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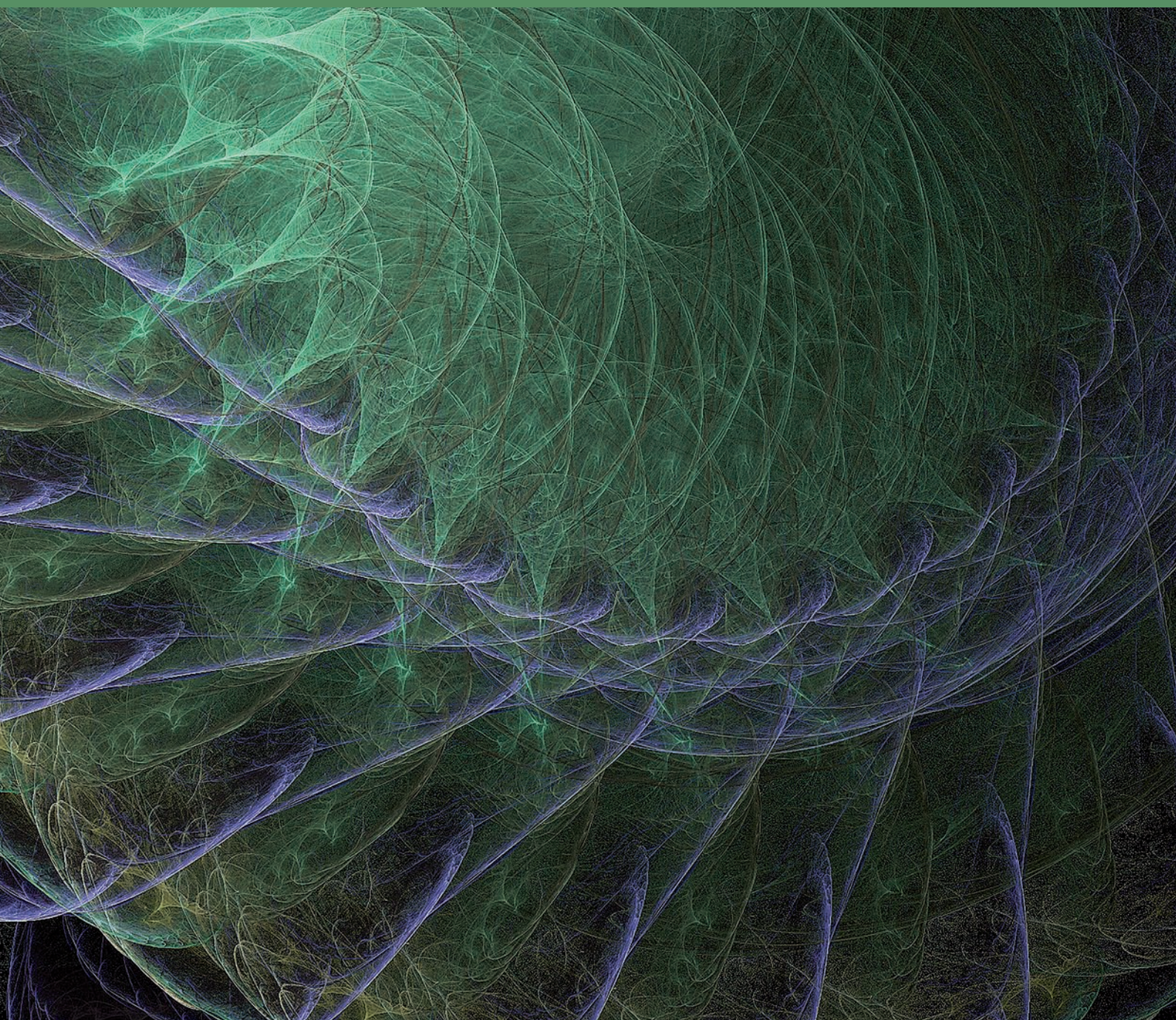
UNU-IAS Report

Queensland Biodiscovery Collaboration

The Griffith University AstraZeneca Partnership for Natural Product Discovery

An Access & Benefit Sharing Case Study



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Foreword

This study examines the Natural Product Discovery partnership between Griffith University, an Australian University based in the State of Queensland, and the pharmaceutical company AstraZeneca. Commissioned by the Australian Government Department of Environment, Water Resources, Heritage and the Arts, and carried out by UNU-IAS, the study was initiated in 2007 and represents developments up to the current time.

The partnership, which represents a multi-year, 100 AUD investment by AstraZeneca, has involved the screening of extracts of flora and fauna by Griffith University's Eskitis Institute to identify bioactive molecules as potential leads for pharmaceutical discovery and development of novel pharmaceuticals. More than 45,000 samples of regional biota, both marine and terrestrial, have been collected since the start of the partnership. Collections have derived from several jurisdictions within Australia, including plants from Queensland's rainforest and sponges of the Great Barrier Reef - as well as from Papua New Guinea, China and India. Notably, the partnership spanned a critical time in the development of policy guiding access to "genetic resources" and sharing of benefits from their use, beginning in the same year, 1993, that the Convention on Biological entered into force. As the authors note, the partnership stands as one of the few 'developed to developed country' natural product discovery models for technology transfer.

The intention is that this study is interesting not only on its own terms, but that it offers observations relevant to a broad international audience whose interests lie in areas including genetic resource management and regulation; the science of natural products discovery,; the challenges, successes and limitations of partnerships between the private sector and academia; and issues surrounding traditional knowledge and genetic resources.

This study should also serve as a grounded example to help inform debate during the negotiations for an International Regime on Access and Benefit Sharing that are currently taking place within the Convention on Biological Diversity. In these negotiations, which involve many controversial issues and that are developing in the context of fast evolving science and fast changing industry practices, knowledge of real experience will be key to negotiating functional outcomes that will assist the objectives of the Convention to be realised

To this end, this study examines the partnership between Griffith University and AstraZeneca in light of the standards for "best practice" in access and benefit sharing which have developed over the last 14 years under the Convention on Biological Diversity. It begins with an overview of the Australian natural product research and commercial contexts, and the State and Commonwealth regulatory environments in which the partnership has operated. It then examines the development of the partnership and the preconditions that were necessary for its agreement and implementation, the core elements of the partnership, and the range of benefits accruing to the various partners and interests involved. The study concludes by discussing ways that the case reflects standards of best practice in ABS partnerships, challenges faced by and concerns expressed about the partnership and lessons that might be drawn for other such partnerships which might inform the ABS policy process.

The study concludes that the Griffith/AstraZeneca natural product drug discovery partnership, which ran over 14 years, has provided an opportunity to examine the ways bioprospecting partnerships can yield benefits for provider countries and for biodiversity conservation over time. Particularly, it has shown the extent of scientific and technological capacity that can be built, the enormous wealth of biodiversity information that might be collected and analysed, and the ways that the many benefits regularly articulated in ABS policy documents can come together over time to add up to more than the sum of the parts.

The authors note, however, that the pre-conditions that attracted AstraZeneca are also the very things that make this a difficult model to reproduce in many other countries. Nevertheless, study of this partnership is instructive in terms of providing an example of what ABS "best practice' in partnerships generally seeks to achieve. The study also notes the concerns raised about the partnership, and the importance of making the terms of such partnerships as transparent and publicly-accessible as possible, and undertaking outreach activities as a standard part of a wider project. Finally, the study observes how the conclusion of the exclusive nature of the partnership is providing an opportunity to view, over the coming years, how the significant accumulated benefits of such a "best practice" partnership can be leveraged to form new collaborations with a range of partners, serving a wider range of public needs.

For UNU-IAS, this study has represented a continuation of the Institute's commitment to supporting, through analysis and capacity building, improved understanding and access to information relating to Access and Benefit Sharing, as part of its wider Biodiplomacy Programme.

Bringing this study to completion required the generous sharing of information and opinions, and the giving of time, by those who were interviewed and/or who offered comments on the draft report. While all of these people are acknowledged in the report, the authors and UNU-IAS would like to offer more formal thanks: without the level of cooperation that was achieved, often involving several rounds of interview and many requests for data, this study could not have taken place.

A.H. Zakri
Director, UNU-IAS
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1. Introduction

In 1993, the Australian State of Queensland's Griffith University formed a partnership with Astra Pharmaecuticals to pursue a natural product (NP) drug discovery programme under the banner of the Queensland Pharmaceutical Research Institute (QPRI). This partnership persisted through the merger of Astra Pharmaceuticals with Zeneca to form AstraZeneca AB in 1999. QPRI was renamed AstraZeneca R&D Brisbane, then evolved into the Natural Product Discovery Unit (NPD), and finally moved under the aegis of the Eskitis Institute for Cell and Molecular Therapies.

Now in its fourteenth year, Eskitis screens extracts of flora and fauna - including plants from Queensland's rainforest and sponges of the Great Barrier Reef - to identify bioactive molecules as potential leads for pharmaceutical discovery and development of novel pharmaceuticals. More than 45,000 samples of regional biota have been collected since the start of the partnership. Terrestrial collections are made by the Queensland Herbarium, who have discovered more than 100 plant species new to science; marine collections are made by the Queensland Museum, with several thousands of new species discovered – of the more than 3,000 sponge species collected, around 70% are new to science (Camp and Quinn, 2007; Hooper, 2007). Collections have also been made under sub-contract in Tasmania, China, India, and Papua New Guinea. The drug discovery programme at Eskitis has discovered over 800 new bioactive compounds from its approximately 45,000 specimens. In addition to collections of marine and terrestrial organisms that identified new species and populations of endangered species, the NPD provided critical information on biodiversity 'hot spots', and was used not only in drafting the Queensland Biodiscovery Act 2004, but in environmental planning and management throughout the region.

To date, AstraZeneca has invested more than AUD$100 million in the collaboration, which has resulted in a state of the art natural product discovery capacity. In mid-2007, the partnership employed fifty scientific and support staff, including ten High Throughput Screening biologists, twelve natural product chemists, seven medicinal chemists, five compound management chemists and two NMR anaylsts. The drug discovery programme at Eskitis has served, in effect, as an arm of the AstraZeneca R&D network, and as such has had an exclusive partnership with AstraZeneca. The exclusive nature of this relationship concluded in 2007, although collaboration on specific projects will continue. The end of this exclusive arrangement with AstraZeneca will allow Griffith University to leverage its facilities, know-how, and staff to build collaborations with other research and commercial groups. While commercial products from the partnership have not yet reached the market, this is not unusual given the long timelines for drug-discovery and development, particularly for natural products, and the high attrition rate observed during development of commercial products in this sector. The collaborative agreement and consequent investment in Queensland has resulted in significant technology transfer and plays an important role in the development of the state's Brisbane biotechnology hub. It stands as one of the few 'developed to developed country' natural product discovery models for technology transfer.

1.1 Legal frameworks

The Griffith University/AstraZeneca partnership spanned a critical time in the development of policy guiding access to "genetic resources" and sharing of benefits from their use, beginning in the same year – 1993, that the Convention on Biological Diversity (CBD) entered into force (Box 1). The CBD established that States have sovereign rights over their genetic resources. It also confirmed the authority of States to determine access to genetic resources, and sets out that Parties to the CBD should facilitate access to genetic resources by instituting legislative, administrative or policy measures that ensure fair and equitable sharing of benefits arising from the commercial use of these resources.

These international access and benefit-sharing obligations were provided for by the Government of Australia in the Environment Protection and Biodiversity Conservation Act (1999) and later detailed in Part 8A of the Environment Protection and Biodiversity Conservation Regulations. In 2002 and consequent to the adoption of the Bonn Guidelines, all Australian states and territories agreed to a nationally consistent approach to access to genetic resources which applies the Guidelines. In Queensland and the Northern Territory this has resulted in specific legislative measures: the Queensland Biodiscovery Act 2004 and the Northern Territory Biological Resources Act 2006 (DEWHA, 2007). In other states and territories no dedicated legislation yet exists, though in some jurisdictions there are limited access and benefit sharing measures implemented pursuant to more general legislative and policy instruments. All states remain committed to the implementation of the Bonn Guidelines, with most having already initiated legislation. For example, in Tasmania a comprehensive access and benefit sharing approach is currently being developed in a process led by the Tasmanian Department of Primary Industries (K Kent, pers.comm., 2007). Western Australia has also indicated in its Biotechnology Industry Development Strategy that dedicated legislation will be developed in that jurisdiction by the end of 2008 (DOIR, 2007, p. 22).

This study examines the partnership between Griffith University and AstraZeneca in light of the standards for "best practice" in access and benefit sharing which have developed over the last 14 years under the CBD (See Box 1). It begins with an overview of the Australian natural product research and commercial contexts, and the State and Commonwealth (Federal) regulatory environments in which Eskitis' NP Drug discovery programme operates. It then proceeds to examine the development of the partnership and the preconditions that were necessary for its agreement and implementation, the core elements of the partnership, and the range of benefits accruing to the various partners and interests involved. The study

concludes by discussing ways that the case reflects standards of best practice in ABS partnerships, and lessons that might be drawn for other such partnerships, which could inform the ABS policy process.

BOX 1: ACCESS AND BENEFIT SHARING AND THE CONVENTION ON BIOLOGICAL DIVERSITY

The Convention on Biological Diversity is a multilateral environmental agreement that entered into force in 1993. The Convention has 190 Parties, of which Australia is one. The objectives of the Convention are *"the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.*"

The provision of the Convention most relevant to Access and Benefit Sharing is Article 15, which recognizes the sovereign rights of States over their natural resources and that the authority to determine access to genetic resources rests with national governments and is subject to national legislation. Article 15 also specifies that access shall be on mutually agreed terms (Article 15. 4) and subject to the prior informed consent of the Contracting Party (Article 15.5). Contracting Parties are to take legislative, administrative or policy measures as appropriate with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources, with sharing to be on mutually agreed terms (Article 15.7).

Ongoing CBD processes relevant to Access and Benefit Sharing include the Conference of the Parties (COP), the Ad hoc Working Group on Access and Benefit Sharing, and the Working Group on Article 8(j), the provision of the Convention on traditional knowledge.[1] This provision is relevant to access and benefit sharing as it calls for Parties to "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices."

As with all multilateral environmental agreements, while the overarching concept and framework for Access and Benefit Sharing has been articulated at the international level, implementation must take place through nationally developed legislative and other measures. In order to guide parties as they develop and implement ABS measures, the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation were developed. These are voluntary guidelines that were adopted by the sixth Conference of the Parties of the CBD in 2002 (Decision VI/24). The Australian Government, as described below, has referenced the Bonn Guidelines in development of its ABS approach.

Pursuant to COP Decision VII/19 in 2004, the mandate of the Working Group on ABS now includes the elaboration and negotiation of "an international regime on access to genetic resources and benefit-sharing with the aim of adopting an instrument/instruments to effectively implement the provisions in Article 15 and Article 8 (j) of the Convention and the three objectives of the Convention." These negotiations are ongoing.

BOX 2: NATURAL PRODUCT DISCOVERY PARTNERS

AstraZeneca

Based in the UK, AstraZeneca is one of the largest pharmaceutical companies in the world, ranked number six in 2006 with global sales of $26.7 billion USD (IMS Health, 2007). AstraZeneca employs over 12,000 people in R&D, around 4,500 of which are part of Global Discovery. There are six major Discovery and Development facilities in the UK, US and Sweden, and four Discovery sites in the US, Canada and France. In Japan, the company runs a facility for clinical development. R&D investment in 2006 was $3.9 billion USD, and twenty one candidate drugs were added to the early development portfolio in 2006 (AstraZeneca annual report, 2006; Paul Denerley et al, pers. comm., 2007). More than 1,700 external R&D collaborations and agreements have been formed to complement in-house capabilities, reflecting an industry-wide trend towards such external partnerships in the industry. In 2006 alone, 325 new collaborations were formed (Paul Denerley et al, pers comm., 2007). In Australia, AstraZeneca employs more than 1,000 people as part of its export, sales and marketing to the region, through research collaborations at major academic hospitals and universities, and as part of its collaboration with Griffith University (Paul Denerley, pers. comm., 2007). The major research areas for AstraZeneca are respiratory (asthma, COPD), inflammation (osteo-arthritis), CNS (Alzheimer's, depression, anxiety, psychosis), pain (neuropathic, and chronic nociceptive), infection (antibacterials), cancer (anti-invasives, anti-angiogenics), and cardiovascular (thrombosis, metabolism, arrhythmia) (Paul Denerley et al, pers. comm., 2007).

Eskitis Institute for Cell and Molecular Therapies, Griffith University

The natural product drug discovery partnership was originally established between Astra Pharmaceuticals and Griffith University's Queensland Pharmaceutical Research Institute in 1993, following a submission by QPRI to Astra in 1992. The Eskitis Institute is a research centre of Griffith University, founded in 1988 and located in Brisbane, the capital of Queensland (Griffith University, 2007). The Eskitis Institute undertakes research on the molecular and cellular mechanisms of human diseases, specifically cancer, infection and immunity, neglected diseases, neurological diseases, and stem cell biology. Specific research programs include Bioactive Molecule Synthesis, Cancer Biology, Discovery Biology, Chemical Biology, Clinical Neurosciences, Drug Discovery and Design, Molecular Libraries, Stem Cells, Structural Chemistry and Systems Biology (Eskitis, 2007). Of these, the Drug Discovery & Design Molecular Libraries and Discovery Biology programs are evolutionary developments from the GU/AZ partnership. The Eskitis Institute also includes five key features that add considerable strength to the institute – the Queensland Compound Library, the National Centre for Adult Stem Cell Research, the Queensland node of Cancer Therapeutics CRC Ltd, *Nature Bank* and Eskitis Molecular Screening (Eskitis Institute, 2007).

QUEENSLAND COLLECTING INSTITUTIONS

The Queensland Herbarium

The Queensland Herbarium was established in 1855, and is located on the grounds of the Queensland Botanic Gardens in Brisbane. Administratively, the Herbarium falls within the Queensland Environmental Protection Agency, an authority of the Queensland Government. The Herbarium undertakes a range of activities including maintaining historical specimens and reference collections, surveys and mapping of Queensland vegetation, and research into plant diversity (Environmental Protection Agency Queensland, 2007). The Herbarium in 2003 employed 68 staff, including 33 botanists (Queensland Herbarium, 2003).

The Queensland Museum

The Queensland Museum, established in 1862, is a Statutory Authority of the Queensland Government, situated in Brisbane with regional services delivered through the Museum Resource Centre Network in six regional sites across the State of Queensland (Queensland Museum, 2007). The Museum provides museological services in science, natural environment and cultural heritage, and employs over 215 people and many volunteers (P.Riley, pers.comm., 2007). The museum's organisational structure reflects its focus on the themes of knowledge generation, knowledge management and knowledge dissemination. Falling within the Knowledge Generation theme are the substantive divisions of Biodiversity and Geosciences, Cultures and Histories, and Science and Technology in Society (Queensland Museum, 2006). Within the knowledge management theme falls the museum collections maintenance and accession activities. In recent years, these accessions to Museum collections have been from a range of activities including but not limited to the Griffith/AstraZeneca partnership. Other collection programs include a monumental seabed mapping of invertebrate marine life and fish throughout the Great Barrier Reef inter-reed region (GBR Seabed Marine Biodiversity Project), and the Torres Strait Seabed Mapping Project, undertaken by a consortium of agencies including the Museum, Australian Institute of Marine Sciences (AIMS), Australia's Commonwealth Scientific and Industrial Research Organisation (CSIRO), Marine & Atmospheric Research and Queensland Department of Primary Industries and Fisheries (DPI&F), funded by Commonwealth agencies and industry. The Museum, like most public institutions in Australia, is funded through a combination of government funding, research grants, consultancies, corporate sponsorships for particular activities, and business endeavours, such as retail shops (Queensland Museum, 2006).

2. The Australian Biota, Commercial Context and Research Environment

Australia has several features proving attractive to investors and researchers in the natural products area. This includes, not least, access to a diverse and unique biota. More generally, the features of Australia conducive to research and commercial activity include its robust system of law and stable democratic system of government, its stable and resilient economy[1], transparent and efficient regulatory environment[2], comprehensive intellectual property protections and high scientific and technological capacity. These strong capacities in scientific research stem from investments in basic education, a developed tertiary sector, and government incentives for research and development. The following discussion further highlights features of the Australian biota, research environment and commercial context particularly relevant to natural products research and investment.

2.1 The Australian Biota

Australia is one of only 17 mega-diverse countries in the world and is renowned for the uniqueness of its biota. Due to its status as an island continent, and its geologic history, Australia has remained relatively isolated over time compared to most countries. Consequently, Australia has a high proportion of endemic species – that is, species not occurring naturally elsewhere. For example, in the case of mammals, approximately 83% are endemic to Australia. These include such iconic Australian animals as the Kangaroo and Koala, but also many lesser known species. In the case of flowering plants, approximately 85% are considered endemic to Australia (DEWHA, 2007). Notoriously, Australia is also home to some of the world's most venomous creatures including several endemic snakes and spiders, which is one feature of the Australia biota that has attracted particular attention by natural products researchers (see, for example, the work of Entocosm, and Xenome in Box 3). Australia's unique marine environment contains the world's largest areas and highest diversity of tropical and temperate seagrass species and of mangrove species; some of the largest areas of coral reefs; exceptional levels of biodiversity for a wide range of marine invertebrates; and it is estimated that around 80% of the southern marine species occur nowhere else in the world (DEWHA, 2008).

The biological diversity within Australia also reflects the large size of the continent. Stretching from the Indian Ocean in the South to the Arafura and Timor Seas in the North, and from the Indian Ocean in the West to the Pacific Ocean in the East, and encompassing approximately 7,700,000 square kilometres, Australia spans several climatic zones and encompasses many ecosystem types. These include such diverse ecosystems as inland deserts, tropical savannahs and floodplains, mangrove swamps, tropical rainforest, coral reefs, salt plains, coastal dunes, offshore islands, mountain plains, temperate grasslands, cold temperate rainforest, and many temperate forest types including box ironbark, mountain ash, river red gum, and mallee scrub. Of these, Australia's coral reefs and tropical rainforests have been given particular attention by natural product researchers.

2.2 The Australian Research Environment

In the tertiary sector, the 2006 annual Times World University Rankings place six Australian universities in the top fifty universities in the world (Times, 2006). With only 0.3% of the world's population, Australia contributes 2.5% of the world's medical research and 2.9% of global scientific publications (Invest Australia, 2007, p.6). In 2005, Australia ranked eighth in the OECD in terms of the proportion of researchers in the total labour force. This is above the OECD average. On a per capita basis, Australia has a research output twice the OECD average (Invest Australia, 2007, p.19).

In terms of biotechnology research, Australia has several dedicated biotechnology research institutes. These include the Australian Genome Research Facility, the Australian Proteome Analysis Facility, the QUT Cluster for Molecular Biotechnology, the Institute for Molecular Bioscience, the Australian Centre for Plant Functional Genomics, the Australian Research Council Center of Excellence in Biotechnology and Development, the Griffith Institute for drug discovery (the Eskitis Institute and the Institute for Glycomics), the Queensland Brain Institute (QBI), and the Australian Institute for Bioengineering and nanotechnology (AIBN). Many Universities have some degree of biotechnology focus, and consequently approximately 50 per cent of Australia's biotechnology companies have emerged from within publicly funded research institutes. More than 70 government funded "Cooperative Research Centres" operate across Australia (Invest Australia, 2007, p.19). These are across a range of industry sectors, with several focused on biotechnology. These centres often involve public/private partnerships, and contribute significantly to the Australian economy. The Australian Government's Commonwealth Scientific and Industrial Research Organisation (CSIRO) is an important research organisation in Australia, and has a dedicated biotechnology division (CSIRO, 2007).

Natural products research in Australia takes place in a range of contexts, though research in public institutions tends to be largely directed towards commercial ventures, such as the commercialisation of their services, collection libraries or research outcomes or through the work of corporate arms of public institutions. This is discussed further under "The Australian Commercial Context" below.

2.3 The Australian Commercial Context

The Australian Pharmaceutical Industry represents approximately 1.3% of the global market (Medicines Australia, 2007, p.1.). The Australian Government Department of Innovation, Industry, Science and Research reports that the Australian Pharmaceutical Industry is diverse, encompassing bio-medical research, biotechnology firms, originator and generic medicines companies and service related segments including wholesaling and distribution (DIISR/DRET, 2007). The

Industry includes over 300 firms and institutions including both multinational companies such as Pfizer and Sanofi-Aventis and local companies such as CSL. The Department notes that in 2006-2007 the Industry turned over around $18 billion AUD, and in 2006-07 employed around 40,000 people, of which just under half were employed in manufacturing, and spent approximately $750 million AUD on research and development. In 2006-07, pharmaceutical exports were Australia's second largest manufactured export (DIISR/DRET, 2007).

The government vision for the Australian pharmaceutical industry is represented by the Pharmaceuticals Industry Action Agenda, the objective of which is to double Australia's share of the global pharmaceutical revenue by 2012. Government initiatives to support the Pharmaceutical Industry include the Pharmaceuticals Partnership Program, a AUD$150 million initiative from 2005 to 2009 which supports R&D by encouraging the development of medicines for global markets and the partnership of international firms with local companies (DIISR/DRET, 2007).

Australia's biotechnology industry is steadily growing, with activity across biotechnology fields including biomedicine, agricultural biotechnology, industrial biotechnology and environmental biotechnology (Ausbiotech, 2007). In 2006, core biotechnology companies in Australia numbered at470, employing over 14,000. In 2004-5 the industry represented an R&D expenditure of $254 million AUD (DITR, 2007, p.1)).

Biotechnology research and development in Australia takes place within both public sector research institutions and the private sector. By the end of 2006 more than seventy biotechnology companies were publicly listed, up from forty-five in 2003 (DITR, 2007, p.1). Notably, approximately half of the biotechnology companies listed on the Australian Stock Exchange are said to have emerged from publicly funded research institutes (Invest Australia, 2007, p.20). Biotechnology R&D in Australia frequently involves partnership arrangements, with many of these being with overseas partners. In 2006, Australian biotechnology companies formed 166 partnerships, among which partnerships with US companies were most numerous, followed by companies from the EU, Asia, and other nations (DITR, 2007, p.1). Most Australian biotech companies are in the small to medium enterprise category. In what has been described as a sign of a maturing local industry, the first merger and acquisition in the Australian biotech sector occurred in 2006 (Invest Australia, 2007, p.6).

Government support for research and development in biotechnology is strong. In 2000, the Australian Government instituted a multi-billion dollar science and innovation strategy, "Backing Australia's Ability". This strategy represents continuing public investment in the development of Australia's biotechnology industry. Implementing Australia's National Biotechnology Strategy and funded by the Australian Government since 2000 is "Biotechnology Australia", a government organisation linking the work of five Australian Government partner departments (Agriculture, Fisheries and Forestry; Environment, Heritage, Water Resources and the Arts; Health and Ageing; Innovation, Industry, Science and Research; and Education, Employment and Workplace Relations). In January 2008, the Federal Government Minister for Innovation, Industry, Science and Research announced a wide ranging review of Australia's national innovation system that recognises the vital role of innovation in boosting productivity.

The Australian States have, to various degrees, instituted their own policies to support research and innovation in science and technology. In Queensland, for example, the "Smart State" strategy has focused state development on knowledge, creativity and innovation as the principles on which to build economic growth (Queensland Government, 2007). The Queensland Government reports that from 1998, biotechnology has become increasingly important, and that currently there are around 90 core biotechnology companies employing 1,900 biotechnologists; there are sixty-six biotechnology-related research institutes employing 5,700 researchers; revenues of AUD$395 million for companies and $501 million for research institutes in 2006/07; and twenty-three drugs in clinical trials in Queensland (Queensland Government Department of Tourism, Regional Development and Industry, 2008) .

In terms of natural products research and development, Australia is home to a range of initiatives, primarily involving Australian companies or corporate arms of government-funded institutions developing natural product libraries or conducting natural product screening. Product development, as the range of activities being undertaken by companies/institutions described in Box 4 demonstrates, is aimed towards a broad range of industries including the pharmaceutical, agrochemical, cosmetic and nutraceutical industries.

BOX 3: NATURAL PRODUCTS RESEARCH IN AUSTRALIA

Companies and institutions currently undertaking natural products research in Australia include:

Australian Institute of Marine Science (AIMS)
AIMS is a government established and funded institute, based near Townsville, Queensland, next to the Great Barrier Reef. AIMS had an annual income in 2006-2007 of approximately AUD$35 million and employed 164 staff. AIMS is primarily a scientific research institution undertaking a range of research activities in the area of marine science. One of these areas of research is bioactive molecule discovery. AIMS has developed a large marine diversity collection sourced from most jurisdictions around Australia, containing material from over 20,000 marine macro and micro organisms. AIMS has been involved over the last decade in screening samples from its ever growing collection for compounds demonstrating activity. Extracts showing activities are chemically analysed with the active compound identified and isolated. Candidates are shared with Industry based collaborators, for example, in 2006 - 2007, a compound with herbicidal properties was identified for NuFarm Pty Ltd, an Australian agricultural company and AIMS samples have previously been screened for anti-microbial, anti-cancer, anti-viral and central nervous system activity. In 2000, AIMS formed a benefit sharing agreement with the State of Queensland. Thus far, AIMS has discovered hundreds of marine organisms containing antibiotic, anti-cancer, and herbicidal chemicals, and currently has a portfolio of novel compounds with commercial potential that are available for licensing (AIMS, 2007).

EcoBiotics
EcoBiotics is a biodiscovery company located in Queensland's tropical rainforests which has a diverse portfolio of new molecules from natural rainforest products. EcoBiotics has benefit sharing agreements with government and private landholders in Queensland and Melanesia. EcoBiotics advertise themselves as using a proprietary collection approach called EcoLogic, described as being based on ecosystem dynamics and knowledge of chemical properties in taxonomic group, to design biodiscovery strategies to identify small molecule drug candidates for use in various therapeutic contexts including oncology, inflammation, infectious diseases and parasite control. EcoBiotics has current R&D collaborations with Antisoma, a British biotechnology company specialising in oncology applications, and Jurox, an Australian Veterinary Pharmaceuticals companies (EcoBiotics Ltd, 2007).

Marinova
Marinova is a company based in Hobart, Tasmania, that specialises in bio-prospecting on fucoidans (sulphated polysaccharides in brown marine macroalgae and echinoderms). The company provides various products including seaweed blends and characterised component fractions for investigational research. To date, Marinova has isolated fucoidans from over 10 different species of macroalgae, and supplies material to the global pharmaceutical, nutraceutical and cosmetics industries. Source materials come from Tasmania, Nova Scotia, Patagonia and Tonga. Marinova has a dedicated research and development program with extraction and fractionation capability (Marinova, 2007).

Australian Commonwealth Scientific and Research Organisation (CSIRO) & Entocosm
The CSIRO is the Australian government science agency and an internationally recognized centre of scientific excellence. It has significant capability in science including in biotechnology, with a dedicated Biotechnology division focused on drug discovery, diagnostics, therapeutic delivery, gene silencing, bioprocessing, bioinformatics and biomaterial and tissue engineering (CSIRO, 2007).

Entocosm is a Canberra-based company formed in 2002, evolving as a separate entity from its origins within the CSIRO. Entocosm is focused on discovering small molecule therapeutics from insects and currently is focused on antibacterials and antifungals. Entocosm's collection of insects was sourced from the states of Queensland, New South Wales and Victoria, and the Australian Capital Territory (S.Trowell, pers.comm 2007). Entocosm has developed experience in taxonomic classification, develops and applies methods for extracting, fractionating, and screening insect extracts, isolates bioactives, and determines the chemical structures of insect derived compounds. Entocosm is seeking to attract investors and partners to develop the programme and to work towards the patenting of products and clinical evaluation. Patents based on termite extracts are pending (CSIRO, 2007 (2)).

BioProspect
Bioprospect is an Australian company and listed on the Australian stock exchange that aims to provide biological samples for the agrochemical, pharmaceutical and nutriceutical industries. BioProspect has a collection license granted by the Government of Western Australia. BioProspect currently has a library of over 1000 plant extracts and is collecting further biota samples including micro-organisms.

BioProspect is engaged in a variety of activities designed to either produce or commercialise its own products, and to supply active compounds to others in, mainly, the agricultural and pesticides sector. BioProspect produces extracts and derived products from plant material, stores extracts in its library for BioProspect's licensed drug discovery programs, isolates and identifies bio-active compounds through assay guided fractionation, performs structural analysis, and otherwise aims to perform programmes to identify and develop for the market, compounds with agrochemical, herbicidal, fungicidal, and other commercial potential. To date, BioProspect has developed two products for termite control, both derived from Australian native species. BioProspect has formed a partnership with the Australian biotechnology company Solagran Ltd. for research into the anti-bacterial, anti-viral and anti-oxidant properties of

"bioeffectives" derived from the needles of a range of coniferous tree species, none of which are native to Australia (Bioprospect, 2007).

Xenome

Xenome is an Australian company based in Queensland. Xenome's research focuses on peptide toxins found in Australia's venomous creatures toward use in pharmaceuticals for pain relief, inflammation and as tools in oncology. Xenome forms screening collaborations and partnerships with companies around the world across broad target classes. Drug discovery partnerships have been formed with several companies including Cytopia Ltd, Vernalis, Icagen Inc. and TheraSCi Ltd. The companies lead candidate Xen2174 is in clinical development within Xenome focused on a range of pain interventions (Xenome, 2007).

Cerylid Biosciences

Cerylid Biosciences Ltd is an Australian company based in the State of Victoria that focuses on the discovery and development of novel small molecules for the treatment of thrombosis, cancer and inflammation, with a particular emphasis on inhibitors of the various isoforms of phosphoinositide-3-kinase (PI3K).

Cerylid has two promising lead compounds under development - an antithrombotic compound and and anticancer compound isolated from the bark of the shrub *Aglaia leptantha* in Sarawak, Malaysia. The company has a library of over 370 novel inhibitors of the various isoforms of PI3K, a target for cancer and inflammatory disorders. The company continues to work on identifying and optimising compounds from its PI3K library for development as anti-inflammatory and anticancer agents (Bioscreening, 2007).

Biosignal

Biosignal is a publicly listed Australian company developing "biofilm" technology. The technology was originally based on observations at the University of New South Wales of the properties of an Australian seaweed *Delisea Pulchra* collected originally from Australian waters, and subsequent identification of the chemicals, furanones that are responsible for the seaweed being kept free of biofilms. Biosignal has a compound library of synthetic analogues of these furanones. Biosignal is at the early commercialization phase for a number of new technologies that may provide an alternative to antibiotics for the control of bacterial infection and, for a range of commercial applications, protective coatings that incorporate furanone compounds (Biosignal, 2007 (1)). Biosignal is collaborating with several partners in the development of various commercial applications, such as with the Japanese company Saraya Co Ltd on minimising contamination in cooling towers, the Swiss company CIBA Speciality Chemicals on industrial applications such as paints, and is being supported by BHP Billiton and Santos to develop a product for preventing microbial contamination in oilfields (Biosignal, 2007(2)).

3. The Australian Regulatory Environment

3.1 Introduction

The Commonwealth of Australia is a parliamentary democracy, with a system of laws based on the inherited English Common Law system. Australia has a written constitution that defines the powers of the federal government, all other powers being left in the hands of the States and Territories, of which there are six and two respectively.

Generally, the states legislate on environmental matters, except where the Commonwealth has competence vested through one of the enumerated powers of the Australian Constitution. These powers of the Commonwealth do not specifically refer to the environment; however, the Commonwealth does have an 'external affairs' power (s51(xxix)), which has been used to enable legislation to implement obligations stemming from international environmental treaties. The scope of the competence of the states vis a vis the Commonwealth on the environment, while not always clear and still susceptible to reshaping, has been somewhat clarified over the years through judicial interpretation and legislative developments, including the enactment of the Environment Protection and Biodiversity Conservation Act of 1999 (EPBC Act). (Anton, 1993; McGrath 2003). It is within this context that Australia took steps to implement the Access and Benefit Sharing provisions of the Convention on Biological Diversity, to which it became party in 1993. Implementing Australia's obligations under the Convention, therefore, has entailed steps at both the federal and state/territory level.

The Australian Department of Foreign Affairs identified three notable features of how Australia has implemented its international obligations that may be of interest to other jurisdictions as they develop their own regimes (DFAT, 2007(2)).

- Australia has included not only "genetic resources" but "biochemical compounds" in access and benefit sharing regimes. Derivatives are not provided for explicitly, however in the Queensland Biodiscovery Act 2004 the definition of "native biological material" includes a substance sourced, whether naturally or artificially, from a native biological resource – therefore capturing derivatives (Sue Coke, Office of Biotechnology, DTRDI, Queensland, pers. comm., 2007). The scope of access is to depend on the terms of agreement between the user and provider that may include return of benefits from derivatives. This definition has been developed to ensure that ABS regimes reflect ongoing technological developments.

- Australian jurisdictions tightly define the type of activities covered to be limited to the purpose of research and development of genetic or biochemical compounds. Other uses, such as harvesting, etc., are either expressly or by implication excluded from the various access and benefit sharing regimes.

- ABS legislation does not necessarily cover all lands. The department offers the example that private land holders in Queensland are not covered by any legislation[3], noting that as it is the sovereign right of states to determine access to genetic resources, it is also consistent with the CBD that ABS regimes do not regulate all access – prior informed consent is required only "unless otherwise determined by that Party" (Art 15 CBD; DFAT, 2007(2)). Some Australian jurisdictions, such as the Northern Territory, do cover private land in their ABS legislation (Biological Resources Act 2006). Their intention is to provide landholders and any possible partners or users with legal certainty and support.

3.2 The Nationally Consistent Approach

In 2002, the "nationally consistent approach for access to and the utilization of Australia's native genetic and biochemical resources" was endorsed by the Natural Resource Management Ministerial Council, a committee of Ministers set up by agreement of the Australian Federal, State and Territory Governments to better integrate Australia's conservation objectives. The nationally consistent approach is in line with Australia's Environment Protection and Biodiversity Act 1999. It supports implementation of Objective 2.8 of the National Strategy for the Conservation of Australia's biological diversity which is to "*ensure that the social and economic benefits of the use of genetic material and products derived from Australia's biological diversity accrue to Australia*."

The nationally consistent approach is designed to provide all Australian governments with a set of principles around which to base the "*development or review of legislative, administrative or policy frameworks or other mutually agreed arrangements in Australian jurisdictions for access to biological resources*." The approach explicitly references the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilisation, voluntary guidelines adopted by the Conference of the Parties of the CBD. The approach defines fourteen general principles that should underpin frameworks, including that they: should develop terms of access to resources that encourage local, national and international investment in Australia's biotechnology R&D capabilities, including biodiscovery research, bioprocessing and product development; should be consistent with various existing national legislation including the *Native Title Act 1993*; should recognize the need to ensure the use of traditional knowledge is undertaken with the cooperation and approval of the holders of that knowledge and on mutually agreed terms; shall facilitate continued access for non-commercial scientific research, particularly taxonomic research; should recognize the differences between commercial scientific research and non-commercial scientific research and their needs; and should be integrated into

biotechnology development polices and strategies to ensure the continued development of those industries in Australia (DEH, 2002).

The nationally consistent approach then goes on to identify eleven suggested common elements of Access and Benefit sharing Arrangements that are to be taken into account in application of the fourteen general principles. These include but are not limited to:

- A requirement for a person seeking access to seek permission from the relevant authority;
- That collection take place in an ecologically sustainable and ethical way; with equitable sharing of benefits between providers and applicants;
- That arrangements are designed such that processing of applications is timely, that transaction costs are low, and that access permissions should allow flexibility in their scope and duration;
- That certainty should be maximized by providing a legal basis for access and benefit sharing;
- That transparency and accountability should be a feature of the arrangements, supported by disclosure of all criteria against which access is granted, appropriate integration of decision making into administrative review systems and making public information about benefit-sharing agreements where consistent with commercial, privacy and cultural confidentiality;
- That in granting access the decision should be able to attach conditions for ensuring ecological sustainability and such conditions may include the application of collection protocols;
- That in the development of model contracts consideration should be given to the Suggested Elements for Material Transfer Agreements that from an Appendix to the Bonn Guidelines;
- That the jurisdictions should try to build approaches that are as consistent across Australian jurisdictions as possible.

3.3 Access to Genetic Resources on Commonwealth Lands

Certain lands and waters in Australia are controlled by the federal government[4], even when occurring within the geographic boundaries of the States and Territories. This led to the need for the enactment of specific regulations on access to genetic and biochemical resources found in Commonwealth areas. These regulations were developed only after a lengthy and inclusive Public Inquiry known as the Voumard Inquiry into Access to Biological Resources in Commonwealth Areas. These regulations were introduced under the Environment Protection and Biodiversity Conservation Act 1999. They cover only the taking of biological resources of native species for research and development on any genetic resources, or biochemical compounds, comprising or contained in the biological resources (Part 8A of the Environment Protection and Biodiversity Conservation Regulations). The regulations extend to leased/private land but they do not include biological resources taken for any other purpose. The regulations reflect the nationally consistent approach described above and apply the Bonn Guidelines. The regulations have specific provisions for access to biological resources depending on whether the access is for commercial or non-commercial purposes.

In the case of Indigenous owned land leased to the Commonwealth (certain national parks including the world famous Kakadu national park), access to biological resources is only granted where the applicant can demonstrate the traditional owners have granted prior informed consent. Benefits accrue only to the traditional owners, not to the federal government. Following the landmark Mabo High Court Judgement, and the subsequent enactment of the *Native Title Act 1993*, Australia has a system to recognize certain prior rights of indigenous peoples. The regulations are subject to the provisions of this Act. For the purpose of the environment protection regulations, Native Title holders are access providers and must give informed consent to any benefit sharing agreement concerning access to biological resources on lands subject to Native Title.[5]

In line with the nationally consistent approach, applicants can apply for a permit online through the Australian Government Department of the Environment, Water, Heritage and the Arts.[6] The permit requires a benefit sharing agreement to have been negotiated with the access provider(s), for which informed consent must be demonstrated. In determining whether there has been informed consent from Indigenous land owners or rights holders, the Minister must be satisfied that the negotiation process for the benefit sharing agreement was fair and equitable and must refer to a number of specified considerations listed in the regulations. Whether or not the resources are accessed from Indigenously owned land, a benefit sharing agreement must provide for reasonable benefit sharing arrangements, including protection for, recognition of and valuing of any indigenous people's knowledge to be used. Information that must be provided is listed in detail in the regulations, for example, there must be "a statement regarding any use of indigenous people's knowledge, including details of the source of the knowledge, such as, for example, whether the knowledge was obtained from scientific or other public documents, from the access provider or from another group of indigenous persons"(Environment Protection and Biodiversity Conservation Regulations (Cth) Part 8A.08). Model contracts to guide parties in negotiation have been developed by the federal government, in

consultation with the States and Territories. The have been published on the internet.

In the case of an applicant seeking access to biological resources for non-commercial purposes, the applicant must make a statutory declaration to that effect, again with information required as part of the declaration specified in the regulations (Environment Protection and Biodiversity Conservation Regulations (Cth) Part 8A.13). As part of the declaration, the applicant undertakes to offer a taxonomic duplicate of each sample taken to an appropriate Australian public institution on permanent loan.

When the Minister assesses applications, the Minister must consider whether all requirements have been met and whether environmental assessment is required. If the Minister considers that the access provided for in the permit is likely to have any more than a negligible environmental impact, the application must go through a "public notice" process. The Minister must be satisfied that collection will be ecologically sustainable.

When a permit is granted, details of the permit grant and the samples collected are posted on a database available through the website of the Department of the Environment, Water, Heritage and the Arts, and can be searched by any member of the public.

In line with the principle of flexibility of access arrangements identified in the nationally consistent approach, the regulations allow for permits to be varied, transferred or revoked, subject to certain processes and considerations.

If there is non-compliance with the regulations, a penalty of AUD$5,500 is enforced (at March 2008, approx USD$5000).

3.4 Queensland

Apart from the Commonwealth, only two other Australian jurisdictions have ABS regimes already in operation. The others are in the process of developing measures. Those jurisdictions are Queensland and the Northern Territory.

The Queensland Government was the first Australian government to enact specific biodisovery laws, with the Biodiscovery Act 2004 which sets out a framework regulating biodiscovery, with the purpose of facilitating sustainable access to Queensland's biodiversity and ensuring the fair and equitable sharing of any benefits derived from these activities with the State of Queensland. The purpose of the Act is achieved through a permitting regime (administered by the Environmental Protection Agency) involving a single Biodiscovery Collection Authority and a benefit sharing regime based on contractual Benefit Sharing Agreements (administered by the Department of Tourism, Regional Development and Industry).

The aim of the Biodiscovery Act 2004 (Qld) is to deliver the following benefits to community and industry:

- Certainty for all stakeholders through streamlined and clear legislative regulation;
- Ecologically sound and sustainable collection activities;
- An equitable sharing of benefits by all Queenslanders;
- Increased investment in the State's biodiscovery research and development sector; and
- Increased knowledge of the State's biodiversity.

The Act asserts that it has extra territorial application, applying both within and outside Queensland[7], subject to the Commonwealth constitution and to the full extent of the extraterritorial legislative power of the Queensland parliament (Queensland Biodiscovery Act 2004, Section 9).

The Act sets out a permit system. Before engaging in collection, a biodiscovery entity must create a benefit sharing agreement, which regulates the use of native biological material for biodiscovery, with the State of Queensland. This agreement must, along with other details, state the benefits to be provided to the State, when the benefits are to be provided, if the benefits include money, the amount, proof of a collection authority where required, and define reporting requirements. The biodiscovery entity must also submit a "Biodiscovery Plan." This plan sets out information such as proposed commercialization activities, timetable, intended activity outside the State of Queensland, activities that are going to be contracted to other parties, benefits that are likely to be provided to the State under a benefit sharing agreement, disclosure of grants given for the activities (unless confidential pursuant to a law or contract). Biodiscovery plans are registered and recorded by the Department of Tourism, Regional Development and Industry. It is at the discretion of the chief executive to publish details contained in the register.

To satisfy the requirements of the Act, collectors must appropriately identify the material, and also must provide a sample of the material collected to Queensland Museum, Herbarium, or another "receiving agency" as specified in the benefit sharing agreement.

Prospective collectors also need to obtain a "collection authority" from the Environmental Protection Agency pursuant to Part 3 of the Biodiscovery Act. This collection authority grants the right to collect "minimal" quantities of biological materials and is designed to ensure that collection takes place in an ecologically sustainable way.

Penalties apply for non compliance with the Act. The Act sets out the powers of officials to monitor and enforce compliance with the Act. It also details procedures for

review of decisions, rights of appeal and rules of evidence for any legal proceedings that may eventuate. The Act specifies that the Freedom of Information Act 1992 does not apply to benefit sharing agreements.

The Act is accompanied by the Queensland Biotechnology Code of Ethics which declares the ethical framework for the development of biotechnology in Queensland - among other issues dealt with it sets out a code of ethics for biodiscovery. While the code is not legally binding, it is mandatory for all organizations undertaking biotechnology activities, including biodiscovery, who receive State funding or assistance. Those involved in biotechnology may sign a "Statement of Intent" which is registered with the Department of Tourism, Regional Development and Industry and which essentially demonstrates an intention to abide by the code, and to institute monitoring and reporting of non-compliance with the code. A Public Register of Biotechnology Organisations that have signed a Statement of Intent is available on the internet and from the Department of Tourism, Regional Development and Industry. Failure by an organization receiving public funding to comply with the Code can lead to withdrawal of funding. Other organizations are encouraged to sign a Statement of Intent. The Code will be reviewed in 2011.

This Code refers to obligations under the CBD and those signing a statement of intent indicate that they will:

- comply with the Biodiscovery Act 2004 (Qld);
- collect native biological material from state land and Queensland waters only with the prior informed consent of the state.
- Before collecting samples from privately owned land, ensure that the prior informed consent of the landowner is obtained and that there will be the negotiation of reasonable benefit sharing arrangements with the landowner in return for access to the samples.
- Recognizing that there may be culturally significant aspects of the knowledge of Aboriginal and Torres Strait Islander people, treat this in a sensitive and respectful manner if used in the course of biotechnology.
- Where in the course of biodiscovery traditional knowledge from indigenous persons is obtained and used, negotiate reasonable benefit sharing arrangements with these persons or communities.
- comply with the *Native Title Act 1993* (Cth).
- Not commit acts of biopiracy[8] and will not assist a third party to commit such acts.

BOX 4: ABS IN OTHER ESKITIS COLLECTING JURISDICTIONS

Papua New Guinea (PNG) does not yet have a coherent arrangement for regulating access and benefit sharing, but is in the process of developing a national framework for access and benefit sharing. This process is being overseen by the Ministry of Environment and Conservation, with the main issues and elements still subject to government consideration and stakeholder consultation (A.Kambu, pers.comm., 2007). Current arrangements for access are complex, with the process for obtaining access depending on the relevant jurisdiction, land and resource type in question. For example, access to fauna in certain types of protected areas falls under the authority of the Conservator of Fauna, who is generally the Secretary of the Ministry of Environment and Conservation, and who can grant permission for access to fauna for research. As another example, obtaining access to resources in an area designated as a conservation area requires application to the Conservation Area Management Committee, established pursuant to the Conservation Area Act. Despite the complexity and fragmentary nature of current ABS approaches in PNG, collection has taken place over the years. In a number of cases, access to PNG genetic resources by foreign institutions has been facilitated through collaboration with PNG based Universities, who have mandates within their instruments of establishment to access and research biological resources, and who have developed memoranda of understanding with these foreign institutions covering issues including benefit sharing (Kwa, 2004).

China also does not yet have a comprehensive, coherent access and benefit sharing system though it has established an inter-ministerial process for the Conservation of Biological Species Resources led by the State Environmental Protection Authority (SEPA, 2005). China does, however, have a number of regulations that are relevant to the transfer of genetic resources in various contexts. These include the Regulation Concerning Protection of New Plant Varieties, issued by the State of Council in force since 1997, for which the Ministry of Agriculture is the implementing and supervisory agency. The Law and Regulations on Seeds that came into force in December 2000 is also relevant. Some Provinces have promulgated provincial regulations on seeds, administration and trade (SEPA, 2005). Several Material Transfer Agreements have been executed in China with international research institutes and organisations (Y.Wang, pers. comm., 2007).

India since 2002, with the enactment of the Biological Diversity Act 2002, has had comprehensive legislation for the regulation of access and benefit sharing. This Act is focused on regulating access to biological resources and associated traditional knowledge so as to ensure equitable sharing of benefits arising out of their use, in accordance with the provision of Article 15 of the CBD. The National Biodiversity Authority, established in 2004, implements the Act, along with the State Biodiversity Boards and local Biodiversity Management Committees (www.nbaindia.org). There are certain exemptions from access and benefit sharing requirements including exemptions for collaborative research through government-sponsored institutes subject to overall guidelines and approval of the Government of India; as well as limited exemptions relating to value added products and some exemptions relating to normally traded commodities, the scope and guidelines for which are still being contemplated by an expert committee (S.Subramanian, pers.comm., 2007).

Also relevant to genetic resources in India are the Plant Varieties Protection and Farmers' Rights Act (PVPFRA) 2001 and the PVPFR Rules 2003 which are concerned with the protection of plant breeder's rights and the rights of farmers to register new varieties and also to save, breed, use, exchange, share or sell the plant varieties that they have developed, improved and maintained over many generations. Also, the Patent Second Amendment Act 2002 and Patent Third Amendment Act 2005, provide, among other things, that plants and animals are not patentable, and require mandatory disclosure of the source and geographical origin of the biological material in patent applications (Government of India, 2005).

4. The Griffith University/AstraZeneca Partnership

4.1 The Context

The partnership between the Eskitis Institute of Queensland's Griffith University and AstraZeneca AB came about at the intersection of a number of trends: first, advances in science and technology in the 1980s and 1990s made it possible to more quickly, inexpensively, and efficiently research natural products; second, changes in funding in the Australian tertiary sector created incentives for academic researchers to form partnerships with the private sector; third, the Factor F scheme instituted by the Federal Government attracted increased pharmaceutical industry investment in Australia; and fourth, the Queensland Government initiated the "Smart State," a program in the early 1990s to promote scientific and technological capacity in the state.

Natural Products Research Trends

In the last few decades, advances in informatics, automation and imaging technology have made it possible to screen 100,000s – 1,000,000s of small molecules against a specific biological target or cellular assay per day, compared with 10s-100s of compounds tested on animals over many months previously (Camp and Quinn, 2007). High-throughput screening (HTS), as this is called, led to demand for large libraries of compounds that might inhibit or activate a specific biological target, such as a cell-surface receptor or enzyme. For much of the 1990s, scientists thought the best way to generate compounds for screens was through mass-produced combinatorial libraries, rather than structurally complex natural products (Class, 2004; Newman et al, 2003; Camp and Quinn, 2007). Considered too slow, too costly, and too problematic, natural products were over-shadowed in the 1990s by chemical approaches that use combinatorial chemistry and biological approaches such as the manipulation of biosynthetic pathways of microbial metabolites through combinatorial biosynthetic techniques (Cragg et al, 2005). Disease categories for which natural products are well-suited – in particular infectious disease – also lost ground within big pharma companies (Koehn and Carter, 2005; Handelsman, 2005).

However, after a multi-billion dollar investment in combinatorial chemistry since the 1980s, large pharmaceutical companies found little in the way of new structurally diverse entities from this approach (Newman and Cragg, 2007).[9] Growing awareness of the limitations of these approaches, and breakthroughs in robotics technologies, such as those used in separation and structure determination, have made screening mixtures of structurally complex natural product molecules easier, and have expanded the potential role of natural chemical diversity in the drug discovery process (Koehn and Carter, 2005; Laird and Wynberg, 2005). Griffith University was at the forefront of R&D driven by natural products and HTS, commencing its HTS of extracts of Australian plants and marine organisms in 1994, ten years before any public group in the country had an HTS program (Camp and Quinn, 2007). When its partnership with AstraZeneca began, Griffith University was the only part of the AstraZeneca network of researchers that undertook natural products research, and the first and only one with an HTS program (Quinn, pers comm., 2007). Today the company has four HTS sites in Europe and the US.

Changes in funding in the Australian tertiary sector

Significant reductions in the proportion of tertiary funding coming from government during the 1980's and 1990's in Australia meant that academics were forced to become more entrepreneurial, with the logical conclusion that private sector partnerships became more attractive, indeed, more necessary (Illing, 2007; R.Quinn, pers. comm., 2007). Private sector partnerships at Griffith University were specifically encouraged and academics instructed to seek them. In this environment, the Director of then QPRI, Professor Ron Quinn, presented a number of domestic and international companies with proposals for collaboration, including AstraZeneca, then Astra Pharmaceuticals. At the same time, Astra was considering a range of projects in Australia under the "Factor f" scheme.

The Federal Government "Factor f" scheme

The "Factor f" scheme was launched in 1988 and ended in 1999. It was designed by the federal government to attract increased pharmaceutical investment in Australia. In return for investments in the research or manufacture of pharmaceuticals, the Australian government would pay a higher price for a company's drug for a set number of years, with the maximum price increase set at the average European price of the product, and with payments a maximum of 25% of the value of additional research or manufacturing activity over the level that existed in the base year (Industry Commission, 1996). The Industry Commission Report of 1996, presenting an evaluation of the scheme, was inconclusive as to whether the scheme achieved its objectives and suggested that it incorporated a number of design features that hampered its effectiveness and reduced its ability to efficiently create more benefits for the Australian community than costs. Nevertheless, and as in the case of the Eskitis Partnership, the report notes that the scheme attracted investments that would not have taken place without it.

In the early 1990s, the Australian medical director of Astra Pharmaceuticals proposed a range of 34 projects with various institutions for consideration by the parent company. A partnership with Griffith University was selected, and in 1993 the first five year contract was signed, and the natural product discovery partnership officially began. At the time, AZ had neither an HTS or a natural products research programme, so the Eskitis partnership complemented their in-house capabilities. Factor f played an important role in launching the partnership, but in subsequent years the agreement was renewed (1998 and 2002) without the incentive of the subsidy through Factor f.

Queensland Government Support

At the same time, the State of Queensland sought to attract investment in science and technology, in particular projects that added value to basic research. The State of Queensland's support included provision of some equipment and the facilities in which Eskitis was to be housed, which proved important factors in the decision of AZ to come to Queensland. In 1999, Queensland's emphasis on R&D continued, culminating in the biotechnology field with the announcement of a ten year AUD$270 million biotechnology plan (Queensland Government, Department of State Development 2000). Today, the Queensland government's emphasis on research and development continues, and since 1998 it has spent over $3 billion on research and development (Queensland Government, 2007).

The combination of investment incentives, a low cost research environment, high quality research infrastructure, scientific expertise, the enormous and unique biotic resources of the region, and the opportunity to become a leader in an emerging technology field led to AstraZeneca's decision to choose the Griffith University proposal and to launch a new drug discovery research programme (Paul Denerley, pers.comm., 2007; EFPIA, 2007).

4.2 The Griffith University/AstraZeneca Partnership

Griffith's partnership with AstraZeneca was launched in 1993, renewed in 1998 and again in 2002, and is due to conclude in 2007. Over this time, AZ invested more than AUD$100 million in the program. This change to a non-exclusive relationship on a project by project basis ensures that Griffith University and Astra Zeneca can continue to collaborate on particular projects, and brings to a close the highly funded exclusive partnership.

The GU/AZ partnership has yielded numerous promising leads, but a commercial product has yet to emerge. This is not surprising given the high project attrition rates involved in developing a drug and the long lead times (averaging 10-15 years), particularly for natural products (EFPIA, 2007; PhRMA, 2007; Camp and Quinn, 2007). It is too soon to rule out the possibility that a commercial product will be developed from the partnership at some point in the future, and the status of compounds in industry R&D programs is highly confidential for commercial reasons. One of the best examples of this point (low probability - long lead time) is the blockbuster cancer drug, taxol. Taxol was commercialized in the early 1990s, more than 30 years after the original collections of *Taxus brevifolia* in the Pacific northwest of the United States by the US Department of Agriculture. Should a commercial product result from the NPD, Griffith University will receive a royalty falling within the range common to industry (see the discussion in ten Kate and Laird, 1999, for example), and a portion of this is then shared with collecting institutions.

As part of the partnership, AstraZeneca provides funding to Griffith University to participate in their biodiscovery and commercialization efforts. Griffith University in turn partners with domestic and overseas collecting institutions to undertake biota collections (see below), make extracts of samples, and then run these samples through high throughput screens (HTS) against targets provided by and of therapeutics interest to AZ. Active compounds are then identified and isolated at Griffith University via bioassay guided fractionation, and structures are elucidated using nuclear magnetic resonance spectroscopy (Quinn et al, 2002; Camp and Quinn, 2007; Paul Denerley, pers.comm., 2007; Chart 1). The role of Griffith University evolved during the course of the partnership – originally, the HTS and lead discovery were to be done at Griffith and the leads sent to collaborators at AstraZeneca, but over the years Griffith also performed selected lead-optimization and medicinal chemistry components based on their in house expertise (Ron Quinn, pers. comm., 2007).

HTS focused on receptors, enzymes, and mechanism-based cellular assays in the area of cardiovascular, respiratory, inflammation, gastrointestinal, pain control CNS, infection, and oncology (Quinn et al, 2002). Continuous screening, in which a panel of around twenty screens was assayed each year against 10,000 extracts, ran between 1994-1997. In 1997, continuous screening was replaced by campaign screening, which allowed the entire extract library – then at 30,000 – to be screened in a semi-automated manner within four weeks. After purchase of state-of-the-art robotic liquid handling and assay building work stations, in May 2000 the first 100,000 extract campaign was achieved (Quinn et al, 2002). In 100,000 extracts there are between 5-7 million unique compounds. In order to manage the large amount of data generated by HTS of extracts, fractions or compounds, Griffith University wrote its own proprietary software package – HiTbaSe.

The high level of involvement of Griffith University researchers in the discovery process is unusual for ABS partnerships, most of which involve collections in high biodiversity regions and higher level discovery within the company. However, the partnership was viewed within AstraZeneca as an extension of the R&D programme, meaning that Griffith researchers were in almost daily contact with those at AstraZeneca, and expertise on HTS of natural products was greater at Griffith University than within AstraZeneca during the course of the partnership. Griffith University staff headed up the Natural Product Competence Centre within Astra Pharmaceuticals, sat on the Global Chemistry Forum of AstraZeneca, and worked closely with the other research programmes within the company. Integration of Griffith University's work into the company to this extent meant that work with other parties, whether academic, governmental or commercial was not possible as Astra Zeneca had exclusive rights to the samples collected during the lifetime of the agreement. Griffith University staff were also required to seek permission prior to publication of any articles reporting on the research,

the same as staff of Astra Zeneca. During the lifetime of the partnership, Griffith University staff published over 140 articles on natural product drug discovery research. This high level of collaboration with AstraZeneca, and the attached conditions, however, also account for the unusually extensive benefits that accrued to the institution and the country (see discussion below). Today, with the switch to non-exclusivity, Griffith University can leverage the fruits of the partnership – in expertise, capacity, infrastructure, and collections – to strike new partnerships with government research institutions, industry, public private partnerships and academic researchers, and the samples collected are the property of Griffith University and are housed at the Eskitis Institute (see below).

The natural product drug discovery activities undertaken under the aegis of the partnership are subject to the laws of Queensland and the Commonwealth of Australia (see "Australian Regulatory Environment above). When accessing materials outside Queensland (whether in other states and territories of Australia or internationally), the University is also subject to any applicable laws in the jurisdiction in which collections take place, as well as the CBD, which Australia has ratified. To meet its access and benefit sharing obligations under the Queensland Biodiscovery Act 2004, the GU/AZ partnership has an approved Biodiscovery Plan lodged with the Queensland Department of Tourism, Regional Development and Industry. When collecting on Commonwealth lands or waters, collection is subject to obtaining the appropriate permits under Part 8A of the Environment Protection and Biodiversity Conservation Regulations 2000. When research is for commercial purposes, as it is in the case of the partnership, a benefit sharing agreement with the access provider must also be lodged with the Department of the Environment, Water, Heritage and the Arts. The Queensland Museum obtained permits for collection of marine organisms within Commonwealth territories prior to Commonwealth biodiscovery legislation.

4.3 Collection of samples

The first step in the discovery process is the collection of samples. Griffith University subcontracted collections to the Queensland Herbarium for terrestrial samples, and the Queensland Museum for marine samples. Most collections were made in Queensland, but others came from Tasmania, China, India and Papua New Guinea. In 2007, the biota collection, containing collections from the lifetime of the NPD partnership, has in excess of 45,000 biota samples, including vascular plants, algae and macro fungi from Queensland (>20,000), PNG (5,743), and China (6,545). Marine invertebrate samples number more than 9,500 biota from tropical and temperate Australian waters. The collection also includes more than 2,000 soil and aquatic microbial extracts from India and Australia (Camp and Quinn, 2007). The plant collection represents more than 9% of the world's species diversity of higher plants, with representation from 73% of the world's plant families. The marine collection contains more than 10% of global diversity of sponges and ascidians, and 5% of soft corals and gorgonians (Griffith University, 2007; See Table 1). The 2004 Queensland Biodiscovery Act requires samples of all specimens collected to be lodged with the Queensland Museum or Herbarium, something which has been done since the beginning of the partnership in 1993.

The Queensland Museum

The sea is considered by Eskitis to be a greater potential source of genetic diversity than the land, having a much larger variety of life forms (phyla). Of the 28 marine phyla less than a third of the total number of species living in Australian waters – which are in turn estimated to comprise about 30% of the world's marine fauna – were known to science at the start of the partnership (Quinn et al, 2002). Over the course of the partnership, the Queensland Museum has collected more than 12,000 specimens of around 5,000 species of marine invertebrates and algae. 8,000 specimens have been extracted and subjected to HTS. Target phyla were predominantly sessile invertebrates - animals fixed to the seabed - including soft corals and gorgonians (cnidarians), lace corals (bryzoans), sea squirts (ascidians) and sponges (Porifera). Of particular interest are sponges, which show the greatest bioactivity at low "tissue" concentration, highest diversity, and span a greater range of marine habitats (Hooper, 2007). Sponges have extraordinary chemical diversity compared to other phyla, and along with ascidians have yielded the majority of novel compounds and new bioactive natural products. Sponges show such proportionally high chemical bioactivity compared to other marine phyla because: toxins are produced to repel predators, 'free-loaders', and provide a competitive advantage in crowded encrusting communities; many sponges excavate the substratum, breaking down and recycling calcium carbonate back to the reef system; they have a chemical mechanism to facilitate mutualistic associations in the reef; and they form symbiotic relationships with microorganisms (Hooper, 2007).

Examples of sponge species from the Great Barrier Reef demonstrating significant bioactivity include: *Stylissa flabellata*, with a new compound showing significant activity as an anti-inflammatory agent; *Aplysinella rhax*, showing bioactivity against cardiovascular and metabolic assays; *Haliclona ('Adocia') aculeata*, with several new compound analogues showing potential efficacy against osteoporosis; and *Citronia astra*, a new genus and species of sponge, showing significant bioactivity against anti-thrombosis screens (Hooper, 2007).

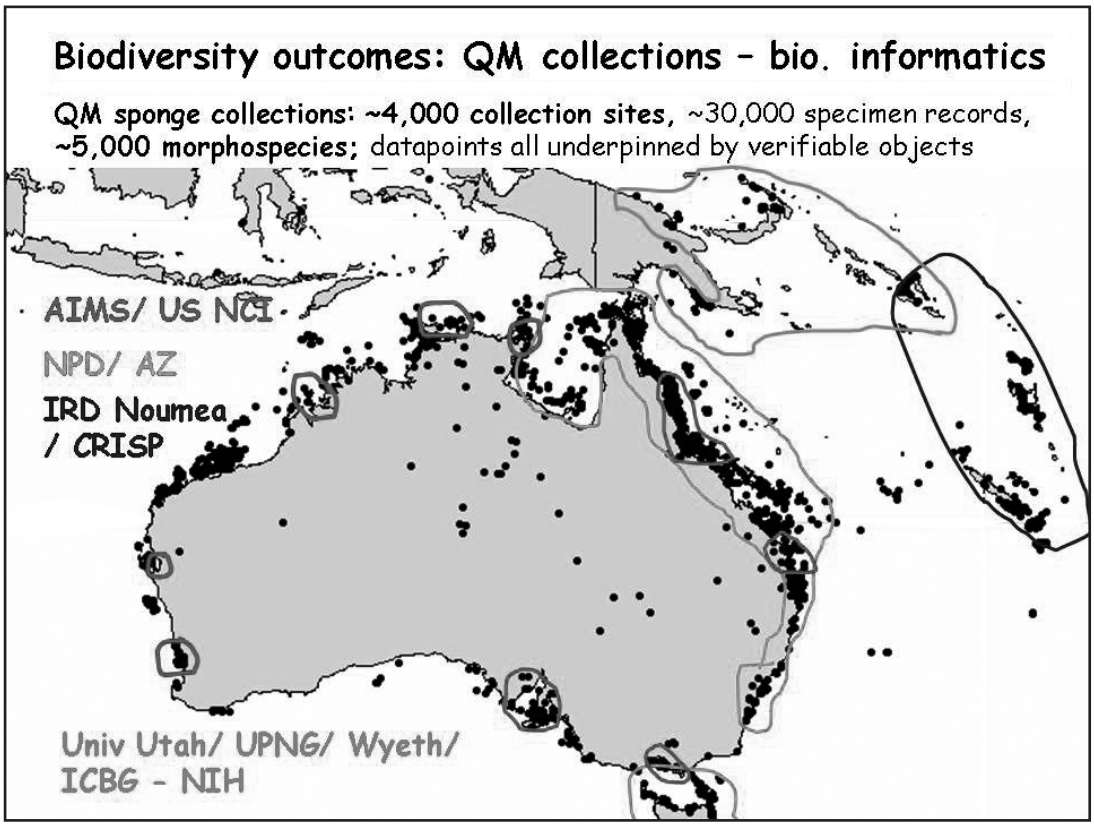


Chart 1: Collections undertaken by the Queensland Museum

For both the Queensland Museum and the Queensland Herbarium, agreements were made with Griffith University that guided the collections and provided up front payments to the institutions to complete the work, including hiring professional staff to manage the project, undertake collections and identify specimens, and to purchase equipment and other materials. A percentage of the royalty received by Griffith University from any commercial product developed was also negotiated, to be shared with the State of Queensland as both institutions are part of the government.

The Queensland Herbarium

The Queensland Herbarium began a scientific partnership with Griffith University in 1990, and in 1992 entered into a contractual agreement with Griffith to supply plant samples for the AstraZeneca biodiscovery program. During the first ten years of the agreement, the Herbarium supplied plant samples for the growing collection, and in the last five years focused only on re-collection of species of interest. The collection of plant samples and herbarium vouchers were initially to include all species occurring in Queensland, but as the partnership progressed families without intebioactivity were eliminated (e.g. Poaceae, Cyperaceae and later Eucalypts). Collections for the partnership were undertaken only in Queensland, and by staff of the Herbarium. Collections were comprised of plant material of either flowers, fruits, leaves, stems, and sometimes roots, up to a maximum of 100g dry weight for each taxon (species, subspecies variety), plus a herbarium voucher specimen. During the course of the collections, more than 16,000 plant specimens were added to the Herbarium collection, and at least 100 species new to science were discovered (G. Guymer, pers. comm., 2007).

Unlike the Museum, which provides taxonomic and location details with samples, the Herbarium initially supplied plant samples without these details, and instead provided a bar code to trace specimens within the Herbarium collection. This was done in part because it is easier to manage data by number rather than scientific name, and because it required a return to the Herbarium for re-collection, and so protected the identity and location of rare and endangered species (G. Guymer, pers. comm., 2007). In 2001, after many years of collaboration and building of trust between the partners, the Herbarium provided Griffith University with family and genus level taxonomic information on all species in the collection. This assists with literature and database searches on promising leads, and clustering plants for further analysis and de-replication. Griffith University can also obtain species-level detail upon request. Locations for collections remain sensitive, and are not necessary for the partnership on a regular basis in any case, although these too are provided if there is a specific request.

Table 1: The Eskitis Biota Collection, 1993-2007

Regions/countries of collection and type of collection	Number of samples	Number of species (or Operational Taxonomic Units, OTUs)	Number of families	Collecting institution
Queensland vascular plants, algae and macro fungi	>20,000	>8,000	276	Queensland Herbarium
Queensland marine invertebrates	>8,000	>3,500		Queensland Museum
Tasmanian marine invertebrates	>1,200	>700		Queensland Museum
China plants (ZiYuan county, Guangxi Province)	6,545	>2,000	183	ZiYuan Medical Company
Papua New Guinea plants	5,743	>1,500	163	Biodiversity Limited

Source: Griffith University, 2007

China

Terrestrial collections in China are made in Zi Yuan county, of Guangxi Province in the southwest of the country. It is a mountainous region with interesting biological niches, and one of the five most biologically-diverse areas of China. Collections are undertaken by the Zi Yuan Medicine Company, which is a major supplier of Traditional Chinese Medicine (TCM). Collections include plants used in TCM, as well as those of taxonomic interest (i.e. from families showing interesting biological activity). However, traditional knowledge about species use within TCM is not supplied with samples – the fact of their use in TCM is used instead as a general screen for activity of any kind (A Carroll, pers.comm., 2007). Voucher specimens for the collection are retained within the company. A taxonomist from the Department of Biology at Guangxi University coordinates collection programs for the Zi Yuan Medicine Company, of which he is a director. Zi Yuan Medicine Company was a state-owned company in the early years of the partnership, which began in 1997, but has since become a privately run company.

Collections of new samples in China concluded in 2003, although re-collection of larger volumes of species already in the collection continues. These recollected samples are now provided in extract form, with Zi Yuan Medicine Company subcontracting extraction to an industrial facility that specializes in TCM extracts (A. Carroll, pers.comm., 2007). It proved difficult to get large quantities of "unknown" bulk plant material into Australia, due to strict quarantine requirements given government concerns about pests, diseases and invasive species, and China has high levels of capacity in extraction that are utilized by botanical medicine and other companies around the world.

The original agreement between Griffith University and the Central Chinese Government was signed in China in 1997, after several years of discussions between partners, and with a range of government institutions. The Zi Yuan Medicine Company facilitated the dialogue with government, hiring a lawyer from the region to negotiate with the central government in Beijing for the first agreement. For the second agreement, negotiation took place with the Zi Yuan County Peoples Government of the Zi Yuan Autonomous Region, which granted the collecting permits, and signed off on the partnership between Zi Yuan Medicine Company and Griffith University. The Trade, Development, and Food and Drug Bureaus within the County government reviewed and approved the permits. For the second agreement, the central government said that only county government approval was necessary, and that they, rather than the provincial or central governments, should review and grant such permits. China did not have a central body dealing with ABS, or a national ABS focal point through which the agreement passed during the negotiation of these agreements (A. Carroll, pers. comm., 2007) (see Box 4).

The agreement between Griffith University and Zi Yuan Medical Company is similar in content to those signed with the Herbarium and Museum, guiding sample quality (e.g. specifying moisture content, mesh size for grinding), quantity of samples supplied per year, information supplied with samples (e.g. identified to species level, GPS location of samples), and detailing benefits to be received by the company. The latter include payments for the agreed-upon work plan and samples, provision of a vehicle and the equipment necessary to do this, and royalties (of the same percentage received by the Herbarium and Museum) should a commercial product be developed (A. Carroll, pers. comm., 2007).

Papua New Guinea

Terrestrial collections in Papua New Guinea were undertaken by Biodiversity Limited, a small company run by a natural products researcher who is also based at the Department of Chemistry of the University of Papua New Guinea in Port Moresby. Collections began in 1997. Voucher specimens were lodged with the Papua New Guinea National Herbarium, Lae. As in the case with China, Griffith staff felt they had large and representative enough collections for the library and the AstraZeneca partnership, and so concluded collections in 2003. Collections were made throughout the country, and of the more than 1,500 species collected, many were new

or previously unknown to science. The collections did not include traditional knowledge, and were random or taxonomically-driven (A. Carroll, pers. comm., 2007).

Negotiation of an agreement with Papua New Guinea took a few years to conclude. This process included discussions between Biodiversity Ltd and Griffith University, and subsequent approval for collections from the PNG Department of Environment. At the time, the government of PNG did not have an ABS measure in place, nor a national focal point to deal with these issues, so permission was sought through the traditional agency within government for plant collections, the Department of Environment. The elements of the agreement are similar to those described above for China, although in this case royalties go to the government of PNG, rather than the company.

Tasmania

Marine collections in Tasmania were undertaken by Aquenal Pty Ltd., a marine environmental consultancy company. The focus of the collection was temperate marine invertebrates and algae. Around 1,600 samples were provided to Griffith through this partnership. Aquenal has expertise in collecting and cataloguing samples, and do some in-house taxonomic identifications, particularly for bryozoan, ascidian and algae, but they also partner with the Tasmania Museum on identifications. The Queensland Museum does all the sponge identifications and is paid separately for this by Griffith. Voucher specimens are held at Aquenal, the Tasmanian Museum, and the Queensland Museum. Aquenal use the collection data for their surveying purposes and to assist with recommendations for coastal management in the region (A. Carroll, pers. comm., 2007).

Two, three year agreements have been signed between Aquenal and Griffith University since 2002. Tasmania does not have biodiscovery legislation, so government approval for collections was obtained by Aquenal through collection permits. The agreement between Griffith and Aquenal is similar in content to those used for the Queensland Museum and the Queensland Herbarium, in terms of samples received, payments, and royalty sharing.

India

Between 1996 – 2000 a collection of approximately 1,800 strains of soil fungi were provided by Biocon Ltd, a private company based in Banglalore, India. The agreement between Griffith and Biocon is similar in content to those used for the other international collections (A. Carroll, pers. comm., 2007).

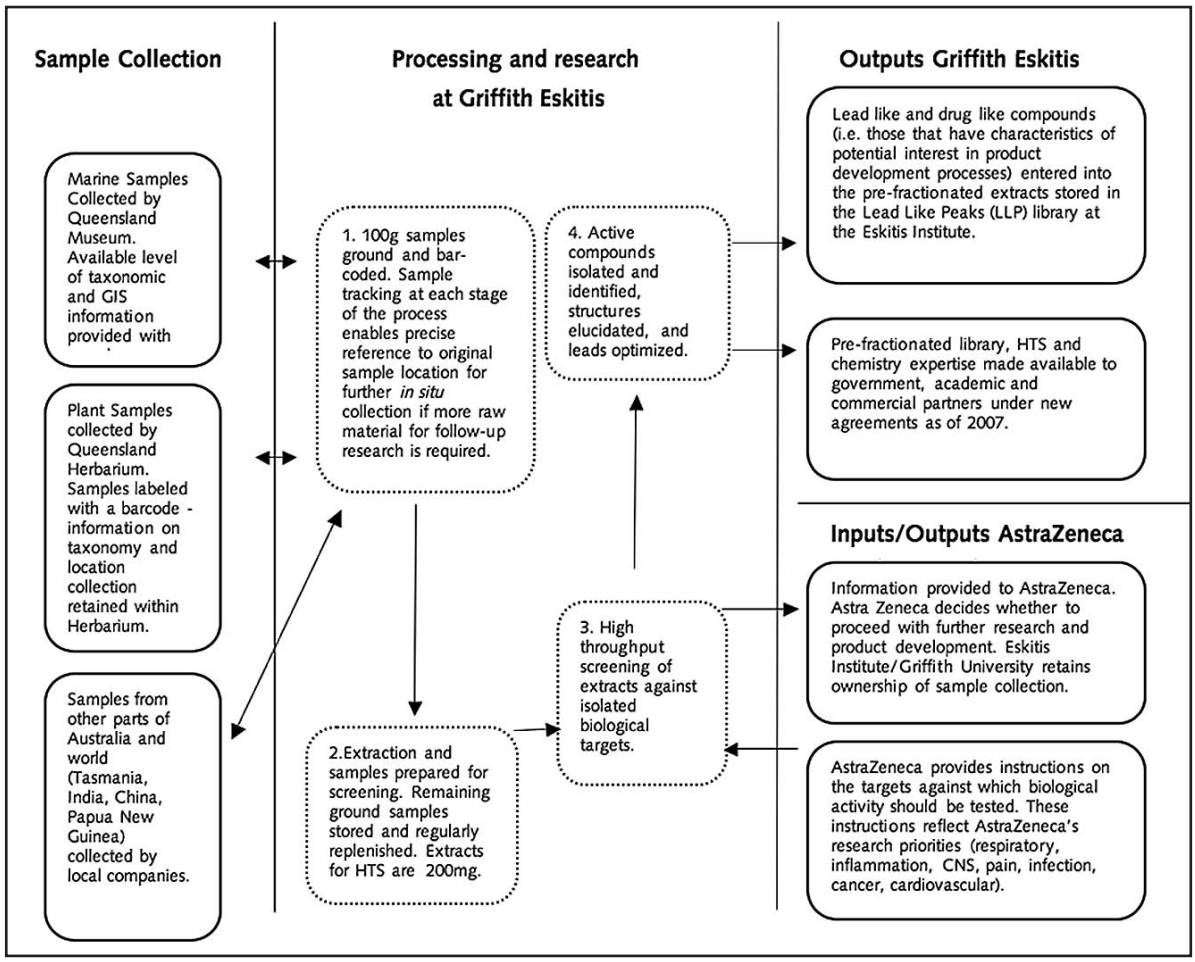


Chart 2: The Griffith University/AstraZeneca Process at a Glance

4.4 The Samples

The Herbarium and Museum register and maintain the collections of voucher specimens of all samples collected, and provide sub-samples of these for biodiscovery. Institutions in China and PNG also maintain voucher specimens. Plant samples are air dried and ground to a powder, and marine samples freeze-dried and ground. Eksitis maintains its collections in powder form. Funds to cover collections over the course of the Astra Zeneca partnership have totalled AUS$9 million, and the collections are entirely owned by Griffith University (R.Quinn, pers. comm., November 2007).

Biota samples collected for extraction and screening are 100 grams. This is a great deal less material than previously required by screening programmes. Advances in screening technology, in particular minaturization, means that 200mg of a sample can provide sufficient extract for screening. In contrast, for example, between 1974-1981 the Roche Research Institute of Marine Pharmacology (RRIMP) in Sydney screened 2,100 extracts against a panel of screens over seven years. Sample collections were 10kg of wet marine organisms, in contrast to the 100 gms of today's samples (Camp and Quinn, 2007; Griffith University, 2007). Advances in technology support requirements in the Queensland Biodiscovery Act (2004) that collections be of the minimal amount of biota necessary (See Part 1 3(1)(a), Part 3 and Schedule to the Act).

Once samples enter the building, they are numbered and information associated with the sample - e.g. on taxonomy, collection date and location, collecting institution and individual collector, and species abundance – is entered into a database. This assists with both tracking and monitoring samples throughout the research process for access and benefit-sharing purposes, re-collection (including any concerns associated with sustainability), and identifying factors that contribute to bioactivity such as season, location, and stage in reproductive cycle.

4.5 The Role of Traditional Knowledge

Traditional knowledge was not collected as part of the AstraZeneca- Griffith University partnership. This is primarily because for the disease categories of interest to AstraZeneca – in particular those afflicting older and more affluent populations – traditional knowledge is not considered an important lead for drug discovery efforts (Ron Quinn, pers. comm., 2007). In some cases, species that show promise in the NPD discovery process have also been used in traditional medicine, but traditional knowledge, given the broad, systematic screening process undertaken at Eskitis, did not lead researchers to these species. Indirectly, traditional knowledge informed collections in China, in that species, genera, and families used in TCM were requested as part of collections made by the ZiYuan Medical Company, but this was as a way

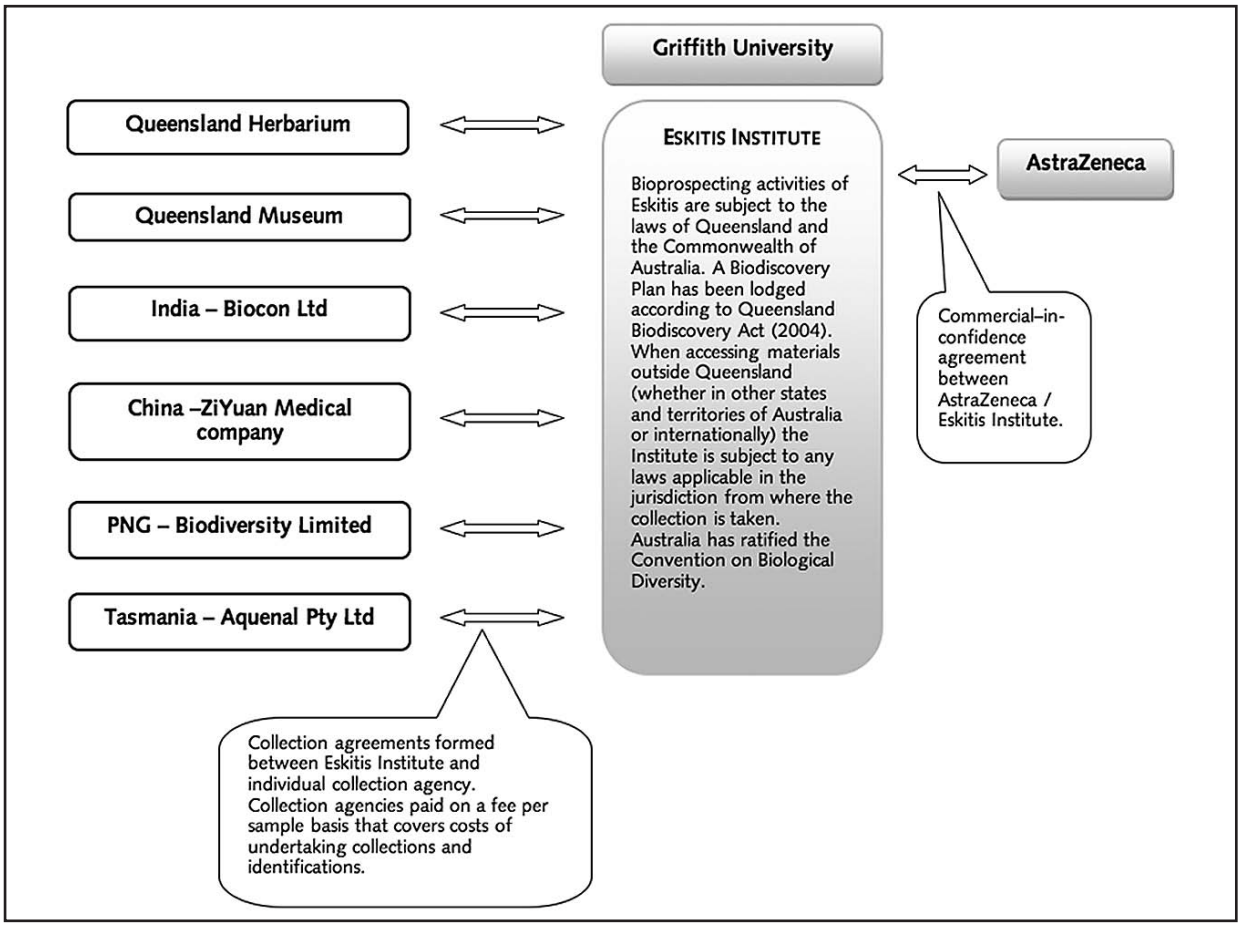


Chart 3: Legal and Institutional Arrangements at a Glance

of selecting broadly for activity, and information on how species are used traditionally was not supplied with the samples.

Concerns associated with traditional knowledge and indigenous peoples' rights to control the use of their knowledge and resources have also been raised about collections, especially those made on Aboriginal lands, and the need to develop side agreements with the Aboriginal people whose land and resources are accessed (e.g. Background Briefing, 2001). It is clearly critical that the role of indigenous stewardship and ownership over resources found on their lands is recognized and respected, even if traditional knowledge is not used in the research process (e.g. see Article 8j of the Convention on Biological Diversity). In this regard, the Queensland Herbarium assert that they did not collect on Aboriginal lands as part of this partnership, and most collections were made in national parks like the Daintree Rainforest or otherwise on crown lands (P.Forster, pers. comm., 2007; G.Guymer, pers.comm., 2007). Broader concerns around such issues are discussed further below under "Concerns Expressed About the Partnership."

4.6 Queensland and Federal ABS Measures and the Partnership

The partnership between Griffith and AZ was formed in 1993, the same year that the Convention on Biological Diversity entered into force. As such, formation of the partnership pre-dated the CBD, and Queensland and Commonwealth government ABS measures. It was only eleven years later that the Queensland Government enacted the Queensland Biodiscovery Act (2004), the first specific state based access and benefit sharing legislation in Australia. This followed adoption in 2000 of the Commonwealth Regulations pursuant to the Environment Protection and Biodiversity Conservation Act 1999 (the ABS provisions of which - Part8A - did not come into force until 2005) and the endorsement by the States and Territories in 2002 of the "nationally consistent approach for access to and the utilization of Australia's native genetic and biochemical resources." For many years prior to these legislative developments, the partnership operated in an ABS policy vacuum, without specific guidance from government, but following then standard procedures for permission from the Department of Environment and Heritage (now Department of Environment and Water Resources).

Experience generated through the AstraZeneca and Griffith University partnership helped to shape the Queensland Biodiscovery Act, as well as Commonwealth policy and legislative development.

Commonwealth officials and the Chair of the Commonwealth Inquiry, Mr. John Voumard, were early visitors to the Eskitis Institute and a consultative relationship has continued over the last seven years. Information gathered during marine and terrestrial collections also helped in the development of the legislation through inputs of data submitted during the public consultations process.

Although the NPD partnership pre-dated the CBD and domestic legislation, adherence to these measures is a significant part of the partnership's strategy. This makes sense not only legally and ethically, but it supports sound science and recollection efforts, and provides potential industry partners with the legal certainty they seek. Reference to supporting and adhering to the CBD, and Queensland and Federal ABS measures, is a regular feature of NPD outreach and publications (e.g. Camp and Quinn, 2007; Eskitis Institute, 2007).

4.7 Concerns Expressed about the Partnership

A range of concerns about the drug discovery partnership were expressed at various stages in the partnership. For example, successive radio programs on the Australian Broadcasting Corporation gave voice to interviewees who objected to the exclusivity of Griffith University's relationship with AstraZeneca and the "locking up" of Australia's resources by multi-national companies. They also expressed concern about collections on Aboriginal lands, and some alleged that collecting on lands soon to be subject to Native Title was hurried to avoid the extra burdens for collectors that Native Title determinations were thought to bring. Other concerns related to insufficient attention to the rights and interests of traditional knowledge holders, as well as the fairness of royalties paid by AstraZeneca to Australia in the event of commercial product development (Background Briefing, 2001; Background Briefing, 2002).

Partnership members responded that, while other researchers and companies could not access the samples collected under the programme, it was possible for any group to collect the same species through other avenues. The Museum and Herbarium also argued that samples collected through the partnership would not have been collected without the support of AstraZeneca, and that a period of exclusivity is a small price to pay for this outcome. It was also asserted that collections were not made on Aboriginal lands, traditional knowledge was not an element in the research process, and that royalties accruing to Australian institutions were within the standards of 'best practice' common for bioprospecting agreements around the world, and the wider benefits far more substantial.

In part, these concerns reflect global expressions of unease with the ethical, legal and political implications of new biotechnologies, commercialization and ownership of life forms, patenting of gene sequences, and broader concerns about globalization and corporate behaviour which have been absorbed into the ABS policy debate (Laird and Wynberg, 2005). In Queensland they were partly addressed through the 2004 Queensland Biodiscovery Act. In any agreement between a public body or publicly-funded institution and a private enterprise involving a publicly-held resource, tensions will exist between the public's need for transparency

and the commercial sensitivities and requirements for confidentiality. A balance must be struck between these respective needs. It is clearly necessary for public-private partnerships and all bioprospecting agreements that trade in the "national patrimony" of genetic resources, to engage in a transparent and open process of consultation and information-sharing with the public throughout the lifetime of the agreement.

It is also the case, however, that within Australia particular attention must be paid to the equity and benefit-sharing associated with any commercial partnership that relies on Indigenous peoples' land, resources, and/or knowledge. Currently, Indigenous peoples who are Native Title holders are recognised as the access providers for the purpose of the Federal Regulations. Indigenous peoples having no such title, but nevertheless asserting that they are the rightful custodians of lands have lesser protections. These people may fall into the category of those who have put in an application for a Native Title Determination and been rejected, have been waiting for a Native Title Determination, or are not eligible to apply for Native Title. There are many reasons why a Native Title Determination may fail, and the process of determining Native Title is not lacking in contention (Strelein, 2006; Reilly, 2002). That Native Title rights are inadequate as a complete redress for Indigenous dispossession and disadvantage has also been acknowledged in judicial comment, such as, for example, the remarks of Justice Callinan in the High Court of Australia case Western Australia vs. Ward, when he stated "it might have been better to redress the wrongs of dispossession by a true and unqualified settlement of lands or money than by an ultimately futile or unsatisfactory, in my respectful opinion, attempt to fold native title rights into the common law" (Western Australia vs. Ward [2002] HCA 28, p. 970), It is the assertion of some Indigenous advocates and legal experts that the Australian approach to access and benefit sharing must strengthen the rights of Indigenous peoples who are not Native Title Holders, but who nevertheless assert themselves as the traditional owners of lands on which bioprospecting may take place (Christine Black, Griffith University, pers. comm., 2007; Megan Davis, pers. comm., 2008).

Currently, many of these non-native title holders fall within the jurisdiction of the States and Territories. In the case of Queensland, for example, obligations to share benefits with Indigenous persons whose knowledge is used is restricted to an obligation to share benefits as set out in the Queensland Biotechnology Code of Ethics. Most other jurisdictions in Australia, as described in Section 3, are still developing their ABS approach. It is important that, in the course of their policy development, states adequately take into account the interests of Indigenous peoples who are not Native Title holders, and explore ways to ensure that an ethical and equitable approach to ABS is instituted in these cases. Suggestions include broad benefit sharing with Indigenous peoples, whether or not commercial products are derived from traditional knowledge, in recognition of Indigenous peoples as the prior custodians of all Australian lands. These benefits might include access by Indigenous Health Centres, particularly in areas where collections take place, to any drugs developed; and development of a philanthropic fund, fed by a portion of any royalties received by the State, that addresses Indigenous peoples' priorities and needs (Christine Black, pers. comm., 2007; Megan Davis, pers. comm., 2008).

5. Benefits from the Partnership

AstraZeneca invested more than AUD$100 million over the fourteen year lifetime of the partnership, and Australian institutions contributed expertise, infrastructure, and financial incentives. Queensland, and to a lesser extent China, India, PNG, and Tasmania, provided access to their remarkable biological diversity. Of the AstraZeneca investment, AUD$45 million went to build the research unit at Griffith University, annual costs of running the partnership came to roughly AUD$9 million/year, and AUD$9 million went towards collection of samples by partner institutions. Benefits accrued to the range of collaborators in the partnership – Astra Zeneca, Griffith University, the Queensland Herbarium, the Queensland Museum, and companies and institutions in China, India, Papua New Guinea, and Tasmania. At the same time, broader benefits were achieved or may still emerge for the State of Queensland, the Australian research community, the Australian public, and the international community. Benefits that accrue to a cross-section of stakeholders include those that helped build scientific and technological capacity within the State and country, and contributed to the management and conservation of biodiversity.

Benefits included monetary remuneration like fees for samples (or to cover the costs of an agreed-upon workplan) and royalties. Non-monetary benefits included the provision of vehicles, equipment, technology, training, building of a state-of-the-art natural product discovery unit, and increased knowledge of biodiversity. Royalties may or may not materialize, since they are dependent upon a drug reaching the market. However, immediate monetary benefits in the form of funds to support the work of collaborators - e.g. collecting samples, undertaking extractions, HTS, and optimizing leads - and non-monetary benefits like facilities, equipment, training, and capacity-building were shared throughout the partnership. The following is a discussion of the benefits that accrued to various partners and groups during the course of the partnership.

5.1 The Eskitis Institute, Griffith University

The Eskitis Institute received the bulk of monetary and non-monetary benefits over the course of the partnership. Monetary benefits include royalties, within a range common to the industry but not publicly available (as is standard practice in bioprospecting agreements with pharmaceutical companies). Financial support for agreed workplans, including hiring staff, purchase of equipment and infrastructural support was also significant, with annual payments to Griffith University averaging AUD$7 million/year.

The most significant benefit for Griffith University is the combination of enhanced expertise, biota collections and compound libraries, scientific and technological capacity and know-how, and infrastructure in the form of a new state-of-the art facility, acquired during the course of the partnership which – together – have created a leading natural product discovery unit. Now that the exclusive partnership with AstraZeneca has switched to a non-exclusive project-by project basis, Griffith University can leverage these assets into new partnerships with academia, government, public-private partnerships and most significantly, with other companies.

The Griffith/AZ was extremely unusual for bioprospecting partnerships, which generally involve little more than the collection of samples sent to companies for screening. The high level of involvement of Griffith University staff in the R&D process, and their close and regular contact with researchers at AstraZeneca, resulted in enormous benefits for science and technology in the region. It allowed staff to gain experience in working with industry according to their requirements and timescales, as well as in the science and technology of HTS, robotics, separation of complex mixtures, and medicinal chemistry, and to become a leader in those areas within the country. Griffith University is now able to identify, separate and convert a natural product into a normal medicinal chemistry product, which removes much of the complexity and cost traditionally associated with natural products. At a time when in-house natural product discovery programs are starting to become outsourced by the large pharmaceutical companies (Koehn and Carter, 2005), natural product discovery is increasingly done by smaller companies and academic and government research institutes, which then license compounds to large pharmaceutical companies for development, Griffith University is well-situated to play an important role in this field in the coming years.

Specific benefits to the Eskitis Institute that combined to create this state-of-the-art natural product discovery unit over the last fourteen years, include:

Building expertise

Roughly 113 staff received training and worked for the partnership at Griffith University over the course of fourteen years; many of these have gone on to other institutions and companies (e.g. MerLion in Singapore, Walter & Eliza Hall Institute, Bionomics, Kyoto Pharmaceutical University, Victorian College of Pharmacy, Institute for Molecular Bioscience). Given the shortage of training opportunities in natural product research, this building of expertise is a significant benefit not only for the University, but for the country and the field of natural product research.

Students were not actively involved in the partnership's research, given their need to publish and constraints placed on publications resulting from the partnership. However, students are involved in new research projects that grew in part from the partnership, such as that on neglected diseases (see below). A stream of graduates were also hired over the years as research assistants by the partnership, and after their work with advanced technologies and equipment, fourteen went on to do PhDs.

BOX 5: THE QUEENSLAND COMPOUND LIBRARY- BENEFITS FOR GRIFFITH UNIVERSITY, AUSTRALIA AND THE REGION

Until relatively recently, large pharmaceutical companies have been the sole beneficiaries of substantial compound libraries and automated platforms to facilitate the identification of small molecule modulators for the druggable genome. Over the last five years, however, a growing number of non-industry organizations have emerged with high-throughput screening (HTS) capabilities to interrogate biology space not typically prosecuted by industry and also to undertake early phase drug discovery, including neglected diseases like malaria and sleeping sickness. The most prominent non-industry programme is the U.S.A.'s National Institute of Health's (NIH) Molecular Library Initiative.

The Queensland Compound Library (QCL) is the first non-industry compound management and logistics facility in the southern hemisphere. It was established in 2005 at the Eskitis Institute for Cell and Molecular Therapies at Griffith University with funding from the Queensland Government and Griffith University.

Biological screening is arguably the strongest mechanism to engage both the biology and chemistry research communities. The consolidation of Australasian chemistry at a central repository will result in a greater coverage of chemistry space than any single collection in the region currently achieves (Camp and Quinn, 2007; Camp et al, in press). This, in turn, provides a resource of tremendous value to biomedical researchers. The QCL employs microtube technology, as opposed to a plate based system, to assist rapid cherry picking of individual samples. Microtube subsets for retest and counter screens can be accessed as easily as the entire set is for a primary screening campaign.

The QCL provides a mechanism for chemists to increase the potential value of their compounds through testing for biological activity by targets emanating from biomedical researchers (Camp, 2007; Camp and Quinn, 2007; Camp, pers. comm., 2007). Storage of compounds can be 'passive' or 'proactive', with passive storage occurring when a chemist submits samples for potential access by biologists, and proactive storage where the chemist pursues third-party collaborations with, for example, an industrial partner (Camp and Quinn, 2007). Any organization, including academia, publicly and/or privately funded research institutes, and industry can access the QCL.

The composition of a compound library can vary depending on whether the ultimate goal is chemical biology or drug discovery. Lead generation libraries include molecules that are used in drug discovery and have a more limited range than, at the other extreme, a compound library that could be comprised entirely of "probe" compounds or chemical "tools" used to further our understanding of biological processes. Ways that molecules may be derived to contribute to the diversity of a compound library include: natural products and semisynthetics inspired by natural products; targeted-oriented synthesis; diversity-oriented synthesis; and combinatorial chemistry libraries (Camp and Quinn, 2007).

The "Lead-Like Peaks" (LLP) library, which enriches lead and drug-like components from natural products extracts, is stored at the QCL. It is a pre-fractionated library containing either pure compounds or mixtures of 2-4 compounds. The LLP library contains around 300,000 natural products with the following advantages over conventional crude natural product extract screening including: natural products with drug-like physico-chemical properties; it is devoid of salts, sugars, and most lipids; and minor active compounds are more likely to be discovered using the LLP library. The HiTbaSe program tracks all extraction, screening, and isolation operations to the original biota, including location data to aid recollection (Eskitis Institute, Griffith University, 2007).

Australia has high quality basic science, funded by the Australian Research Council and National Health and Medical Research Council, but it is weaker in translating innovative discoveries to commercial outcomes. To help create incentives for commercialization, the QCL does not claim any intellectual property owned or generated by users of the facility, adopting instead a unique IP model somewhere between the proprietary culture of industry and the NIH policy of placing data in the public domain. Investors are given 100% ownership of the IP they create, thereby creating a protected IP environment for progression of promising commercial ventures (Camp, 2007; Camp and Quinn, 2007; Camp et al, in press; Burton, 2006).

Researchers from Australia are in the process of rolling out the Molecular Screening Collaboration (MSC) which incorporates a fully automated compound management facility (QCL) and two HTS sites (the Eskitis Institute and Walter and Eliza Hall Institute). The aim of the MSC is to provide researchers across Australasia with coordinated and affordable access to compound libraries and HTS. The MSC platform is "well-equipped with technology that would not be out of place in an industrial setting." (Camp et al, in press). Specific project costs will typically be borne by the user, and other overheads evaluated on a case-by-case basis. Industry may be charged at full cost, for example, whereas academic groups could bear project-related costs only.

The QCL and the GU/AZ partnership

Although the Queensland Compound Library was established through Griffith University and the Queensland State Government, it benefited enormously from the AstraZeneca partnership. David Camp, the Director of the QCL, was also part of AstraZeneca's Compound Management Network and was able to access pertinent information through the company for building the QCL. AstraZeneca also largely financed the HTS capabilities within Griffith University that are part of the MSC initiative. The Eskitis Institute's *NatureBank*™ consists of 45,000 specimens representing unique biological diversity collected during the AstraZeneca collaboration, and the LLP library. AstraZeneca funded Eskitis' in-house development of a proprietary process to retain and enhance the lead- and drug-like components suitable for the pharmaceutical industry to prosecute as potential therapeutics from biota specimens. These optimized extracts were fractionated and termed the LLP library (Eskitis Institute, Griffith University, 2007) and are available for screening by third parties as *NatureBank*.

Biota collections and compound libraries

Griffith University retains ownership over the samples collected as part of the NPD. The result today is the *NatureBank*, a collection of over 200,000 optimised natural product extracts derived from a biota collection of plants and marine invertebrates from the region. This screen-ready set of fractions, stored in the Queensland Compound Library, has been developed using proprietary optimisation techniques to create a library of "Lead-Like Peaks."

The entire biota collection is composed of 45,000 samples from biologically diverse terrestrial and marine sites in Queensland, Tasmania, China, India, and Papua New Guinea. These represent "unparalleled taxonomic breadth containing almost 60% of global plant diversity at the family level, including all major plant families containing more than one genus... and 9,500 samples of marine invertebrates, including 10% of global diversity of the world's sponges and ascidians and 5% of global diversity of soft corals and gorgonians" (Eskitis Institute, 2007).

The Institute has developed advanced systems for chemical isolation and structure identification that led to the discovery of more than 800 bioactive compounds, some of which have been developed further by AstraZeneca, and some of which are stored in the Queensland Compound Library.

Scientific and technological capacity and know-how

The partnership exposed Australian scientists to natural product discovery in an industry setting, and access to the latest scientific and technological advances. HTS was first performed at Griffith University in the early 1990s, some ten years before any public group in the country. The partnership, by incorporating the most advanced and 'cutting edge' equipment and technologies, also allowed Australian science to stay abreast of new developments in imaging and separation technologies (Camp and Quinn, 2007).

Intellectual Property Rights

Griffith University retains ownership over the biota samples and compound libraries that resulted from the partnership. Intellectual property rights to commercial products developed from the partnership remain with AstraZeneca.

Publications

Publications are a measure by which individual scientists, scientific institutions and universities are judged. Past publication records are often directly linked to recruitment criteria, and to institutional funding allocations. The ability to publish is also a feature that helps to attract the best students and staff to a project, and ensures research results reach a wider audience with the associated benefits that the free flow of information generate. Despite restrictions placed on their ability to publish scientific articles from research arising from the drug discovery program, staff of Eskitis Institute published more than 140 articles on natural product drug discovery over the course of the partnership.[10]

5.2 Griffith University

Beyond the Eskitis Institute, Griffith University benefited from the partnership with AstraZeneca through the contribution of the partnership to its overall funding base and enhanced research reputation, and as a result it has been significantly more competitive in university league tables. The University also benefits from the resulting facility and assets of the Eskitis Institute, which are now available to researchers and scientists within the University, and other Australian and international research institutions, as well as new public/private partnerships.

5.3 The Collecting Institutions

The benefit-sharing package in place for collecting institutions is standard across institutions and includes up front fees per sample that cover costs of collection including staff, equipment (e.g. compound microscopes, computers, field equipment), and vehicles, as well as identification of species, and royalties should a commercial product be developed. Roughly AUD$9 million was spent on collections over the course of the fourteen years of the partnership. Royalties accrue to the State of Queensland for collections made by the Queensland Herbarium and Queensland Museum, to the government for collections in Papua New Guinea, and to companies collecting under contract in China, India, and Tasmania. The benefit sharing received by collecting agencies is fifteen percent of that received by Griffith University.

Staff and training

The Queensland Herbarium was able to employ a botanist and technical officer for the duration of the program, which required an experienced botanist who knew what to collect, how to collect, and with good field knowledge and good knowledge of the flora (G. Guymer, pers. comm., 2007). Graduate students associated with the Queensland Herbarium used collections to discover new compounds, and these were published in the scientific literature with Herbarium staff as joint authors (G. Guymer, pers. comm., 2007).

The Queensland Museum supported four full-time parataxonomic positions at the Museum each year, some individuals remaining for many years, and receiving more in-depth training in taxonomy, curation, and marine collection skills. A total of twenty individuals received training over the fourteen years of the partnership, and five of these have gone on to become taxonomists, and a few to also study molecular biology and chemistry, one of whom now heads-up the Sponge Barcoding Project (Hooper, 2007; J Hooper, pers. comm., 2007;

www.spongebarcoding.org). Taxonomic research on newly acquired collections was also supported through postdoctoral research fellowships partially funded by the NPD collaboration and partially by other traditional sources of funding (Hooper, 2007).

The value of support for staff, and training in collection, curation and taxonomy cannot be overstated. Although the government promotes academic and commercial partnerships based on the country's unique flora and fauna, and there is increasing demand for taxonomic skills to assist with environmental planning, management and conservation, funds for taxonomy remain limited. The Australian Marine Sciences Association reports a steady decline in the number of taxonomists over the last decades, with the latest count showing twenty-three marine taxonomists in Australia's museums and research agencies. Nine have retired in the past five years and have not been replaced (Leung, 2007). State governments are the main employers of taxonomists through their herbaria and museums, but are unable to maintain the taxonomic work force in the face of competing claims on State budgets. The Federation of Australian Scientific and Technological Sciences has initiated a research project looking into the taxonomy skills shortage in marine, plant, insect and parasite science (Leung, 2007).

"There are potentially millions of species that remain undocumented and yet fewer and fewer people are employed in this area, or have the necessary taxonomic expertise. Commercial partnerships are currently a major source of employment and support for the development of taxonomic capabilities in research institutions in this country, especially long term collaborations such as that with NPD for which a few key staff were employed for over a decade..." said John Hooper of the Queensland Museum, "Some people, particularly those with political and managerial agendas, feel naming things is futile without a direct economic outcome – this is another reason why biodiscovery has been good in Australia. Not only does the partnership have immediate non-monetary benefits (data for management decisions, conservation planning, and so on), and potential downstream monetary outcomes (royalties), but it also has the knock-on effect of making government more interested in supporting these kinds of jobs." (J Hooper, pers. comm., 2007).

Biodiversity information

The most common and significant benefit cited by collecting institution staff from the NPD is the support for collections that would otherwise not be possible within institutions dependent upon limited government support, and the biodiversity information with important scientific and conservation applications that resulted. Marine invertebrate biodiversity, in particular, is poorly known, expensive to collect, and the expertise to document it is grossly inadequate (Hooper, 2007). Taxonomic identification is expensive and time-consuming, and most research institutions have backlogs which cannot be covered with government support; commercial partnerships are seen as an important way to get this work - central to the Herbarium and Museum's mission – done. As Geoff Burton put it:. "Without knowledge about what species exist, their distribution and their interaction, no informed and sensible environmental management decisions can be taken. Without a comprehensive taxonomy governments cannot safely allocate resources and set priorities for conservation and natural resources utilisation" (Geoff Burton, pers. comm., 2007).

The Queensland Herbarium "always viewed the increase in the knowledge about the State's flora as its [the partnership's] major benefit and the funding from the program delivered this outcome" (G. Guymer, pers comm., 2007). The GU/AZ drug discovery partnership supported collections and research by the Herbarium that resulted in the discovery of more than 100 species new to science, many of conservation concern, together with hundreds of new records for the distribution of species (e.g. the extension of range), and collections in parts of Queensland that had never before been systematically surveyed (G. Guymer, pers. comm., 2007).

Expansion of institution collections are a significant benefit of the partnership. More than 16,000 plant specimens were added to the herbarium collection (G. Guymer, pes comm., 2007), and the Queensland Museum incorporated 12,000 specimens of roughly 5,000 species of marine invertebrates and algae into its permanent collection (Hooper, 2007).

These marine specimens yielded more than 200 bioactive compounds, most with novel bioactivity, and twenty-three new structural classes discovered. Sponges (Porifera), in particular, were most productive, both in terms of new chemical compounds and species diversity (Hooper, 2007). In 1994, there were 1,385 species of sponges described for the entire Australian fauna (including its external territories), with less than half of these known to live in tropical waters; this knowledge took 200 years to acquire (Quinn et al, 2002). In contrast, over the past fifteen years, 3,000 sponge species were discovered, about 70% new to science, providing a three-fold revision of previous estimates of sponge diversity in Australia and worldwide (5,000 and 15,000 respectively). (Hooper, 2007). The conservation benefits linked to the biodiversity information yielded by accumulation of plants and marine invertebrates for the Eskitis biota collection are further discussed below.

5.4 Benefits for Conservation of Biodiversity

Although "access and benefit-sharing" (ABS) arrangements are linked to the conservation of biodiversity within the Convention on Biological Diversity and national ABS measures, in practice many ABS partnerships manifest few concrete benefits for conservation. When samples are provided but specimens are not lodged with national research institutions, and these institutions are not supported through collections,

BOX 6: ESKITIS RESEARCH ON NEGLECTED DISEASES

The Eskitis Institute is working with a range of international organisations in the search for new therapies to combat neglected diseases. These include the Seattle Biomedical Research Institute (SBR) on the biology of disease-causing parasites, the Medicines for Malaria Venture (MMV) and the Drugs for Neglected Diseases Initiative (DNDi). These groups are supporting HTS campaigns at Eskitis Institute to identify natural products that show promise against malaria and sleeping sickness (Quinn, pers comm, 2007; Eskitis 2007). The Institute is also part of an NIH-funded Trypanosome Drug Development Consortium alongside Seattle Biomedical Research Institute, University of California at San Francisco, University of North Carolina at Chapel Hill and Dundee University. Through these partnerships, the Eskitis Institute is leveraging the scientific and technological capacity built through the partnership, as well as the biological diversity represented in its library, to address the medical needs of the world's poor, to which industry devotes limited resources. This research is also supported by the Queensland Governement's Smart State Innovation Projects Fund.

BOX 7: DEVELOPMENT OF A NEW ANALGESIC PRODUCT FROM TRADITIONAL KNOWLEDGE: THE GRIFFITH UNIVERSITY AND JARLMADANGAH BURU PARTNERSHIP

Independent of the Astra Zeneca partnership, but building in part on the scientific expertise and institutional capacity supported by the partnership, the Eskitis has investigated new analgesic compounds from the bark of Barringtonia acutangula, a mangrove found in Northern Australia, Asia and eastern Africa. Used extensively in traditional medicine, as well as a fish poison, the species was brought to the attention of Eskitis researchers by the Jarlmadangah Buru people of the Kimberly region of North West Australia in the early 1990's. "We are working with an Aboriginal group from Western Australia who have brought traditional knowledge of when and where to collect the bark to ensure the active ingredients are present. The Institute's research team has already confirmed the bark's biological activity in an animal model assay and is focusing on large-scale extraction and isolation of the compounds in quantities that will allow for their pharmacological evaluation as potential analgesic drugs," said Ron Quinn, Eskitis Institute Director (Griffith University, 2007). The project recently received AUD$175,000 from the National Health and Medical Research Council to undertake large-scale extraction and isolation of the novel compounds in quantities sufficient for pharmacological evaluation as potential analgesic drugs. (National Research Council, 2004).

A company is being incorporated to manage the commercialization of the product, which might be a botanical remedy, a pharmaceutical, or both. The partnership between Griffith University and the Jarlmadangah Buru has taken a number of years to develop, and included many visits by Griffith University staff to Western Australia, and Jarlmadangah Buru representatives to Griffith University. Jarlmadangah Buru representatives also visited Canada to meet with indigenous groups there and learn about commercial partnerships based on traditional knowledge. The agreement between Griffith University and the Jarlmadangah Buru provides that, should a commercial product be developed, any returns will be split 50:50 between the Aboriginal group and Griffith University (Skatssoon, 2004). This is based on the premise that traditional knowledge on the species use and collection, and scientific expertise to isolate and develop compounds, contribute equally to realization of the final product. Outside companies approached to commercialize and market the product will negotiate directly with both (Quinn, pers. comm., 2007).

the benefits for conservation can be limited to none. In very few cases, bioprospecting partnerships include payments to protected areas or direct support for local conservation institutions, such as InBio's work with Merck in Costa Rica (Reid et al, 1993), the Yellowstone National Park and Diversa in the US (ten Kate et al, 2002), and partnerships between the Kenya Wildlife Service and the biotech companies Novozymes and Diversa (Laird and Wynberg, 2008). In almost every case, however, the most significant conservation benefits resulting from bioprospecting partnerships are found in the generation of biodiversity information critical for setting conservation priorities, for conservation planning, and for management (Laird and ten Kate, 2002).

The collections that took place under the GU/AZ partnership are a striking example of this type of benefit for conservation, providing support for collections of marine and terrestrial organisms, particularly in Queensland, that identified new species and populations of endangered species, provided critical information on biodiversity 'hot spots', and was used not only in drafting the Queensland Biodiscovery Act 2004, but in environmental planning and management throughout the region.

In addition to collecting and identifying 100 plant species new to science[11], and new records on the distribution of species, the Queensland Herbarium also found new populations of threatened species in remote areas that provided genetic resources for propagation, and documented weed encroachment in native forests that has helped inform forest management (DTRI, pers comm., March 2008). The Herbarium conducted surveys in areas that had never been explored botanically, such as the northern part of the Daintree National Park in the wet tropics, and Bladensberg, Lochern and Diamantina National Parks in western Queensland; "…essentially,

the state was criss-crossed, with over 16,000 plant specimen collections made", said Gordon Guymer of the Queensland Herbarium.

The Queensland Museum made dramatic taxonomic discoveries as a result of their work for the partnership, and has also made some major advances in the knowledge of spatial distribution of marine organisms across northern Australia, which in turn has contributed to marine conservation and planning processes. This has included the delineation of Marine Protected Areas (MPAs) based on faunal characteristics. It also provided data to undertake biodiversity "hot spot" analysis across northern Australia, identifying areas of comparative species richness, high endemism, and phylogenetic relationships amongst these regional faunas (Hooper, 2007). The material collected from the Eskitis biota collection and other projects also allowed the study of population genetics of some species, and an analysis of "beta diversity" trends (spatial patterns where there are major species turnover points across an environmental gradient) at medium and large spatial scales. As a result, it was possible to delineate a number of biogeographic transition zones across northern Australia and compare these data to traditional marine biogeographic models for Australia. These sorts of data were useful to national bioregional planning processes in both State and Commonwealth waters such as the Great Barrier Reef Marine Park Authority and the Representative Areas Program (Hooper, 2007).

5.5 AstraZeneca

AstraZeneca benefited from the partnership with Griffith through access to the remarkable marine and terrestrial biological diversity of Queensland, and to a lesser extent Tasmania, China, India and Papua New Guinea. They also benefited from collaboration with an increasingly sophisticated natural products discovery unit that worked closely with AstraZeneca researchers, from the existing high levels of scientific expertise within Griffith University and the country, and from working in a country with a robust legal system, and an increasingly clear ABS regulatory environment that grants them legal certainty over the material they study. The Commonwealth and Queensland State governments also provided financial incentives to AstraZeneca in the form of pricing incentives through the Commonwealth's Factor F scheme, and provision of the research building and other support through the Government of Queensland.

5.6 Queensland, Australia and the International Community

The State of Queensland and Australia at large benefited from the investment of AUD$100 million by AstraZeneca in Griffith University, the employment and building of expertise it provided, as well as increased scientific and technological capacity, including the first natural product HTS facility in Australia, and the Queensland Compound Library and Molecular Screening Collaboration that resulted in part from the partnership. Enhanced capacity in working with industry, and improved skills to translate innovative discoveries into commercial outcomes, are also benefits of the partnership (Burton, 2006; Camp, 2007). Opportunities for private/public partnerships and investment in Australia have been enhanced, as well as the potential to employ Australian scientists and thus to alleviate the scientific brain drain which has afflicted the country. Australia will also benefit from the type of innovative business partnerships described in Box 7 that build upon the unique biological and cultural diversity of the country. The Queensland Department of Tourism, Resources and Industry stated "The AstraZeneca/Griffith University collaboration initiated in 1993 has contributed valuable monetary and non-monetary benefits to Queensland. The collaboration contributed to the understanding of Queensland's plant and marine biota with the discovery of 37 new plant species and nearly 1500 new marine organisms. It also resulted in more than $100 million in investment in biodiscovery R&D in Queensland and created 43 fulltime jobs and directly supported some of the research work of the Queensland Herbarium and the Queensland Museum. The types of jobs created have expanded Queensland's highly skilled workforce, and attracted new scientists to Queensland" (DTRI, pers comm., March 2008).

The range of benefits for biodiversity conservation described above serve the public in Queensland, Australia, and worldwide, as do the contributions to scientific knowledge and the potential development of new medicines. New efforts to conduct research on neglected diseases will also serve the world's poor (See Box 6).

Table 2: Benefits From the Griffith/AstraZeneca Natural Product Drug Discovery Program

Collection Agencies	Eskitis Institute	Griffith University	Astra Zeneca	State of Queensland	Australia	International Community
Contribution to overall Institutional funding base. Enhanced knowledge of local species (including several new to science) and their distribution, and use of funded expeditions for expanding own sample collections. Resources and opportunities for training taxonomists (in context of worldwide shortage of taxonomic expertise). Remaining possibility of receiving royalties if any pharmaceutical products based on screening are commercialized (where contracts included provision for royalties) .	Assets (Sample collection of more than 45,000 biota samples, equipment, proprietary methods, expertise of personnel) remaining in possession of the Institute at end of contract term and able to be used by Eskitis for ongoing scientific research and as part of commercial endeavour offering screening services. Collaboration led to the Institute becoming a global centre of excellence, with the capacity to attract expertise, funding, and commercial partners. Employment of over 110 scientists and support staff. Scientific publications. Training for Students. Remaining possibility of receiving royalties if any pharmaceutical products based on screening are commercialized.	Contribution to university funding base. Enhanced research reputation. Enhanced funding and research base led to Griffith being significantly more competitive in university league tables. Ongoing capacity to attract other public/ private sector partnerships. Remaining assets at Eskitis and ongoing resources available to other research scientists at Griffith and throughout Australian and international academic community.	Access to 45,000 biota samples for use in drug discovery. Access to benefits of proprietary techniques (e.g. LLE/LLP) developed by Griffith researchers. Security of conducting research activities in jurisdiction with a clear access and benefit sharing regime, and a robust system of law. Advantages of conducting research in State committed to fostering research and innovation, providing good research infrastructure, a highly qualified pool of expertise, and financial incentives for investment. Remaining possibility of developing pharmaceuticals resulting from sample screening.	Enhanced research reputation. Capacity to attract further investment/ expertise due to assets retained in Queensland. Enhanced knowledge of biota can be used for conservation purposes. Development of Queensland Compound Library. Creation of employment opportunities.	Collaboration attracted private sector investment to the benefit of the Australian economy. Ongoing capacity to attract international investment to the benefit of the Australian economy. Collaboration attracted Australian expertise, alleviating scientific brain drain. Personnel increasing their expertise within collaboration have taken their expertise to other Australian Institutions. Most staff indicate a wish to remain in Australia. Enhanced knowledge of biota from Queensland and other Australian jurisdictions useful for Australian scientists and for conservation management.	Enhanced knowledge of global biodiversity. Continued access on mutually agreed terms by public and private sector to samples. Potential for collections, expertise and capacity to be used as part of research for the public good, including neglected diseases. Potential for global public health to benefit from any pharmaceutical products eventually developed and commercialized.

6. Conclusions

The Griffith University/AstraZeneca natural product drug discovery partnership provides a valuable opportunity to examine the ways bioprospecting partnerships can yield benefits for provider countries, and for biodiversity conservation, over time. Running for fourteen years – much longer than most other such ABS partnerships – it offers a window onto the extent of scientific and technological capacity that can be built and the enormous wealth of biodiversity information that might be collected and analysed. It also illustrates how the benefits articulated in ABS policy documents can come together over time to add up to more than the sum of the parts.

Monetary and non-monetary benefits in this case fall within the standard package for "best practice", but it is in the accumulated and multi-faceted nature of the benefits that the real gains for the State and country are to be found. These include the collections and compound libraries, the advanced natural product discovery unit, and the enormous gains in taxonomic and ecological understanding that resulted from the collections. This case demonstrates that these benefits can be of equal, or greater, importance to the potential monetary benefits from royalties should a product be commercialized.

The pre-conditions that attracted AstraZeneca make this a difficult model to reproduce in many other countries – e.g. existing high levels of scientific and technological capacity, unique biodiversity, a legal system that provides legal certainty, and government incentives for investment. However, study of this partnership is instructive in terms of providing an example of what ABS 'best practice' in partnerships generally seeks to achieve. This includes a wide range of benefits in the short, medium and long term, undertaking high levels of research within provider countries, building scientific and technological capacity, and significant benefits for biodiversity conservation. The building of capacity within partner institutions (i.e. AstraZeneca, Griffith, Queensland Museum and Herbarium) in ABS policy under the CBD, and working within new state and federal ABS regulations, is also a significant benefit of the partnership.

In many countries, widespread concerns about such a partnership would have forced a process of public outreach and consultation more extensive than was found in this case. As awareness grew of the need for ABS arrangements to be 'fair and equitable', however, the State and Commonwealth governments undertook development of ABS measures that addressed many of these concerns and relieved the partners of having to fill this gap with their own 'consultation' and policy framework, as has been the case for research institutions in many other countries. It is still necessary, however, for research institutions like those involved in the Griffith University/AstraZeneca partnership to make the terms of such partnerships as transparent and publicly-accessible as possible, and to undertake these outreach activities as a standard part of the wider project.

Legal ambiguity in China, PNG, and India during the time of collections appears to be addressed within the agreements reached, which meet most country's standards of best practice in benefit-sharing, however changed regulatory environments in those countries may require revisiting these agreements, in particular the local beneficiaries of monetary benefits in the future.

Conclusion of the exclusive Griffith University/ AstraZeneca partnership provides an excellent opportunity to view in the coming years how the significant accumulated benefits of such a "best practice" partnership can be leveraged to form new collaborations with a range of partners, serve a wider range of public needs (e.g. research on neglected diseases, innovative partnerships based on the country's biological and cultural diversity, support for Indigenous peoples' priorities), and generate benefits for science, medicine, and biodiversity conservation over time.

Endnotes

[1]With growth rates of 3.3 % on average since 1990, low inflation of 2.5 % over the same period, and low levels of unemployment (currently below 5%) (DFAT, 2007).

[2]Assessed by the World Bank in 2005 as being the easiest place in the world to start a business. Australia has been judged as one of the top seven countries in the world for encouraging enterprise competition (Invest Australia, 2007).

[3]However, Sue Coke of the Office of Biotechnology in the Queensland Department of Tourism, Regional Development and Industry, notes that paragraph 10 of the Queensland Biotechnology Code of Ethics requires subscribers to ensure they obtain prior informed consent and negotiate reasonable benefit sharing arrangements in return for access to samples.

[4]Commonwealth areas include:

- land owned by the Commonwealth or a Commonwealth agency (including land owned in Norfolk Island) and airspace over the land;
- an area of land held under lease by the Commonwealth or in a Commonwealth agency (including an area held under lease on Norfolk Island, Kakadu National Park, Uluru-Kata Tjuta National Park, and Booderee National Park) and airspace over the land;
- land in an external Territory (except Norfolk Island) or the Jervis Bay Territory;
- airspace over the land;
- the continental shelf, and the waters and airspace over the continental shelf;
- the waters of the exclusive economic zone, the seabed under those waters and the airspace above those waters; or
- any other area of land, sea or seabed that is included in a Commonwealth reserve.

From http://www.environment.gov.au/biodiversity/science/access/permits.html .

[5]The Minister may be satisfied that informed consent has been given by any native title holders who may be affected by the issue of a permit if the benefit sharing agreement meets certain criteria relating to procedures under the Native Title Act - See Part 8A.10 (3) of the *Environment Protection and Biodiversity Conservation Regulations 2000.*

[6]Applications can be lodged through http://www.environment.gov.au/biodiversity/science/access/permits.html#rop.

[7] Note that the Offshore Constitutional Settlement, an agreement between the Commonwealth of Australia and the State of Queensland, which deals with the Commonwealth and State jurisdiction in the territorial sea, assigns the State responsibility for coastal waters up to three nautical miles from the territorial sea baseline (Australian Government Attorney-General's Department, 1980).

[8]Defined within the Queensland Code of Ethics, "Biopiracy refers to the appropriation of developments or discoveries involving biological resources by another party without consent."

[9]Despite reduced investment from industry, natural products continue to play "a dominant role in the discovery of leads for the development of drugs" and contribute significantly to the bottom lines of pharmaceutical companies: between January 1981- June 2006, for example, 47% of cancer drugs, and 34% of all small molecule new chemical entities (NCE) for all disease categories, were either natural products or directly derived therefrom (Newman and Cragg, 2007).

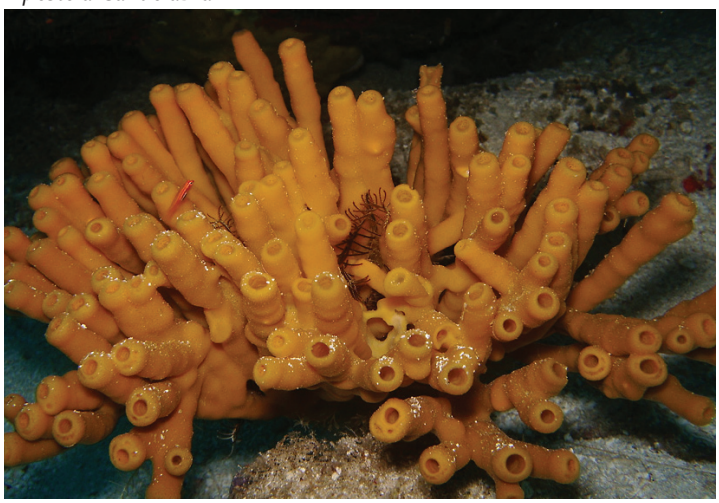
[10]See Annex III. A selection of these are listed on the Eskitis web page of the director Ron Quinn at http://www.griffith.edu.au/professional-page/professor-ron-quinn/publications.

[11] Examples of taxa with specimens collected during the GU/AZ partnership upon which types were based (*=totally new discoveries): **Wahlenbergia celata* P.I. Forst., Austrobaileya 5:661 (2000); **Cycas cupida* P.I.Forst., Austrobaileya 6: 153 (2001) - cycads are 'flagship' species in conservation biology and come from a lineage predating the age of the dinosaurs; *Hydrocotyle oraria* A.R.Bean, Austrobaileya 6: 544 (2003); *Centipeda pleiocephala* N.G.Walsh, Muelleria 15: 54 (2001); **Eucryphia jinksii* P.I.Forst., Austrobaileya 4: 592 (1997) - this species has significant biogeographical importance and is of an ancient angiosperm lineage; *Goodenia debilis* A.E.Holland & T.P.Boyle, Austrobaileya 6: 256 (2002); **Plectranthus fasciculatus* P.I.Forster, Haseltonia 6: 14 (1999); *Plectranthus thalassoscopicus* P.I.Forst., Austrobaileya 4: 653 (1997); *Corchorus subargentus* Halford, Austrobaileya 6: 617 (2004); *Micromyrtus delicata* A.R.Bean, Austrobaileya 4: 457 (1997); **Cryptandra pogonoloba* A.R.Bean, Austrobaileya 6: 930 (2004); *Phebalium distans* P.I.Forst., Austrobaileya 6: 438 (2003); *Solanum dumicola* A.R.Bean, Austrobaileya 6: 770 (2004).

Axinellidae

Sorting sponge collection samples on deck

Pipestela Candelabra



Collecting Marine Samples

Diving for marine samples by Queensland Museum staff

Eskitis Institute for Cell and Molecular Therapies

All photos courtesy of the Queensland Museum

Annex I Interviewees

Geoff Burton
Principal Consultant Genetic Resources Management
Jean Shannon & Associates
Formerly Director Genetic Resources Management Policy
Department of the Environment & Heritage, Australia

David Camp
Head, Biota & Compound Management
Natural Product Discovery
Eskitis Institute for Cell and Molecular Therapies
Griffith University

Anthony Carroll
Associate Professor
Head, Natural Product Chemistry
Natural Products Discovery
Eskitis Institute for Cell and Molecular Therapies
Griffith University

Paul Denerley
IP Strategy Director
Global Intellectual Property
AstraZeneca

Paul Forster
Senior Botanist
Queensland Herbarium

Gordon Guymur
Director
Queensland Herbarium

John Hooper
Head of Biodiversity & Geosciences Programs
Queensland Museum

Mark Jacobs
Manager
Office of Biotechnology
Queensland Department of State Development

Ronald J. Quinn
Director
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Annex III List of Publications Resulting from Partnership

ESKITIS INSTITUTE

List of publications arising from the GU/AZ collaboration (provided by the Eskitis Institute)

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THE QUEENSLAND MUSEUM

List of Publications derived from NPD-funded collections and/or made possible through NPD funding (as provided by the Queensland Museum)

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QUEENSLAND HERBARIUM

Selected List of publications and taxa naming reports arising from the GU/ AZ collaboration (as provided by the Queensland Herbarium)

Collaborative Publications between Queensland Herbarium staff and Griffith University Staff resulting from biodiscovery collaboration. An additional 16 plus manuscripts are currently in production.

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UNU World Institude for Development Economics Research (UNU-WIDER), Helsinki, Finland
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UNU Institute for Natural Resources in Africa (UNU-INRA), Accra, Ghana
Focus: natural resources management
Email: unuinra@inra.unu.edu.gh, URL http://www.inra.unu.edu/

UNU International Institute for Software Technology (UNU-IIST), Macau, China
Focus: software technologies for development
Email: iist@iist.unu.edu, URL http://www.iist.unu.edu/

UNU Programme for Biotechnology in Latin America and the Caribbean (UNU-BIOLAC), Caracas, Venezuela
Focus: biotechnology and society
Email: unu@reacciun.ve, URL http://www.biolac.unu.edu/

UNU International Leadership Institute (UNU-ILI), Amman, Jordan
Focus: leadership development
Email: mbox@la.unu.edu, URL http://www.la.unu.edu/

UNU International Network on Water, Environment and Health (UNU-INWEH), Hamilton, Canada
Focus: water, environment and human health
Email: contact@inweh.unu.edu, URL http://www.inweh.unu.edu/

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