

Australia
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Australia appreciates this opportunity to provide comments relating to the invitation from the Convention on Biological Diversity (CBD) Conference of the Parties (COP) to the World Intellectual Property Organization (WIPO) to prepare a technological study, and to report its findings to the COP on methods consistent with obligations in treaties administered by the WIPO for requiring disclosure within patent applications of, *inter alia*:

- (a) Genetic resources utilized in the development of the claimed inventions;
- (b) The country of origin of genetic resources utilized in the claimed inventions;
- (c) Associated traditional knowledge, innovations and practices utilized in the development of the claimed inventions;
- (d) The source of associated traditional knowledge, innovations and practices; and
- (e) Evidence of prior informed consent.

As a signatory and committed party to the CBD and Intellectual Property treaties (IP treaties), such as the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement), the Patent Cooperation Treaty (PCT), the Paris Convention and the International Convention for the Protection of New Varieties of Plants, Australia reiterates comments it has made previously in the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (WIPO IGC), the CBD and other fora, that Australia sees no conflict between the CBD and IP treaties and considers that these can and should be implemented in a mutually supportive way.

Australia considers that while IP treaties are concerned with the creation of legal rights to protect inventive assets, the CBD, in so far as it impacts on intellectual property (IP) issues, could be characterised as creating the environment in which (i) inventors and others can access genetic resources and traditional knowledge to be used as inputs in inventive and other processes, and (ii) the benefits from the use of those genetic resources and traditional knowledge are equitably shared. While there are certainly overlapping interests involved there is no necessary conflict between the two as they currently stand.

Australia, is a mega-biodiverse country, with possibly the world's highest level of endemic genetic resources¹, much of which has yet to be characterised. Additionally, Australia's indigenous peoples have accumulated traditional knowledge during their occupation of the land. Many specific genetic resources 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 genetic resources 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 clearly reliant on access to genetic resources.

¹ Pages 26-29, 179-180 *Megadiversity* Mittermeyer *et al.*

Australia therefore has a strong interest in:

- facilitating research;
- encouraging innovation and the capturing of benefits from that innovation;
- ensuring that it can exercise appropriate control over access to genetic resources and the use of traditional knowledge; and
- ensuring the benefits from granting access to genetic resources and traditional knowledge are shared equitably.

To do this successfully, it is important to balance the rights of those with interests in the different assets so that research and innovation prosper, and genetic resource and traditional knowledge owners are respected and obtain benefits, as appropriate. This requires that we balance the incentives and costs for all participants in any system that we adopt.

In recognition of the importance of providing equitable access and benefit sharing arrangements in relation to genetic resources, the Australian government has taken important steps towards providing a framework to control access to, and use of, genetic resources on Commonwealth lands and waters through the preparation of forthcoming regulations to be introduced under the Environment Protection and Biodiversity Conservation Act 1999. Reflecting the federal nature of governance in Australia, the Australian government has reached an intergovernmental agreement on genetic resources management with all Australian States and Territories; the *Nationally Consistent Approach for Access to and the Utilisation of Australia's Native Genetic and Biochemical Resources* (NCA)². The NCA establishes a common basis for new or revised legislative, administrative and policy frameworks for Australia's implementation of the CBD *Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable sharing of benefits arising out of their Utilization*. Australia views these guidelines as an important step in the process of developing equitable access and benefit sharing arrangements, and is working to ensure that there is appropriate use of other nation's genetic resources in Australia.

On 4 November 2004, the Australian Government and the Australian States and Territories took a further step and established a body to facilitate the progressive implementation of the NCA.³

In line with this approach the Queensland State Parliament recently passed the *Queensland Biodiscovery Act 2004*, establishing a framework for access to and use of Queensland's native biological resources for biodiscovery and other purposes. The Northern Territory government recently released for public comment a draft policy document on access to biological resources for bioprospecting in the Northern Territory. The Western Australian government has announced its intention to consider similar legislation and other States are also in various stages of introducing biodiversity arrangements.

Several suggestions have been made in international fora as to how the patent system might be used as a vehicle for the disclosure of the use of traditional knowledge and genetic resources accessed in the development of inventions⁴. Australia supports, in principle, the use of documentation associated with patent applications to disclose the source of relevant genetic resources. For example, there may be potential to use the patent publication system to improve the transparency of transactions involving access to genetic resources. Using this system would

² The text of this Agreement may be found at: <http://www.deh.gov.au/biodiversity/science/access/nca/index.html>

³ This is the Biotechnology Australia: Biotechnology Liaison Committee Working Group on Biodiscovery.

⁴ For example, the Swiss proposal (PCT/R/WG/5/11) to the Working Group on Reform of the PCT of the WIPO and the proposals from the European Communities and their Member States (IP/C/W/383) and Brazil et al (IP/C/W/429) which were submitted to the TRIPS Council of the World Trade Organization (WTO).

have the advantage of utilising a currently available and well-known regime which is readily accessible to a wide range of people in many countries. Given that the patents system has been developed over a long period of time and includes many checks and balances, any decisions on possible new measures must be carefully thought through to prevent adverse consequences arising and ensure objectives are met. Although Australia does not have a patent disclosure regime in place, Australia is of the view that any patent disclosure regime should:

- be easy to implement;
- not impose undue burdens and costs on IP right owners and administrators;
- encourage research and commercialisation;
- not affect the integrity of IP rights, especially since lack of disclosure should not be a bar to a patent, although there may be other legal ramifications outside the IP system (for example, transfer of ownership) for failing to disclose traditional knowledge and/or genetic resources;
- have a minimum impact on current IP systems;
- encourage creators to disclose the relevant inputs into their inventive process, while recognising there may be circumstances in which disclosure is not possible or appropriate; and
- provide useful information and be easily accessible to access providers.

If these broad parameters are not met in relation to proposed patent disclosure regimes then it is possible that unintended consequences may arise that would discourage research and innovation and risk undermining the objectives of a patent disclosure regime. For example, the invalidation or non-grant of patent rights could directly undercut any capacity to share benefits, as without the benefits that can accrue from strong patent rights the benefits to potential access providers could be dramatically reduced or nullified. Similarly without a valid patent right, individuals can still commercialise their IP without any obligation to disclose their invention to the public or to share the benefits unless there is an underlying regime ensuring benefit sharing.

It is also important, when considering modes for a patent disclosure regime, that there be some accommodation for what an inventor ought reasonably be aware of when conducting prior art searches. For example, an inventor may not be aware that relevant traditional knowledge exists and may have developed their invention independently of any such knowledge. This is particularly true in those circumstances where the traditional knowledge may not have been published as a result of cultural and/or religious sensitivities. Consideration could be given to a disclosure regime based on a subjective test (what the patentee knew) rather than an objective one (what the patentee ought to know). Insufficient consideration of this issue runs the risk of introducing unreasonable burdens on inventors. The issues around whether that material may have been part of the public domain in relation to the invention can be dealt with under the traditional patent concepts of novelty and inventive step.

Furthermore, there are often multiple sources from which a person may legitimately obtain access to a genetic resource or traditional knowledge and any patent disclosure regime or access and benefit sharing system must recognise this.

Thus it is imperative that any patent disclosure regime adopted should be able to deliver the benefits sought within the broad parameters described above.

Australia notes that a number of member states have recently introduced disclosure regimes. We encourage WIPO to prepare a questionnaire asking these members how they implemented their regime and seek a full and frank assessment of their regimes. Questions that would enable a full exploration of the issues arising under such regimes might include: how effective the systems are in meeting their objectives, what problems have been encountered, examples of particular successes experienced and, examples of where users and/or authorities that process the additional information have found it useful.

During the seventh session of the WIPO IGC, the European Community and its Member States indicated that it would be submitting a proposal relating to access regimes to WIPO by 15 December 2004 as a submission to WO/GA/31/8. Australia looks forward to the opportunity to give careful consideration to this proposal along with any other proposals that are put forward.

Finally, Australia would like to state its continued commitment to ongoing and constructive discussion of the issues surrounding the access to, and benefit-sharing of, traditional knowledge and genetic resources so as to ensure that effective and efficient measures can be implemented.