

Scientists as Users and Providers: A South African Perspective

Dr. Maureen Wolfson, South African National Biodiversity Institute. E-mail: Wolfson@nbi.ac.za

In South Africa, which is the third most biodiverse country in the world¹, at least 80% of the 18 to 20,000 plant species are known to be endemic. Intra-specific genetic diversity is also unusually high, adding to the potential for developing new medicines, crops, cosmetics, ornamental plants and other useful products.

South Africa's Constitution (Act 108 of 1996) provides the central framework for the management of biodiversity in South Africa. The national and nine provincial governments are accorded concurrent legislative competence in terms of most of the functions which are of relevance to biodiversity, such as agriculture, environment, nature conservation, pollution control, regional planning and development, soil conservation, urban and rural development and tourism. Areas of exclusive national competence include national parks, botanical gardens and marine resources.

Genetic resources and their ownership are, however, not dealt with explicitly in the Constitution and there is still a need for legal clarity on this issue. According to Chishakwe and Young (1993), no country has yet found or developed a workable legal framework because of the difficulties of defining 'genetic resources' and the lack of legal understanding on the matter. Most of South Africa's biodiversity falls under private ownership and under South African law a landowner owns everything beneath and above the land, including plants but excluding wild animals which are considered to be *res nullius* (not owned by anyone). Most State and commercial agricultural land is held under freehold, while 13% of the country is under customary tenure. While statutory laws apply in both circumstances, in communal areas some customary law also applies and is central to the practice of natural resource use.

At the end of May 2004, the Biodiversity Act (No. 10 of 2004) was signed by the President. Chapter 6 of the Act is entitled 'Bioprospecting, Access and Benefit-Sharing' and sets out the framework for the regulation of access and benefit sharing (ABS) in South Africa. The purpose of this chapter is to:

- Regulate bioprospecting involving indigenous biological resources;
- Regulate the export from the Republic of South Africa of indigenous biological resources for the purposes of bioprospecting or any other kind of research; and
- To provide for a fair and equitable sharing by stakeholders in benefits arising from bioprospecting involving indigenous biological resources.

The indigenous biological resources referred to here also include derivatives, chemical compounds and products obtained through the use of biotechnology. Material of human origin is excluded as well as exotic organisms and the indigenous biological resources listed in terms of the International Treaty on Plant Genetic Resources for Food and Agriculture.

¹ World Conservation Monitoring Centre, 1992. *Development of a National Biodiversity Index: A discussion paper*.

III. Specific Issues for consideration in the elaboration of the IR:
Measures to ensure compliance with CBD and access legislation

Under the Act, permits are required for all bioprospecting projects and for the export of any indigenous biological resource to be used for bioprospecting or for any other kind of research. Stakeholders who provide access to resources or knowledge must be consulted and their prior informed consent obtained before a permit will be issued.

The Act distinguishes between the procedures to be implemented when obtaining indigenous biological resources, where a Material Transfer Agreement (MTA) is required between the applicant and 'stakeholder' as well as a benefit-sharing agreement before a permit will be issued, and those involved when accessing knowledge which require a benefit-sharing agreement to be negotiated. Ministerial approval is required for both MTAs and for benefit-sharing agreements and a Biodiversity Trust Fund is established into which all moneys arising from bioprospecting projects must be paid.

Benefit-sharing agreements must indicate how the resources will be used, the type and quantity of resources to be collected, the area of collection, traditional uses of resources and potential uses and the extent to which the stakeholders will share in the benefits. MTAs must set out the particulars of the provider and recipient, the type and quantity of resources to be provided, the area of collection, the purpose of export, potential use and conditions for transfer to a third party. However, provisions requiring benefit-sharing agreements to be developed and approved by the Minister fail to recognise that full benefit-sharing agreements are usually only negotiated once the research and development has proceeded further although benefits such as information sharing, technology transfer and capacity development could be implemented immediately. Furthermore, the requirement for the Minister to approve both benefit-sharing agreements and MTAs may well result in further delays in acquiring access to biological resources. It is doubtful whether this level of bureaucracy is necessary for the approval of MTAs as these simply cover the exchange of material between parties with a proviso to prevent commercialisation of the material unless a benefit-sharing agreement is negotiated.

The procedures relating to the issuing of permits, which are covered in Chapter 7, are not clear with most of the detail being left to be included in the regulations that have yet to be developed. This has resulted in an understandable reluctance on the part of provincial authorities to grant permits for anything other than research purposes until such time as there is greater clarity on this matter.

Other than for export purposes, research has been excluded from the law. However, because it is often difficult to distinguish between academic (basic) research and commercial research, this may result in many bioprospecting projects being excluded from the stipulated permitting and agreement requirements. The Government Gazette (Vol. 472 October 8, 2004) states that it is expected that Chapter 6 of the Act will only be implemented by January 2006, thus making provision both for the development of regulations to implement this chapter as well as the possible introduction of changes which will facilitate the process of access to biological resources and the implementation of benefit-sharing.

Despite the legal vacuum which existed in South Africa before the passing of the Act, a number of research organisations have developed policies on access and benefit-sharing. The Council for Scientific and Industrial Research (CSIR) developed their policy in 1999, which stipulates that they will act in accordance with the Convention on Biological Diversity and all national legislations. The policy does not refer to the necessity to obtain prior informed consent, but states that the CSIR will only undertake bioprospecting research when the provision for fair and equitable sharing of benefits has been made.

III. Specific Issues for consideration in the elaboration of the IR:
Measures to ensure compliance with CBD and access legislation

The National Botanical Institute, which with the passing of the Biodiversity Act has been converted into the South African National Biodiversity Institute, has developed an ABS policy based on the Common Policy Guidelines for Botanic Gardens (García F. L. et al. 2001). This policy recognises the need to obtain prior informed consent and undertakes to acquire and supply genetic resources, their progeny or derivatives under MTA agreements. A commitment is also made for the fair and equitable sharing of benefits with relevant stakeholders.

The provincial authorities in the nine different provinces of South Africa, are at various stages in the development of policies. Ezemvelo Kwa-Zulu Natal Wildlife was the first conservation agency in South Africa to have a bioprospecting policy which was adopted in 2000 and which recognises that traditional communities have the right to control their land and resources and secure benefits from the use of their knowledge. All research is required to contribute to conservation and development in areas in which it takes place. Only requests to collect from protected areas from bona fide South African Research Institutions will be considered until the national and provincial legislation is in place (Wynberg, R. 2004).

In addition to the development of specific policies, there have also been attempts to develop a code of ethics and set of research guidelines for researchers working with South African biodiversity and local communities, through the Indigenous Plant Use Forum. This is a local networking organisation for researchers working on indigenous plants in SA. The code of ethics and guidelines, based on those adopted by the International Society of Ethnobiology and the Pew Conservation Scholars Initiative have been adapted to meet local requirements. The aim is to broaden the acceptance of the code by a wide range of organisations and researchers but it has been found to be rather challenging to engage some researchers on this matter and persuade them about the relevance of these issues to their work (Wynberg, R. 2004).

Within government and many other institutions at national level and other levels, expertise on ABS is deficient, particularly in the areas of contract negotiating skills, legal drafting skills and technical skills to enhance biodiversity assessment work and increase understanding as to the commercial pathways of natural product development. Officials also require training to enforce and implement laws.

Despite the fact that there is substantial scientific and technical expertise in SA, there are deficiencies with regard to the assessment, inventory and monitoring of genetic resources, the valuation of genetic resources, the development of information systems at national and regional levels to enable improved co-ordination and understanding and awareness with respect to benefit-sharing, and the protection and recognition of traditional knowledge about biodiversity. Improved legal understanding is also required, more specifically in terms of ownership of genetic resources and protection of traditional knowledge and farmer's rights. Although much emphasis has been placed on the 'discovery phase', more specifically screening techniques, DNA sequencing and characterisation, marketing and product development are critical gaps because they have implications for the extent to which value can be added to local biodiversity products.

In the past few years, several research consortia have been established in SA to integrate the disciplines of microbiology, chemistry, pharmacology and ethnobotany. Not only have the technical competencies of these disciplines been complimented through this process but also that of a number of different research councils, universities and institutes. This

has been accompanied by the initiation of a number of bioprospecting projects involving consortium members and foreign organisations. The focus of the national bioprospecting consortiums is on the discovery of drugs from indigenous plants in order to make a unique contribution to the search for novel drugs in southern Africa. Key partner organisations include the CSIR, Medical Research Council, South African National Biodiversity Institute, the Agricultural Research Council and several universities.

Funding was provided by the National Research Foundation's Innovation Fund for a major project focussed on the identification and development of anti-malaria drugs. The consortium owns a database containing records of 700 plants, all of which it has been claimed have been used in the treatment or prevention of malaria. The main objective of the project is to develop new medicines based on indigenous plants and indigenous knowledge for the treatment of malaria. The project also aims to create multi-disciplinary scientific capability to derive anti-malarial drugs, create jobs through cultivation and agroprocessing, develop a technology platform for South Africa comprising all the elements of the 'value chain' for drug discovery and to create economic benefits for SA through product innovation and royalty earnings. A Trust Agreement has been set up between the members of the consortium in which it has been agreed that any financial benefits generated as a result of the project are to be divided in half, with 50% of the benefits being shared equally by the partners and the remaining 50% being deposited into a Trust Fund to be shared with the stakeholders who have contributed to the project.

Some years ago, scientists at South Africa's CSIR isolated a chemical entity extracted from *Hoodia gordonia* called P57 that suppresses appetite, and this was patented in 1996. Phytopharm plc, a listed British company was licensed in 1997 by the CSIR to undertake the further development and commercialisation of the patented discovery. In 1998, Phytopharm signed a licensing agreement with the US pharmaceutical giant, Pfizer Inc., for the development and global commercialisation of P57. Pfizer informed Phytopharm in mid-2003 that it would be discontinuing the clinical development of P57 as a result of the closure of the Natureceutical group, and returned the licensing rights to Phytopharm². Phytopharm is presently negotiating with another company to undertake the clinical development of P57.

In July 2001, while describing the research progress of P57, a spokesman for the project that linked the San people with *Hoodia* implied that the tribe had in fact died out. An international outcry followed, resulting in the setting up of the South African San Council in November 2001, who then threatened a lawsuit on the project. Negotiations with the CSIR followed and the San Council demanded recognition of their knowledge and a share of the benefits. An Agreement with the San, who have a long history in Southern Africa and who have used *Hoodia* to suppress hunger and thirst during their hunting trips in the Kalahari, was signed in March 2003.

Under this agreement the CSIR will pay the San 8% of the milestone payments made by its licensee, Phytopharm, during the drug's clinical development over the next three to four years and will make study bursaries and scholarships available to the San community. The San could earn 6% of all royalties if, and when, the drug is marketed, possibly in 2008. Milestone payments for the San could reach between US\$1.2 million to US\$1.8 million while the royalties could top US\$9.4 million annually during the 15 to 20 years before the patent expires.

² Phytopharm Annual Report, 2003.

III. Specific Issues for consideration in the elaboration of the IR:
Measures to ensure compliance with CBD and access legislation

However, the process is further complicated because the indigenous knowledge related to this resource is also held by communities across national borders, in this case, South Africa, Namibia, Botswana, and Angola (Geingos, V. & Ngakaeaja, M., 2002). Consequently, any income generated will go into the San Hoodia Benefit Trust set up by the CSIR and the San. The beneficiaries will be the San people of South Africa and San communities elsewhere who are members of the Working Group of Indigenous Minorities in Southern Africa (WIMSA) and who are identified by the Trustees as eligible beneficiaries. The Trust includes representatives of the CSIR, the regional San councils, WIMSA and an observer from the South African Department of Science and Technology (Terblanche, P., 2003).

Species of biological resources also do not recognise political boundaries and often occur in several countries. Consequently, the Organisation of African Unity Council of Ministers recommended that African countries develop national legislation as well as regional regimes dealing with the exchange of biodiversity, knowledge, innovations and practices, and the African Model Law was developed with the objective of guiding this process.

The African Model Law for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources aims to protect Africa's biological diversity and livelihood systems with a common tool (Ekpere, J.A., 2001). The development of the African Model Law was the result of a number of initiatives from the Scientific, Technical and Research Commission of the OAU, the Ethiopian Environmental Protection Authority and the Institute for Sustainable Development in Ethiopia. However, the social and political realities vary across different African countries and flexibility is required to adapt the African Model Law to the priorities and needs of each African nation.

The SANBI is the South African partner in the Millennium Seedbank Project with Kew Royal Botanic Gardens. The project is an international collaborative plant conservation initiative, which aims to safeguard 24,000 species from around the world against extinction. The major focus of the South African project is the collection of threatened and endemic species. The relationship between Kew and SANBI is governed by a legally binding Memorandum of Understanding which deals with joint collecting activities, exchange of material and transfer, benefit-sharing and ownership of the material, its progeny and derivatives, which remains vested in the South African Government. Repatriation of material, the prohibition of commercialisation and the transfer of material to third parties which requires the supplier's permission and confidentiality of information are also covered in the agreement.

The Darwin Initiative Project, entitled 'DNA Banking, Phylogeny and Conservation of the South African Flora 2003- 2006', and funded by the UK Department for Environment, Food and Rural Affairs (DEFRA), has resulted in the setting up of a DNA Bank at the SANBI Kirstenbosch Research Centre, along with the establishment of technology training, research and educational programs, in collaboration with Kew. The project aims to archive genetic material from at least one species of all the 2,200 South African flowering plant genera. Researchers will be allowed to access plant DNA extracts to produce a phylogenetic 'tree of life'. The Memorandum of Agreement governing the establishment and operation of the DNA Bank also deals with issues such as exchange of material between Kew and SANBI, access to that material and the sharing of information and data. Issues such as non-commercialization, the requirement for separate benefit-sharing agreements in the event of commercialization, ownership of the material which remains vested in the South Africa government and transfer to third parties is also dealt with under the Agreement.

III. Specific Issues for consideration in the elaboration of the IR:
Measures to ensure compliance with CBD and access legislation

SANBI is responsible for the management and execution of the South African component of the Southern African Biodiversity Support Programme, a GEF funded project being carried out in 10 southern African countries. To assist in the implementation of the ABS component of this project, a questionnaire was designed to provide an overall assessment of the use of biological resources in South Africa, the processes and procedures in place to access these biological resources and indigenous knowledge, and the existing benefit-sharing mechanisms.

The questionnaire was sent out to a selection of stakeholders involved in the utilization of biological resources in national and provincial government departments, pharmaceutical companies, academic institutions, industry, traditional healers, NGOs and community-based organizations. Some of the issues covered by the questionnaire included whether the stakeholders entered into any agreements before supplying or acquiring biological resources and indication whether there was any form of benefit sharing mechanism put in place. Stakeholders were also requested to list all the difficulties experienced and lessons learnt when supplying or acquiring biological resources and gaining access to traditional knowledge.

An analysis of the responses to the questionnaire indicated that, in most cases, stakeholders first applied for permits to collect resources. Agreements, in the form of Material Transfer Agreements, contracts, or Memoranda of Understanding (MOU) were signed before the permits were issued and the collections took place. Stakeholders who collected biological resources for academic research and those in the communities frequently did not participate in the drawing up of agreements or equivalent MOUs. Some of the stakeholders in academic institutions explained that this was mainly because collections were carried out primarily for research purposes and there was no intention to commercialise the outcomes of the research.

About 50% of the suppliers of biological resources reported that no benefit-sharing mechanism existed between them and collectors. In some instances, this was because the collections are carried out without any requests for benefits in return for the supply of biological resources. The other 50%, however, indicated that benefits had been identified and ranged from immediate cash, fees per sample collected, to copies of information, reports and data. Some stakeholders reported that difficulties were experienced because the perception existed that the aim of researchers was to make money from the specimens collected and that they were collaborating with foreign companies who had come to Africa to "steal" natural resources. Thus, there was a reluctance to supply information and material. Another major problem was the lack of trust existing between suppliers and collectors.

A difficulty identified by many stakeholders was that the present procedure to obtain permits was often disorganized and not applied consistently throughout all the provinces. In terms of benefit-sharing, stakeholders felt that once the words benefit-sharing were mentioned, most of those requesting material became disinterested and negotiations tended to end at that point.

Research is a crucial basis for both the conservation and sustainable use of biological resources and any International Regime which is negotiated should contribute to the facilitation of access to resources in a controlled manner that ensures the fair and equitable sharing of benefits.

References

- Chishakwe, N. and Young, T., 1993. *Access to Genetic Resources and sharing the benefits of their use: International and Sub-regional issues*. The ABS Project (UNDP, SADC, IUCN, BMZO).
- Ekpere, J. A., 2001. *The African Model Law: The Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources. An Explanatory Booklet*. Published and distributed by OAU, Scientific, Technical & Research Commission, The Gaia Foundation and the Institute for Sustainable Development (Ethiopia).
- García F. L., Williams C., ten Kate K. and Cheyne, P., 2001. *Results of the Pilot Project for Botanic Gardens: Principles on Access to Genetic Resources and Benefit-Sharing, Common Policy Guidelines to assist with their implementation and Explanatory Text*. Published by the Board of Trustees, Royal Botanic Garden.
- Geingos, V. and Ngakaeaja, M., 2002. *Traditional Knowledge of the San of Southern Africa: Hoodia gordonia*. Presented at the Second South-South Biopiracy Summit: Biopiracy - Ten Years Post Rio. August 22-23, 2002, Johannesburg.
- Terblanche, P., 2003. *Case Study: SAN/CSIR Hoodia Benefit Sharing Model*. Presented at "Sharing the Benefit of Plant Genetic Resources" Symposium in Basel, Switzerland, October 2003.
- Wynberg, R., 2004. *Bioprospecting, Access and Benefit-Sharing in South Africa: Towards a Strategic Assessment*. Unpublished paper prepared for the NBI as a contribution towards the Southern African Biodiversity Support Programme and the National Biodiversity Strategy and Action Plan.