

Australian Laws and Practices Relevant to the Misappropriation of Genetic Resources

Australia is a mega-diverse country with a unique indigenous culture and has a strong interest in equitable access to genetic resources and benefit-sharing. Australia considers the TRIPS Agreement and the Convention on Biological Diversity (CBD) are consistent and can be implemented in a mutually supportive manner. Australia's national experience, as detailed below, has demonstrated that effective access and benefit sharing (ABS) regimes which provide for benefit-sharing, including benefits associated with the commercialisation of intellectual property, can be implemented without making changes to the patent system.

Australia's access and benefit-sharing system

Under Australia's Federal system, existing ownership rights to native biological resources depend on whether they are found in Commonwealth, State or Territory government lands or waters, indigenous lands (of which there are different types with different associated rights), freehold or leasehold lands. In 2002, Australian governments reached agreement on the 'Nationally consistent approach for access to and the utilisation of Australia's native genetic and biochemical resources'¹ to promote consistency in the regulation and management of access to genetic resources. This sets out the general principles on which legislation would be based in each jurisdiction and some common elements for ABS arrangements.

Access to biological resources in Commonwealth areas² is governed by the Environment Protection and Biodiversity Conservation Regulations 2000 (Cth) ("the EPBC Regulations")³. Under the EPBC Regulations, those seeking access to genetic resources must apply to the Department of Sustainability, Environment, Water, Population and Communities (SEWPAC) for a permit to access biological resources of native species for research and development of any genetic resources, or biochemical compounds, comprising or contained in the biological resource.

Permits for access to biological resources are available for either commercial, potentially commercial or non-commercial purposes. If the biological resources are for commercial or potentially commercial uses, the permit will not be granted until the applicant has entered into a benefit-sharing agreement with the provider of the biological resources. The regulations require the prior informed consent of the indigenous owner or native title holder, where access is to genetic resources on indigenous people's land. A benefit sharing agreement must provide for reasonable benefit-sharing arrangements, including protection for and valuing of any indigenous people's knowledge to be used.

SEWPAC has developed model contracts as a guide to assist parties developing benefit-sharing agreements, where the Commonwealth is the access provider and where the Commonwealth is not the access provider⁴. Benefits are as determined by the parties to the

¹ The text can be seen at: <http://www.environment.gov.au/biodiversity/publications/access/nca/index.html>

² Commonwealth areas are defined in section 525 of the EPBC Act to include land owned or leased by the Commonwealth, the Australian coastal sea, continental shelf and waters of the exclusive economic zone (EEZ).

³ The full text of the Commonwealth access regime is set out in Part 8A and Part 17 of the EPBC Regulations and is available at <http://www.comlaw.gov.au/comlaw/legislation/legislativeinstrumentcompilation1.nsf/frameLodgmentAttachments/BD9AB11F19E7F55ECA25718F00156738>

⁴ The model contracts are available at <http://www.environment.gov.au/biodiversity/science/access/model-agreements/index.html>.

contract, and can include contributions to conservation and scientific knowledge or any other agreed benefit including revenue generated by the commercialisation of intellectual property arising from research and development using the genetic resource where this is relevant.

Applicants for permits for non-commercial purposes must provide a statutory declaration stating that the applicant does not intend nor allow the collection to be used for commercial purposes, will report on the results of the research, will offer a taxonomic duplicate of each sample to an Australian public institution that is a taxonomic repository, and will not carry out any research for commercial reasons without first negotiating a benefit-sharing agreement.

The Australian system has been developed as a transparent system, where users can browse a record of permits that have been issued and samples collected under those permits⁵. As at 1 January 2011, 91 permits have been issued through the Protected Areas Policy and Biodiscovery Section under Part 8A of the EPBC Regulations since December 2005. These permits have been for non-commercial purposes.

Further, the EPBC Regulations also provide a mechanism to exempt existing regimes that are consistent with the EPBC Regulations' purpose to minimise duplication. Agreements that bring existing permit arrangements within the benefit-sharing policy of the Australian Government have been made with the Great Barrier Reef Marine Park Authority, the Australian National Botanic Gardens, the Australian Institute of Marine Sciences and the Australian Antarctic Division. In total, over 450 permits have been issued under Part 8A of the EPBC Regulations and other regimes accredited under the Regulations.

There are currently seven ABS contracts completed for organisations engaged in commercial research. Four of these are with Australian public institutions and three with foreign research organisations. A further contract for commercial research with an Australian research institution is under consideration. The mutually agreed terms for benefit-sharing followed closely the model contracts provided by SEWPAC.

SEWPAC continues to work with state and territory jurisdictions to ensure their approaches are nationally consistent. In addition to the legislation covering Commonwealth land, the Queensland and Northern Territory Governments have legislation in place, with Victoria and Tasmania recently implementing legally effective measures to implement Australia's nationally consistent approach to ABS.

There are a range of remedies under Australian law in relation to the misappropriation of genetic resources. Under the EPBC regulations, criminal penalties apply in relation to persons who access biological resources without a permit. Further penalties apply to breaches of conditions stipulated in the permit. Mutually agreed terms are established as a precondition of access, and are set out in a contract. Civil remedies exist for breaches of contractual arrangements, and particular remedies may be negotiated and specified in the individual contracts.

Australia's patent system provides additional protection against misappropriation of biological resources. A standard patent is granted for an invention that is a new idea which

⁵ Browse the record of permits at <http://www.environment.gov.au/grid/public/perrep.jsp>

provides a practical solution to a technological problem. In this context, a standard patent would only be granted for subject matter which:

- . involves the technical intervention of a technologist applying their inventive ingenuity to produce something distinguishable from the natural source material; therefore, a patent cannot be granted for a mere discovery of biological material;
- . is new in the sense of not previously being publicly available; that is, a patent cannot be granted for materials in their naturally occurring state or for materials which have previously been made publicly available, either in a document or through prior use;
- . must involve an inventive step;
- . has been fully described in the sense that sufficient information is provided to allow the technologist to make the product or perform the process without having to resort to invention; and
- . has a demonstrated use; the use to which the invention is to be put, for example, for the treatment of human diseases such as cancer or multiple sclerosis, must also be fully described; this means that there must be an actual use for an invention rather than speculation as to future uses.

Each of these factors are taken into account during examination of a patent application. Third parties may also oppose the grant of a patent on these grounds or, after grant, may seek revocation of a patent on any of these grounds.