which bioprospecting is undertaken makes certain that the community benefits directly from any such bioprospecting. This policy is consistent with the Northern Territory's obligations under the Native Title Act 1993.

A summary of the key developments in Biodiversity, biodiscovery and Biotechnology is shown below:

