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INTERGOVERNMENTAL COMMITTEE ON INTELLECTUAL PROPERTY AND GENETIC RESOURCES, TRADITIONAL KNOWLEDGE AND FOLKLORE

Sixteenth Session
Geneva, May 3 to 7, 2010

POLICIES, MEASURES AND EXPERIENCES REGARDING INTELLECTUAL
PROPERTY AND GENETIC RESOURCES: SUBMISSION BY AUSTRALIA

Document prepared by the Secretariat

1. At its fifteenth session, held from December 7 to 11, 2009, the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ('the Committee'):

“invited Member States and observers to make available to the Secretariat papers describing regional, national and community policies, measures and experiences regarding intellectual property and genetic resources before February 12, 2010, and requested the Secretariat to make these available as information documents for the next session of the Committee.” [...]

2. Further to the decision above, the WIPO Secretariat issued a circular to all Committee participants, dated January 15, 2010, recalling the decision and inviting participants to make their submissions before February 12, 2010.

3. Pursuant to the above decision, the Delegation of Australia submitted a document entitled “Genetic Resources and Intellectual Property” and requested it be made available as an information document for the sixteenth session of the Committee.

4. The document is reproduced in the form received and contained in the Annex to this document.

[Annex follows]

ANNEX

GENETIC RESOURCES AND INTELLECTUAL PROPERTY

At its 15th session the Intergovernmental Committee on Intellectual Property and Genetic Resources Traditional Knowledge and Folklore (IGC) invited Member States and observers to make available to the Secretariat papers describing regional, national and community policies, measures and experiences regarding Intellectual Property (IP) and Genetic Resources (GR).

The purpose of the Australian patent system¹ is to stimulate industrial innovation, and encourage technology access and transfer. The system rewards inventors with a period of exclusivity to prevent others from exploiting their invention, in return for disclosing their invention to the public. Diffusion of knowledge in the public domain helps to facilitate research in emerging fields of the patented invention. Patents provide an incentive mechanism for cutting edge research and commercialisation of genetic material in the important fields of biotechnology, pharmaceutical, agricultural and other industries. Under this broad purpose, Australia assesses applications based on GR by applying the same patentability requirements as for all other applications, irrespective of their technological field. Also, Australia's plant breeder's rights system provides protection for new plant varieties.

Under the standard tests for patentability, although standard patents can be obtained for biological material, this material is only patentable if it has been isolated from its natural environment, or has been synthetically produced. For example, DNA or genes in their naturally occurring state are not patentable, however, a DNA or gene sequence which has been isolated from the source may be patentable. Patent specifications must also describe a specific use for biological material. For example, if the invention relates to a gene, the specification must disclose a specific use for the gene such as its use in the diagnosis or treatment of a specific disease or its use in a specific industrial process.

A fundamental requirement of the patent system is that patents are only granted for things that have not been done or disclosed before (novelty). This is assessed by looking to see if the invention has been publicly used or published before. In terms of gene patents, gene sequences and any isolated and purified biological material not previously published or used will usually satisfy the novelty test. If the sequence of a gene is already known, a person cannot claim a monopoly to the sequence itself. However, if the claimed invention refers to an unknown use, function or property of the gene (such as a new association with a particular disease), novelty may be satisfied.

¹ The full text of the Patents Act 1990 and the Patents Regulations 1991 can be accessed at <http://agsearch.ag.gov.au/clsearch/home?query=patents&new=1>

The Australian Patent Office Manual of Practice and Procedure is a reference manual used by patent professional officers at IP Australia in applying the Patents Act and can be accessed at http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent_Examiners_Manual.htm

Inventive Step requires that patents are only granted for inventions that advance technology beyond what is routine or obvious. Determination of inventiveness comprises considering both the common general knowledge and prior art base. In the case of a known gene, claims to uses or applications of the gene may be inventive if a new and non-obvious or unpredictable function is demonstrated for the gene.

Effective patent search and examination systems that identify prior art used in determinations of novelty and inventive step provide the basis for ensuring that patents are not improperly granted on claimed inventions that contain GR. Document WIPO/GRTKF/IC/9/INF/6 contains comprehensive discussion of elements of national experiences in search and examination processes and procedures related to prior art and genetic resources. This includes the legal characteristics of relevant prior art used in determinations of novelty and inventive step, the actual sources of prior art that are used in search and examination, other aspects of search and examination procedures, and provisions or case studies specifically concerning the recognition of GR during search and examination.

Australia's Access And Benefit Sharing System For Genetic Resources

Australia is a mega-biodiverse country, with possibly the world's highest level of endemic GR, much of which has yet to be characterised. Many specific GR of Australian origin have been dispersed to other countries in whole-of-species form for example, eucalyptus trees can be found on most continents and the kangaroo, a national icon, is found in many zoos worldwide.

Australia is also a developed economy to which GR are very important. For example, Australia has a burgeoning biotechnology industry, a large agriculture sector as well as large agricultural and environmental research sectors which are reliant on access to GR.

Australia, like other mega-biodiverse countries, has an interest in the sustainable use of GR. Australia also has obligations under the Convention on Biological Diversity to provide an access and benefit sharing regime for its GR. Access to Australian GR is not regulated by IP law. Australia regulates access to GR by contracts and environmental regulation, including a permit system. IP is broadly addressed in Australian model ABS contracts as commercialisation of GR often involves protecting IP rights, however it should be noted that IP protection is not a necessary step for commercialising GR.

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' 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 the Environment, Water, Heritage and the Arts (DEWHA) 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.

DEWHA 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 contract, and can include contributions to conservation and scientific knowledge or any other agreed benefit as well as any revenue generated by the commercialisation of IP related to 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.

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 10 February 2010, sixty-three permits have been issued through the Protected Areas Policy 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

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>.

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

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 Austrian National Botanic Gardens, the Australian Institute of Marine Sciences and the Australian Antarctic Division. In total over 400 permits have been issued under Part 8A of the EPBC Regulations and other regimes accredited under the Regulations.

There are currently seven access and benefit-sharing contracts completed for organisations engaged in commercial research. Four of these are with Australian Public Institutions and three with foreign research organisations. A further three contracts are under consideration (with Australian research institutions). The mutually agreed terms for benefit-sharing followed the model contracts provided by DEWHA closely.

DEWHA 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 access and benefit sharing.

[End of Annex and of document]