

## National Access Laws: Challenges, Benefit-sharing, Monitoring and Enforcement

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### Introduction

Countries with federal structures of government face very specific challenges when introducing national access laws. Australia is a good case study of those challenges. Its challenges and solutions found may be of interest to other countries dealing with similar issues. Some issues are common whether or not a federal structure exists.

Australia has adopted a pragmatic approach to implementing the CBD's Bonn Guidelines. This approach is guided by the needs of a federal structure, the realities of contemporary scientific research and its market-based, developed economy with a strong stakeholder voice in decision making. This approach is encapsulated in its intergovernmental agreement titled the *Nationally Consistent Approach for Access to and Utilisation of Australia's Native Genetic and Biochemical Resources (NCA)*.<sup>2</sup> All 9 Australian governments agreed to this overarching policy on 11 October 2002 to form the basis for Australia's implementation of the Bonn Guidelines. The agreement forms an accountable basis for all legislation and administrative action for the management of genetic resources currently underway in each Australian jurisdiction.<sup>3</sup>

### Challenges

#### Federalism, Land Management and Consensus

Australia is made up of 6 sovereign States and two self-governing Territories. Under Australian constitution, land management responsibility largely rests with the States. Historically, achieving a common view among all sovereign jurisdictions has not always been easy and land management issues are a current source of acrimonious and divisive debate on such matters land clearing, salinity and allocation of riverine water resources. Australia has a small population (20 million) spread over a wide area: its lands and seas extend from the tropics to the Antarctic with more than 8 million square kilometers of land and it has a marine area of similar size. Accordingly, views on land management issues are often entrenched at the state level. A primary tool for addressing such divisions has been the creation of the Council of Australian Governments (COAG) and the Natural Resources Management Ministerial Council.

The twin drivers for successful coordination and co-operation between Australian governments on the ABS issue and leading to the adoption of the nationally consistent approach were awareness of:

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<sup>1</sup> The Views expressed in this paper are those of the author and do not necessarily present those of the Australian Department of the Environment and Heritage.

<sup>2</sup> See URL: <http://www.deh.gov.au/biodiversity/science/access/nca>

<sup>3</sup> Such action was foreshadowed at Objective 2.8 of the 1996 *National Strategy for the Conservation of Australia's Biological Diversity*. See URL: <http://www.deh.gov.au/biodiversity/publications/strategy/>

- The extent of national biodiversity;
- The value genetic resources to industry worldwide;<sup>4</sup> and
- Jurisdictions' obligations under the CBD.

Australia is one of 17 megadiverse countries. It is estimated to have up to 7-10% of the world's biodiversity, perhaps less than Indonesia or Brazil but comparable to Mexico.<sup>5</sup> It has the world's highest rate of endemism.<sup>6</sup> Much of its biodiversity is also unusual, ancient, rare or inadequately known to science.

Australia is a developed country with a good science base and a burgeoning biotechnology industry with an annual turnover of more than US\$750 Million.<sup>7</sup> Of its 198 biotechnology firms, most are small and are constrained by a conservative capital market and a poor record of successful commercialisation. Australian biotechnology research and development has its foundations in medical research, agriculture and natural product discovery.

The mechanism chosen by the federal government to increase awareness and to begin to build a consensus was to hold a national inquiry<sup>8</sup> involving extensive stakeholder consultation. This involved all governments, indigenous peoples, industry, the science community and environmental groups. The process identified key problems and suggested solutions. By clarifying thinking within government on ABS, Australia was able to give informed consideration to the draft Bonn Guidelines and was thereby encouraged to strongly support their adoption.

#### Implementation - National Consistency

In a federal structure, a coherent legal framework requires either a single national law (not always possible), "mirror" or "model" legislation - where each jurisdiction passes essentially the same law - or a law based on an agreed nationally consistent approach. In Australia the complexities of ABS and existing State or Territory laws and State constitutions led to the adoption of the third option. This is the *Nationally Consistent Approach for Access to and Utilisation of Australia's Native Genetic and Biochemical Resources*, or NCA.

The NCA identifies key problems and agreed solutions. Its common goal is "to position Australia to obtain the maximum economic, social and environmental benefits from the ecologically sustainable use of its genetic and biochemical resources whilst protecting our biodiversity and natural capital".<sup>9</sup> At the time of writing, most Australian governments have

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<sup>4</sup> For example Laird and Ten Kate quote the 1998 annual sales value of pharmaceutical products derived from genetic resources as being US\$75 billion - *Biodiversity and Traditional Knowledge*, p247, edited by Sarah Laird and published by Earthscan Publications Ltd, 2002.

<sup>5</sup> Mittermeyer.

<sup>6</sup> Laird and Ten Kate *op. cit.* Estimates of biodiversity within national jurisdictions vary depending on the assumptions used and the proportion of the nation's biodiversity taxonomically identified and mapped. In Australia's case a significant proportion of its biodiversity, particularly in its marine sphere, remains to be identified. A further complication is that fact that from a biodiscovery point of view the degree of polymorphism within a species can be as important as the number of species evident.

<sup>7</sup> Australian Government Department of Industry Tourism and Regional Services -figures for 2003.

<sup>8</sup> Commonwealth Public Inquiry into *Access to Biological Resources in Commonwealth Areas 2000 (the Voumard Inquiry)* see URL: <http://www.deh.gov.au/biodiversity/science/access/inquiry/pubs/abrca.pdf>

<sup>9</sup> See URL: <http://www.deh.gov.au/biodiversity/science/access/nca/#goal>

begun policy reviews, passed legislation or commenced preparation of new legislation under the aegis of the NCA.<sup>10</sup>

### **Realistic Expectations - the Success Rate**

Stakeholders repeatedly emphasize that the chances of a new product based on natural genetic resources reaching the market is very low: about 1 in 10,000 to 1 in 100,000. Furthermore many discoveries are serendipitous and the development process is often cumulative, expensive and lengthy. While some products may be very valuable in the end, they are the exception.<sup>11</sup> Even at the final stages of the development process there are no guarantees. For example it is estimated that only 20% of new pharmaceutical drugs that undergo Phase 1 clinical trials will survive to be approved by the USFDA.<sup>12</sup> Policy, legislation and public education activities must take this reality into account.

The immediate implication of such low success rates for development from biodiscovery is that bioprospecting as an activity is sensitive to transaction costs – both financial and temporal (delay). This sensitivity is further exacerbated where research is undertaken by small organizations (often the Australian case) or is undertaken as non-commercial research. In such circumstances, burdensome regulatory impediments will reduce research thus further reducing the likelihood of success. Regulatory impediments include:

- cost
- delay
- uncertainty
- duplication
- complexity

The lesson Australia learned from observing the effectiveness of early ABS legislation in South America and in the Philippines is that such impediments are to be avoided. The appropriate response is to balance safeguarding the public interest with arrangements facilitating access by the following:

#### *Simplicity*

Keep the underlying organizing principle simple. For example, for access to be granted on federal land an applicant must apply for a permit, the permit in turn will be granted if the collecting does no harm to the environment and a benefit-sharing agreement has been reached with the manager of the area from which the resources are to be taken. If the collection is for non-commercial purposes the benefit-sharing agreement may be replaced with simplified arrangements.

#### *Reducing costs and delay*

The NCA provides for:

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<sup>10</sup> The federal government has drafted legislation for areas under its control. The Queensland Biodiscovery Bill was passed in August 2004, In September 2004 Northern Territory released its ABS policy for public comment while South Australia is preparing legislation and Western Australia has announced its intention to draft legislations.

<sup>11</sup> E.g. 1997 sales revenue for Cyclosporin based products amounted to US\$1.2 billion These were developed from a soil fungus found in a sample taken from a nature reserve in what is now Norway's Hardangervidda National Park, but the process took 14 years and considerable cost. - Pp 163-4, Biodiversity and Traditional Knowledge, Edited by Sarah Laird and published by Earthscan Publications Ltd 2002.

<sup>12</sup> Journal Of Commercial Biotechnology Sept 2003 Vol 10 Number 1, page 55.

- processing of applications for access to be timely (eg federal and state legislation includes statutory time limits for decision making);
- transaction costs to be minimised (eg draft federal legislation fixes fees at nominal levels);
- model contracts and dictionaries of contractual terms for benefit-sharing agreements to be developed;
- information to be provided in a clear, readily-accessible and reliable manner;
- reassurance to be provided that arrangements do not alter existing property or intellectual property law (this is reflected in federal and state law);
- access permissions to allow flexibility in their scope and duration; and
- online application processing and information provision be used where possible.<sup>13</sup>

#### *Ownership of resources*

Generally, genetic resources found on public lands or waters are either owned or managed by government bodies. Nevertheless the NCA identifies this as a matter requiring further collaboration, particularly the possible application of frameworks to private land. The new Queensland Act does not regulate the use of genetic resources on private land (including indigenously owned land) while both federal and Northern Territory governments have made clear that they will respect the property rights of private land holders. The property rights of the owners of indigenously owned land in federal areas is explicitly protected in the draft legislation.<sup>14</sup> All benefits negotiated by them are theirs. The federal government takes none. Guiding this debate is the realisation that the conservation of the bulk of Australia's biodiversity will take place within its extensive representative protected areas system ie mostly within public areas.

#### *Avoiding duplication of existing systems*

Under the NCA, regulatory frameworks would allow for possible exemption of public collections administered consistently with its Principles. This might include, for example, institutions such as botanic gardens or herbaria that are participating institutions in the international Common Policy Guidelines for implementation of the "Principles on Access to Genetic Resources and Benefit Sharing for Participating Institutions". The goals here are not to duplicate existing arrangements if they are consistent with the intent of the policy.

Such provisions are especially necessary where systems are in place to discharge obligations under other international obligations or where a state may have been granted control over resources under another federal law.<sup>15</sup> In the latter instance federal policy is that the

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<sup>13</sup> See NCA Common Element 3

<sup>14</sup> This is done, in part by access approval to be given when the applicant demonstrates that the informed consent to the benefit-sharing agreement by the indigenous owners.

<sup>15</sup> Such an exemption might be framed along the following terms: "The Minister may declare that this Part does not apply to specified biological resources or a specified collection of biological resources (including future additions to the collection) if: (i) the resources are held as specimens away from their natural environment (whether in a collection or otherwise) by a Commonwealth Department or Commonwealth agency and there are reasonable grounds to believe that access to the biological resources is administered by the Department or agency in a manner that is consistent with the purpose of this Part; or (ii) there are reasonable grounds to believe that access to the resources is controlled by another Commonwealth, self-governing Territory or State law in a manner that is consistent with the purpose of this Part; or (iii) use of the resources is required to be controlled under any international agreement to which Australia is a party.

*Example:* The International Treaty on Plant Genetic Resources For Food and Agriculture, to which Australia is a signatory, obliges signatories to "control access to the genetic resources of some foods in some circumstances"

arrangement should remain undisturbed, as any benefit received by a State is a benefit to the broader Australian community. The Commonwealth State Offshore Constitutional Settlement is an example of such an arrangement.

### *Certainty*

The Australian experience has been that stakeholders place great value on certainty. To build this into legislation and administration the NCA ensures that transparency and accountability is to be supported by:

- legislation;
- disclosure of all criteria against which access is granted;
- appropriate integration of decision making into administrative review systems; and
- making information about benefit-sharing agreements public, where doing so is consistent with commercial, privacy and cultural confidentiality.

### *Ease of access and administrative consistency across all jurisdictions*

This is supported by the undertaking in the NCA to collaborate on:

- the use of common terms wherever possible;
- agreement on appropriate deterrent penalty levels for similar offences;
- the development of model contracts and contractual terms;
- establishing links between web based on-line information sites;
- developing consistent public information material;
- the use of joint benefit-sharing contracts where intended biodiscovery collection involves crossing jurisdictional borders;
- the adoption of common collection protocols where possible;
- the sharing of common experience;
- the development of whole of government policy positions in relevant international fora;
- common issues such as the ownership of resources and the possible application of frameworks to private land; and
- the development of contract monitoring and access compliance procedures.

### *Fair treatment*

Industry representative bodies including the International Chamber of Commerce have emphasized the concern of members, particular those from outside Australia that Australia's system not discriminate against their members. This is a larger trade concern and is addressed by existing legislation which makes such action unlawful and which binds the States and Territories. Accordingly the NCA makes reference to National Competition Policy and the *Trade Practices Act 1974*.

### *Unintended regulatory consequences*

The scientific community has sought to draw governments' attention to the risk that non-commercial research may be adversely affected by arrangements intended to regulate commercial research. To address this the NCA requires that all jurisdictions facilitate continued access for non-commercial scientific research, particularly taxonomic research. In the case of the federal legislation a clear distinction is made between commercial and non-commercial research.<sup>16</sup>

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<sup>16</sup> The principle difference between the two being that the obligation to enter into a benefit-sharing agreement is not required for non-commercial research in favour of an obligation to share research outcomes, not pass the material

### *Respecting Indigenous Knowledge*

While the NCA requires that all governments “recognise 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” it leaves the method to individual Australian Governments. The federal government employs the use of transparency. It requires that a benefit-sharing agreement includes protection for, and recognition of and the valuing of, any indigenous people’s knowledge used. The agreement must also include a statement regarding the use of indigenous people’s knowledge and provide details of the source of the knowledge, the terms on which it was obtained and benefits to be provided or any agreed commitments given in return for its use.

### *Negotiation disparities*

To the extent that benefit-sharing agreements are negotiated between government entities and research organisations or companies there is no disparity. Where the managers or owners of the genetic resources are Indigenous peoples this is not the case. Accordingly federal legislation provides a safeguard whereby an access permit is granted when the Minister is satisfied according to explicit criteria that the applicant has obtained the informed consent of the Indigenous owners and their benefit-sharing agreement is on mutually agreed terms. As the government is not party to the agreement or its benefits there can be no apprehension of bias.

### **Unauthorized commercialisation of resources**

To date there have been few reported and verified examples of attempted unauthorised commercialisation in Australia. The last significant example was the unsuccessful and unauthorised attempt to take samples of the “Smokebush” from Western Australia in the early 1990s. To date this issue does not appear to be a problem for Australia. Researchers appear to be honoring their contractual obligations. This perception, while at odds with popular perceptions, is shared by OECD researchers who concluded recently that, for at least the short term, unauthorized commercialization does not appear to be significant.<sup>17</sup>

Topical examples of ‘biopiracy’ appear to largely be the product of ‘bad’ patents eg the applications to patent turmeric, neem and varieties of stable traditional Mexican maize, or action taken in circumstances where no legal framework for genetic resources management existed. This raises the issues of the operation of patent systems rather than ABS issues. The Australian Law Reform Commission (ALRC) in its 2003 Inquiry into Gene Patenting and Human Health<sup>18</sup> examined the question of the need for improvements to the operation of the Australian patent system. In its report, *Genes and Ingenuity: Gene Patenting and Human Health* it has made extensive recommendations aimed at tightening the criteria for granting patents and for better decision making. The Australian government is considering these recommendations. It is noteworthy that many of the ALRC recommendations parallel those made by the United States’ National Academies of Science to the US government in April 2004.<sup>19</sup> Any reduction in the number of such bad patents will clear some of the emotion from

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onto third parties and to negotiate a benefit-sharing agreement should they later wish to commercialise their research.

<sup>17</sup> OECD Working Group on Economic Aspects of Biodiversity paper *Economic issues in Access and Benefit-sharing of Genetic Resources: a Framework for Analysis* (ENV/EPOC/GSP/BIO(2001)2/FINAL 04.11.2003

<sup>18</sup> See URL: [www.alrc.gov.au](http://www.alrc.gov.au) and follow the links.

<sup>19</sup> See URL: <http://4.nationalacademies.org/news.nsf/isbn/0309089107?open+document>

the international debate and reduce the cost burden on biodiversity managers needing to challenge patent decisions - often in foreign jurisdictions.

### **Monitoring and Enforcement**

At present existing government contract management arrangements appear to be working well. The cost and administrative burden of such arrangements will, however, grow rapidly as levels of biodiscovery increase and new administrative arrangements are put in place to better reflect best practice as set out in the Bonn Guidelines. The Australian government has responded to this need. Over the next four years it is providing guaranteed additional funding to enhance collaboration among jurisdictions in the implementation of the Nationally Consistent Approach. It is expected one immediate consequence will be the establishment of a body under the National Biotechnology Strategy to undertake that coordination.

### **Disclosure of Information: Patent Applications**

In addition, there are two areas where considerable benefits lie in relation to both the cost and effectiveness of monitoring and enforcement. The first of these lies in the area of improved transparency. While public registers of permits enable managers, the scientific community, business, and venture capital to monitor what is occurring within a given jurisdiction, it does nothing to independently establish what discoveries are taking place globally - but based on the genetic resources of a given area.

The discovery process crystallises value at the point where Intellectual Property rights are taken out. Transparency lies at the heart of that process. The disclosure in patent applications of information about the source from which a discovery is derived and including information about the terms on which that source material was obtained, is of immediate benefit to all parties involved. For general researchers it indicates whether or not their own work risks intruding on another's, whether it is a source of new insights, and it tells where and possibly from whom, similar source material can be obtained. For resource regulators or managers it shows what is happening with their resources and whether contacts are being complied with. For the patent examiners, it may help them to decide whether an inventive step has been taken or resolve issues of prior art. For investors considering obtaining an interest in the IP, it enables them to undertake due diligence, addressing commercial and legal uncertainty and, to more accurately determine the market value of the IP. For industry capital providers, whether they are 'ethical funds' or simply concerned to protect shareholder value, they can determine issues of provenance and satisfy themselves that investing in companies owning the IP involves no risk to their own public reputation. Most importantly for the patent applicants, it allows them to obtain full measure of market reward for their compliance with their legal obligations surrounding their acquisition of the source material from which their inventions derive.

### **Disclosure of Information: Certificates of Origin**

The second area of improved genetic resources management lies establishing a cost effective method of tracking downstream use of genetic resources both within a country and globally. The general introduction of registers of permits recording basic details of what is being collected and by who opens the way for the introduction of systems whereby each sample can be allocated given a unique identifier that then travels with each transfer through the value development chain. Information about samples as determined by the access approving body would be placed in a publicly searchable database. Each party acquiring the sample or indeed, merely acquiring an interest in the sample or something created from it, could then establish its source and provenance simply by reference to the identifier. If cost effective,

such systems would increase certainty, promote the effectiveness of contractual 'reach through' provisions, and encourage investment and research and support compliance and monitoring of genetic resources. If developed into a common standard such identifiers would add value to the associated materials. It also adds a degree of transparency and confidence to each party otherwise engaged in otherwise private dealings that the subject matter of the transaction has a verifiable origin and traceable history.