



## ACCESS TO BIODIVERSITY: A UNIVERSITY PERSPECTIVE

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Universities have a vital role in research and research training and are an important source of innovation and new products and processes. University research and training requires access to biological materials. Such access must recognise the needs of the wider community and of researchers.

The existing and potential economic value of the earth's biodiversity and the organisms which make up this biodiversity has entered the wider political consciousness only recently. For example, the United Nations Convention on Biodiversity (the Convention) came into force on 29 December 1993 and now has 172 signatories. The convention recognises the sovereign rights of States over their natural resources and that national governments have the authority to determine access to genetic resources (Article 15(1))<sup>2</sup>.

The three central objectives of the Convention (Article 1) are:

- the conservation of biological diversity
- the sustainable use of its components
- the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources.

One of the driving forces leading to the Convention has been the developments of the new DNA-based biotechnologies and the rapid expansion of the search for naturally occurring compounds and biologically active molecules; i.e. bioprospecting. These new technologies have enabled a more rapid and greater commercial exploitation of genetic resources. Bioprospecting is not new; the early European explorers such as Joseph Banks and Alexander Humboldt not only described new flora and fauna, but also collected information on its potential use. Most drug companies have also engaged in the collection and screening of plant, animal, fungal and bacterial material in the search for new drugs for a large part of this century. What has changed is that previously the biological resources, including the genetic resources, were considered as open to exploitation by the 'biodeveloper' essentially free of any regulation, whereas now they are explicitly the property of the State.

The problem now is how the State manages appropriate access to its biological and genetic resources and how the benefits arising out of the utilisation of these resources can be shared fairly and equitably. Most countries already have legislation in place which regulates to varying degrees the access to its biological resources, and further legislative changes are constantly being made. Similarly, many countries have plant and animal varieties legislation as well as patent laws which allow the protection of intellectual property including some organisms, gene sequences and processes involving organisms. Of particular interest here is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)<sup>3</sup> which allows for the patenting of microorganisms and plant varieties. Article 27(3) of TRIPS states:

*"Members may also exclude from patentability:*

*(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;*

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<sup>2</sup>This principle had already been stated earlier in Resolution 1803 of the U.N. General Assembly in 1962, and also in Principle 21 of the U.N. Conference on the Human Environment (Stockholm, 1972).

<sup>3</sup>Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods (Annex 1C of the World Trade Agreement establishing the World Trade Organisation and including GATT 1994)



*(b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. ...."*

This part of the TRIPS agreement is generating a great deal of discussion and controversy since it recommends and even mandates the right to patent certain organisms. It is interesting to note that this is the only Article where review of the provisions of a sub-paragraph (i.e. Sub-paragraph 27(3b) is mandated 4 years after the entry into force of the Agreement.

How do these conventions and agreements affect Universities?

Probably the first and most immediate effect of these changes has been to create some uncertainty about access rights and use of organisms. It is now possible that some University activities might inadvertently contravene some of these rights. For example, in Australia there are a plethora of instruments to manage access to biological resources both at the Commonwealth level, and in the States and Territories. The list below summarises the number of items of legislation which affect access.

Commonwealth Acts	13
New South Wales	6
Victoria	7
Queensland	3
Western Australia	3
South Australia	9
Tasmania	6
Northern Territory	3
Australian Capital Territory	24

Such legislation is not always consistent between States and Territories and they do not cover all types of biological resources and all types of access. The various acts were designed primarily for conservation purposes, especially of plants and animals, and not for sustainable utilisation of ALL organisms including protists and prokaryotes. This lack of consistency led to the establishment of the Commonwealth-State Working Group (CSWG) on access to biological resources in 1994, and to the release of a discussion paper prepared by them in 1996<sup>4</sup>. There are also a number of international treaties, agreements, conventions and undertakings which impact on these deliberations<sup>5</sup>. The CSWG will play a valuable role if it can achieve consensus on a workable and equitable model for regulating access to biological resources.

A second potential difficulty lies in the understanding of the living world in the wording of parts of the international agreements and conventions relating to biodiversity. For example the authors of the TRIPS

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<sup>4</sup>*Managing access to Australia's biological resources: Developing a nationally consistent approach.* Discussion paper prepared by the Commonwealth-State Working Group on Access to Australia's Biological Resources. October 1996.

<sup>5</sup>The difficulties in achieving a workable framework for the conservation, sustainable use and access as well as some of the solutions are best illustrated by the development of the International Undertaking on Plant Genetic Resources (adopted by FAO in November 1989) and supplemented and clarified by Resolutions 4/89, 5/89 and 3/91, and the International Code for Plant Germplasm Collection and Transfer adopted by FAO. See also: Correa, C.M. *Sovereign and property rights over plant genetic resources.* Background Paper 2, FAO Commission on Plant Genetic Resources, First Extraordinary Session, Rome, November 1994.



agreement classify living organisms into plants, animals and microorganisms, a classification which has its roots in the 19th Century rather than the 20th. Since microorganisms<sup>6</sup> are to be treated essentially different from other organisms, we need a clear definition of what a microorganism is. As interpreted by the World Intellectual Property Organisation (WIPO) it apparently includes bacteria, yeasts, protozoa and microalgae. Thus, for example, does this mean that macroalgae are to be treated differently from microalgae? Unfortunately the term 'microorganism' cannot be equated to any taxonomic classification of organisms thus making it difficult to delineate as to which organisms this provision is meant to apply and furthermore it is difficult to see why organisms should be treated differentially just on the basis of size.

Clearly there are difficulties in reconciling the commendable aims of the Biodiversity Convention with existing legislation and with the different aspirations of the various stakeholders such as government, industry, the Universities and the public in general. Since there are *potentially* significant financial gains from the exploitation of new organisms, the path to an equitable and widely acceptable solution is even more difficult.

The conservation of biological diversity and the sustainable use of its components are stated objectives of the Convention. To achieve these objectives a large amount of basic research in areas such as systematics, ecology, environmental management and the basic biology of the organisms is required (see the Preamble of the Convention). Much of this research is, and will continue to be, conducted by academic and postgraduate student university researchers. To be effective the researchers need to have reasonable access to the organisms.

The objectives should be (a) to carry out our obligations to the community; and (b) facilitate high quality research which will allow society to conserve and sustain its biota.

From our point of view the following principles need consideration in any agreements on how to manage access to biological resources:

- **Clarity**  
Any legislation affecting access to biodiversity and ownership of intellectual property derived from, or involving, biodiversity should be as clear as possible. It should have clearly defined aims and guidelines as well as have achievable targets. The legislation must deal explicitly with and recognise the value of serendipitous discovery and the rights this confers on the discoverer.
- **Simplicity**  
The process of gaining access to biodiversity and of determining ownership of intellectual property should be simple. The present situation of several, at times overlapping and apparently conflicting jurisdictions, needs to be rationalised and simplified. This applies to state, federal and international jurisdictions and to overlaps and conflicts within and between these jurisdictions.

Applications for any permits required should be simple and non-bureaucratic, and if required, a single permit should be all that is necessary. Reporting requirements should be clearly stated and be as minimal as possible. Contracts should also be as simple as possible and some agreed contract models should be developed.

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<sup>6</sup>The inclusion of microorganisms as patentable organisms reflects the fact that "microorganisms" had already been patentable in most industrialised countries. "Microorganisms" are generally deemed to include cells as well as sub-cellular components, including human cells. *See also*: WIPO (1988) Soluciones sugeridas revisadas relativas a la proteccion de las invenciones biotecnologicas por la propiedad industrial. BIO/CE/IV/3, Geneva.



- **Certainty**

The present situation of uncertainty relating to issues of ownership, access and the rights and responsibilities of universities and researchers needs to be resolved as quickly as possible. Consideration must be given as to which organisms are covered as well as to matters such as publication rights, incorporation of data in international databases (eg. DNA sequence data bases), the international exchange of research material etc.

- **Equity**

Initial access to biodiversity, especially for research, must also be granted equitably. Exclusive access, such as for bioprospecting, is to be avoided, and where it is granted it should be for a narrowly defined purpose or group of organisms and for a limited time only. Any process of granting exclusive access needs to be open and transparent, and should involve consultation with all likely stakeholders.

Biodiversity is a national resource and ultimately its use and exploitation for the national benefit. Organisms themselves have no intrinsic economic value, but rather it is the use of the organisms, or of parts of the organisms, which confers economic value. The development of economic uses requires intellectual input as well as varying degrees of financial investment. This essential intellectual input (i.e. research and development), fuelled by financial investment, should be recognised as significant factors in creating the economic value of biodiversity. Any decisions on the sharing of financial returns arising from research and development must reflect this.

However, it is also important that the research and development effort is not undervalued and that the potential economic benefits are not lost to third parties. It is thus incumbent on universities, granting agencies and government agencies to educate the researchers appropriately and to have mechanisms in place to assist in the protection and exploitation of the intellectual property developed whilst ensuring that this does not excessively restrict open communication and sharing of information between researchers.

- **International Cooperation**

Research and development cannot operate only within national boundaries. This means that data must be shared and the results transferred to other countries where appropriate. International cooperation and technology transfer are important features of the Biodiversity Convention (Articles 1, 16 & 17), The World Trade Agreement, the International Undertaking on Plant Genetic Resources and many others. Particular attention has been placed on plant genetic resources, especially those relating to food and agriculture. Any access provisions developed should therefore also include the option of cooperative agreements for mutual benefit.

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