10

Access to genetic resources legal and policy issues

Kathy Whimp¹

Much of the world's biodiversity is located in developing countries. Many of the food crops we rely on today were originally sourced from countries which are now developing or emerging industrial economies. Germplasm of many kinds has been exchanged for many years for a variety of reasons, mostly associated with agriculture.

During the last 20 years, there have been dramatic changes in the significance of genetic material in economic and social terms. New technologies mean that some kinds of genetic material are now valuable resources for the development of yet other technologies, processes and products. As commercial interest in genetic material has grown, there has been increased pressure for intellectual property right protection to be available to protect those commercial investments. At the same time, developing countries have expressed concern about their genetic heritage being exploited with little or no recompense.

These changes have generated a dynamic and complex environment. There are many developments at national and international levels. Most are at the cutting edge of law and government administration. Many countries are uncertain about how to proceed, while at the same time feeling impelled to act quickly. This chapter examines the background to the emergence of this important international policy debate. It canvasses the possible approaches to securing better protection for national biodiversity resources, including intellectual property rights and access regimes. The chapter concludes that while intellectual property rights on

their own have limited value there are many problems in using existing intellectual property law, particularly where resources are owned by indigenous landowners rather than the state. Countries like Papua New Guinea are likely to gain greater flexibility and broader protection from legal regimes that regulate access to genetic resources and prescribe the terms on which they can be used, including the disposition of any intellectual property rights.

Background: ownership of genetic resources

In a Western cultural context, products of nature were for a long time regarded as the common heritage of humankind (Margulies 1992). In a legal sense, the ownership of genetic information in plants and animals has generally not been distinguished from ownership of the physical biota themselves.

Over the last 50 years, concern has mounted that this heritage might be lost as the pool of genetic stock from which commercial agricultural crops come has shrunk. In response to concerns about the future food security of the world, a variety of plant genetic material was collected into a number of genebanks around the world. Although independent, they are managed through an international network linked by the Consultative Group on International Agricultural Research. The majority of this material is held outside the countries where it was originally collected, and the origins of much of it can no longer be determined.

International Undertaking on Plant Genetic Resources

In the 1970s, developing countries began to express concern that they might lose access to the genetic material held outside their territorial control. In 1983, the UN Food and Agriculture Organisation oversaw the development of an International Undertaking on Plant Genetic Resources, which forms the basis for a global system of access to genetic resources for food and agriculture. Between 1989 and 1994, the Food and Agriculture Organisation negotiated with the Consultative Group on International Agricultural Research to place its genebank collections under the control of the Food and Agriculture Organisation network, and to agree that they should not seek intellectual property rights in relation to any of the material held there.

In 1991 the Undertaking was renegotiated to provide for recognition of individual states' national sovereignty in the biological resources originating within their territory (Margulies 1992). However, the Undertaking was, and is, a non-binding document. It was renegotiated again during April 1999, and a major issue for consideration was its adoption as a legally binding international instrument.

Convention on Biological Diversity

The Convention on Biological Diversity entered into force in December 1993. It is the first international instrument to recognise the national sovereignty of individual states over genetic resources. It specifically addresses the issue of access, and requires that countries take steps to facilitate access by other countries to their genetic resources (Article 15). It also requires that

- access be subject to prior informed consent by the providing country (Article 15.5)²
- the terms of access should be mutually agreed (Article 15.4)
- states should protect indigenous and local knowledge and ensure that these communities share equitably in the benefits of utilising their knowledge (Article 8(j))
- states should make technology for the conservation of biodiversity available to other countries on mutually agreed terms, subject to intellectual property rights (Article 16).

The significance of intellectual property

Concerns about the disposition of genetic material do not relate to the physical substance of the biological material. Rather, the concern is that others may use the genetic information, or the molecular structure of chemicals within the material, and benefit from the use of that information. Intellectual property rights are the principal way in which rights to control the use of incorporeal property (that is, property that does not have a physical form) are recognised.

Information or ideas can be protected in several different ways within the framework of most Western (Euro–American)-based legal systems (see Harroun, this volume). The type of intellectual property right most relevant to a discussion of genetic material is patents, which protects inventions and processes. A patent allows the owner to prevent any other person making the same invention, or using the same process, without his or her permission.

Patents

Commercially valuable ideas only remain valuable while they give the owner of the idea an advantage over her or his competitors. The owner of an idea can maintain this advantage in two ways—either the idea must be kept a trade secret (like the formula for Coca-Cola) or there must be a way to prevent a public idea being used by everyone. Patents provide a legal means of restricting ideas that the inventor has placed in the public domain.

Patents reward individuals for investing their creative effort in developing an idea. In return for protection, the individual must make the idea public through a registration system. This means that other inventors have access to the idea and can use it to develop further technology. A central policy goal of patent systems is to encourage and facilitate scientific and technological discovery.

The protection offered by patents can be described as a 'temporary exclusive economic monopoly right' (Lesser n.d.). The owner of such a monopoly right can stop all others from using his or her invention. In this way, the commercial value of the invention is maximised because its use is limited. However, this special monopoly continues for only a limited period. In most countries, patents last for around 20 years, after which the invention is freely available to be manufactured or used by anyone.

A major reason for the effectiveness of patent protection is the reciprocal recognition that is available in other countries. Under the Paris Convention of 1883, member countries undertake to protect the citizens of other countries in the same way as they treat their own. This protection was expanded in 1970 by the adoption of the Patent Co-operation Treaty, which establishes a system for making one single application for a patent that has effect in all member countries.

The operation of the international patent system is further enhanced by the adoption of common approaches by the majority of industrial countries. Under the Strasbourg Agreement of 1971, a uniform system of classification has been adopted. Difficulties in describing microorganisms for the purpose of a patent application are covered by a system of 'approved depository authorities' established under the Budapest Convention of 1977 (Whimp 1997b).

Intellectual property rights and genetic resources

Traditionally, products of nature could not be the subject of patent protection. This rule was established in a 1908 United States case in which a patent application for an object made from cork was refused (Bozecevic 1987). In order to be granted a patent, an invention must satisfy the criteria of novelty, non-obviousness and usefulness. Non-obviousness means that the invention must demonstrate that some skill or art was involved in the invention. Products of nature usually fail to satisfy both the novelty and non-obviousness criteria.

Plant variety rights

In the 1930s, the United States government enacted a law offering protection for plant varieties, in order to promote the development of a plant breeding industry. Plant breeder rights, or plant variety rights, are a system of *sui generis* (one of a kind) protection for varieties of plants that have been artificially propagated. Protection offered by this type of intellectual property right is similar to patent protection—the breeder is granted a legal right to control other's reproduction of the plant, in return for disclosing the method by which the new variety was derived.

By 1961, there was sufficient interest to establish an international convention dealing with plant variety rights. The International Convention for the Protection of New Varieties of Plants was adopted in 1961 and significantly revised in 1978. Almost all the members are developed countries. Several other countries have plant breeder rights legislation, but do not belong to the International Convention for the Protection of New Varieties of Plants.

The restrictions applied to plant variety rights under the International Convention for the Protection of New Varieties of Plants have meant that it was not of much use to developing countries. In practice it has a fairly limited application to ornamental and some agricultural plants. In 1991, the Convention was updated to make it even more restrictive from a developing country point of view. The provisions of the Convention also now prevent farmers from using saved seed from protected varieties. The requirement to demonstrate that a variety is 'distinct, uniform and stable' means that few indigenous farmers would be able to satisfy the criteria for protection (Crucible Group 1994).

Biotechnology

Perhaps the most important change affecting intellectual property rights as they relate to plants was the emergence of new biotechnology techniques during the 1970s (Lesser n.d.). In particular, the availability of recombinant DNA and hybridoma techniques made it possible to artificially develop organic materials and substances that were quite distinct from their biological components, and therefore able to be patented (Power 1992).

At least in the United States, intellectual property law kept pace with technological developments. In 1980, the US Supreme Court in the decision of *Diamond v Chakrabarty*³ upheld a decision of the Patent Office to award a patent to an artificially modified microorganism. Applications for patent protection in the United States now embrace a wide range of biologically derived materials and processes, including pharmaceuticals, antibodies, vaccines, enzymes, cell lines, first generation plant hybrids, processes for synthesising these materials, diagnostic processes and kits, and treatment processes (Power 1992).

Elsewhere in the world, patent laws are often much more restrictive. A number of countries, principally developing and newly industrialised, do not permit the patenting of a wide range of biologically derived products including pharmaceuticals. These restrictions usually have a moral basis, and emerge from ideas that life forms should not be the subject of private property rights, or that pharmaceuticals should be freely available (Gollin 1993:169; Simpson 1997:72–3).

Intellectual property in the international context

Convention on Biological Diversity

During the debate that preceded the adoption of the Convention on Biological Diversity, a major dispute erupted within the international community about provisions relating to the transfer of technology from industrial to developing countries. While developing countries wanted industrial nations to make technology for the conservation of biodiversity available to them on a preferential basis, the representatives of industrial countries objected that their citizens should be entitled to have their intellectual property in that technology protected. They argued that the owners of technology should be entitled to refuse access in countries where such protection would not be available (Margulies 1992:335).

The compromise provisions appearing in Article 16 of the Convention on Biological Diversity make for confusing reading (Goldman 1994:708). However, it appears clear that developed countries are entitled to refuse access to technology if the recipient country is not able to offer protection for intellectual property.

World Trade Organisation and the Trade-Related Aspects of International Property Rights Agreement

The significance of intellectual property in the international context increased further with the Uruguay Round of the General Agreement on Tariffs and Trade, concluded in 1993. The negotiations resulted in the establishment of the World Trade Organisation and the signing of a major agreement dealing with intellectual property.

Three countries in the Pacific island region (Papua New Guinea, Fiji and Solomon Islands) are members of the World Trade Organisation and are bound by the provisions of the Trade-Related Aspects of International Property Rights Agreement. Under the Agreement, members of the World Trade Organisation must adopt intellectual property rights legislation covering

- patents (in the form specified by the Paris Convention)
- copyright (in the form specified by the Berne Convention)
- protection of plant varieties (either under patent or under a *sui generis* system like the International Convention for the Protection of New Varieties of Plants)
- trademarks, geographic indications and designs, including integrated circuit layout designs
- trade secrets (as required by the Paris Convention) (Whimp 1997b).

Developing countries (including Papua New Guinea) that are making a transition to a market-based economy have until 2001 to comply. Least developed countries have until 2006 to comply with the terms of the Trade-Related Aspects of International Property Rights Agreement (Article 65). Even countries with no intellectual property rights laws are required to accept patent applications for pharmaceutical and agricultural chemical products from the beginning of the transition period, so as to preserve the novelty of the invention for the time when patent laws are in place.

The inadequacies of the Trade-Related Aspects of International Property Rights model of intellectual property rights for protecting

interests in unmodified genetic resources and the traditional knowledge of indigenous people has been the subject of much debate internationally (Simpson 1997:114–29).

Access to and use of genetic resources

A number of developing countries with globally significant biodiversity (and at least one developed country, Australia) are currently experiencing an increased interest in access to these resources for commercial purposes. This interest may provide an opportunity for sustainable use activities, transfer of technology and the potential for some financial gain. However, it also presents real challenges to ensure that these benefits are maximised, and that possible negative consequences are avoided.

Exchange of genetic material has occurred on an informal basis between Pacific island nations for some time. Exchanges have involved genetic material of local food, agriculture and tree crops. Because most of this exchange has occurred either at a customary level, or between government agencies, it has not raised questions about the inappropriate exploitation of the material for commercial purposes. However, recent experience of unauthorised use of genetic material (including, in one case, human genetic material) has caused offence and concern in many quarters.⁴ In addition, there are now fears that the traditional ethnobotanical knowledge of indigenous people may also be exploited.

The issue of greatest concern in controlling access to genetic resources relates to bioprospecting for chemical compounds found in plants that might yield useful material for the production of pharmaceuticals. The way in which bioprospecting is carried out makes it difficult to control. A relatively small amount of vegetative matter is required to produce a sample for screening.⁵ In some cases, screening (for anti-cancer compounds, for example) can be carried out within the country. Illicit export would be very difficult to detect. The difficulty in policing illegal bioprospecting means that attempting to prohibit it is unlikely to be successful. In any case, there may be significant benefits to be gained through properly negotiated and monitored arrangements. These advantages are already being recognised by a number of local research institutions that are entering into agreements with developed country counterparts, usually acting on behalf of large pharmaceutical firms.

Research institutions, however well meaning, may not necessarily be in the best position to consider and balance all the national and local

considerations that should form part of a response to commercial bioprospecting proposals. However, in the absence of national policy or legislation, they at least provide an institution with whom prospective prospectors can negotiate.

A particularly important consideration in the case of commercial proposals for accessing genetic resources is the control of intellectual property rights in something that might be discovered. However, the chances of making a successful find are not high—around one in 10,000 leads produces a drug that proceeds to clinical trials (Reid et al. 1993b:7) (although one plant species can yield hundreds of leads). When a find is successful, the financial returns may not be as high as some expect. Royalties for unproven samples (those that have not been subject to preliminary testing) reportedly range from 1 to 5 per cent of net sales (Laird 1993:11). Net sales in this case would mean profits after research and development costs and production and distribution costs are deducted. In the case of pharmaceuticals, research and development costs are extremely high. In the early 1990s it was estimated that the average cost of producing a marketable drug was US\$231 million, most of which was spent on clinical trials (Reid et al. 1993b:16).

These factors should lead developing countries to be cautious about how much they spend establishing and maintaining regulatory systems to capture what may be a marginal financial benefit, when compared to the cost of administering the system. On the other hand, there are also important social opportunities for the protection of indigenous knowledge, creation of incentives for conservation and the promotion of opportunities for sustainable rural development activities. All these considerations must be balanced in developing a locally appropriate approach.

Regional implications of initiatives to assert sovereignty over genetic resources are also an issue. Problems of this kind are illustrated by the rosy periwinkle biospiracy described by Goldman (1994:718). International pharmaceutical company Lilly manufactured an anti-cancer agent from the rosy periwinkle. Accounts usually attribute the plant to Madagascar, where it was first harvested. In fact, it is cultivated or grows wild in most semi-tropical and temperate parts of the world. Investigation of the periwinkle began because of folklore in the Philippines and Jamaica about its use as a tea in cases of diabetes. The plant was subsequently harvested in India and Madagascar for initial production of the drug, and eventually put under commercial

cultivation in Texas. In such circumstances it is not at all clear who should benefit from is exploitation. This is not to suggest that the developing countries involved were not entitled to compensation, but rather to illustrate the difficulties in equitably distributing it.

The distribution of species across the Pacific and in Asia means that national systems have the potential to disenfranchise neighbouring countries, even though that was not intended. There is a potential for disputes between countries to arise unless bioregional arrangements are in place to resolve them.

Possible approaches

A vigorous and fertile international discussion of these issues and how to address them has emerged over the last decade, and has gathered pace in the last five years. There are two distinct aspects to bioprospecting that involve separate legal issues. First, traditional knowledge about wild plants and their medicinal uses should be protected from exploitation. Second, the use of genetic resources themselves should be controlled through a system that ensures an appropriate level of consent, and an equitable distribution of benefits from their use.

The need for protection of traditional knowledge has generated a number of suggested approaches that focus on recognition of the importance and value of this knowledge

- protection of farmers' rights, partly as a counterbalance to plant breeder rights
- application of trade secrets to traditional knowledge
- development of *sui generis* (one of a kind) intellectual property rights systems to protect indigenous rights
- codes of ethics for researchers dealing with communities.

Not many of these approaches have been carried into effect, and so there is little available precedent to guide countries in adopting them.

The protection of genetic resources has been approached from a number of different angles, and the following solutions are in use or have been suggested.

- Codes of conduct for collectors.
- Development of intellectual property rights for plants (either plant breeder rights or patents).
- Access regimes, including research or materials transfer agreements, sometimes secured by collectors' licences or permits.

Merck-Inbio: bioprospecting partnership agreements

The Merck-Inbio arrangement is an example of an approach adopted by one country which aims to protect indigenous knowledge, to ensure a financial return, provide access to technology and training, as well as leveraging conservation benefits. Under this arrangement, the Inbio institute, on behalf of the government of Costa Rica, entered into a detailed and comprehensive partnership agreement with the pharmaceutical company Merck, to prospect Costa Rica's rich tropical forests (Reid et al. 1993a).

The agreement involves a substantial upfront payment, support for the establishment of local institutions, transfer of technology and equipment and a share of royalties. It should be noted that some commentators have criticised the agreement on the basis that the upfront payment of US\$1.13 million is a small price to pay for access to such a large reservoir of biodiversity (Simpson 1997). However, it is difficult to know the real value to Costa Rica without knowing the terms that have been agreed about royalty sharing, and these are confidential (Laird 1993:111).

Papua New Guinea would do well to study the Merck-Inbio arrangement, and might consider a partnership with one company preferable to managing a number of small contracts. However, it is also important to remember that what makes Costa Rica attractive to a potential bioprospector is its stable and well developed administrative infrastructure, a long history of political commitment and funding for environment projects and the availability of highly skilled professional staff to undertake the taxonomy involved.

The approach adopted in Costa Rica involves a level of state control over biodiversity that might not be acceptable to people in Papua New Guinea. The Costa Rican government has recently enacted a Biodiversity Law (*Ley de Biodiversidad*) that declares that while animals and plants can be privately owned, their genetic and biochemical properties are the property of the state (Rivera and Cordero 1999).

Protecting traditional knowledge and genetic resources with intellectual property rights

Genetic resources in a natural, unmodified state cannot be the subject of patent protection. Traditional knowledge also does not lend itself to

protection under existing patent law systems. Patents create individual rights. In a number of countries, the person applying for the patent must establish that they are the inventor of the process being described. Knowledge about a particular use of a plant that has been handed down through generations may be a sufficient basis for patent protection (Huft 1995), but a patent application may cost around US\$20,000. Even if these expensive rights are obtained, they expire after 20 years, leaving the information legally in the public domain.

Trade secret law is probably a more appropriate form of protection for traditional knowledge, because it does not expire unless the secrecy is waived (by publication, for example), and requires no formal process of proof or registration. However, to maintain protection, the group needs to keep the information secret. Information that is secret can be divulged (for example to a bioprospector) provided there is a contract requiring the third party to maintain confidentiality. Any unauthorised use could be the subject of a legal action and might invalidate a patent based on it.

Ironically, some indigenous communities may be encouraged to give away the possibility of trade secret protection in order to protect their knowledge being copied by third parties. Although traditional indigenous knowledge is rarely of itself the subject of patent applications, many indigenous communities have experienced researchers publishing accounts of their knowledge and obtaining copyright over those publications. The best protection against copyright misappropriation is prior publication by the group itself. However, the voluntary publication of material may also rule out the possibility of trade secret protection.

Codes of ethics for researchers

Some of the infringements of indigenous rights can be addressed through more ethical behaviour by researchers. Guidelines of this kind are included in the *Code of Ethics of the Australian Anthropological Society*. Such a code might include a requirement for knowledge not to be published without the specific permission of those from whom it was obtained, and/or requirements for joint copyright to be specified on publication. The Manila Declaration, adopted at the seventh Asian Symposium on Medicinal Plants, Spices and Other Natural Products, contains some ethical guidelines for scientists engaged in ethnobotanical collecting. Several others are available.⁶

Community intellectual property rights

A number of commentators have proposed that a special *sui generis* form of intellectual property rights should be created to protect the traditional knowledge of indigenous people (Simpson 1997:146). It has also been suggested that this alternative system might provide a way for developing countries to meet their obligations under the Trade-Related Aspects of International Property Rights Agreement (to provide protection for plant varieties), while respecting the traditional knowledge systems that are fundamental to their culture. In 1994, a project by the Third World Network produced a draft Community Intellectual Rights Act setting out a very broad framework for recognition of community custodianship of innovation and commercial use of indigenous knowledge. In 1998, the Organisation for African Unity produced a Declaration and Model Law on Community Rights and Access to Biological Resources. Both drafts are expressed in extremely broad terms and, for example, contain no mechanisms for enforcement.⁷

Sui generis systems have two major disadvantages that should be considered carefully. First, a system of intellectual property rights is only as good as the capacity to enforce it, generally within the country where the law was passed. It is highly likely that infringements of indigenous intellectual property rights—for example, by the patenting of a chemical compound based on traditional knowledge about its use—will occur outside the country where the indigenous owners live. In other words, unless other countries—in particular developed countries whose citizens are most likely to infringe traditional rights—adopt reciprocal or complementary systems, the protection offered by *sui generis* systems will be limited to the country in which the law is enacted.

Second, proposals for *sui generis* systems raise problems about the legal identification of the group that owns traditional knowledge, and how that information is handled in transmission through generations and between groups as a result of customary practices. Still more problems arise if more than one group possesses the same knowledge.

A project is underway in Ecuador to establish a 'cartel' over indigenous knowledge. It involves a system of regional depository databases, that are kept confidential unless it appears that knowledge is registered by more than one group, in which case they may jointly negotiate the release of the information (Simpson 1997:80). It appears

that a large and relatively expensive infrastructure is involved in such a system.

The Ecuador proposal works on the basis of trade secret protection, rather than establishing a new system of rights. On balance, trade secret protection does seem to be the most useful way to protect indigenous knowledge, provided the knowledge is not yet in the public domain and its continued secrecy can be maintained by contracts with third parties. A law that asserts the rights of indigenous people to be protected by trade secrecy, and provides an easy means for them to assert that protection, could provide a useful complement to access and contract systems described below.

Access regimes

By far the most widely adopted approach to protecting the interests of developing countries in genetic resources is through the development of access regimes. An access regime is a framework for setting the terms on which people may access genetic resources within the country. It is an exercise of national sovereignty as envisaged by the Convention on Biological Diversity. To be effective, the framework of a legal regime controlling access to genetic resources should have three elements

- a set of rules (whether imposed by law or as a matter of policy)
- a clear division of responsibility for decision making about access proposals
- the capacity to implement the rules and make decisions.

A number of countries have adopted, or are considering, access regimes. Most, but not all, are imposed through legislation. They include

- Philippines Executive Order 247
- Fiji draft Sustainable Development Bill, clause 254
- Andean Pact (Cartagena Agreement Commission) Decision 391
- Western Australia Conservation and Land Management Act
- Costa Rica *Ley de Biodiversidad*
- International Collaborative Biodiversity Group Peru (see Tobin, this volume)
- University of South Pacific and Verata Agreement
- Samoa draft access regulations
- Organisation for African Unity Model Law on Community Rights and Access to Biological Diversity
- Thailand draft Act on Protection of Thai Medical Wisdom
- proposed amendments to Nigeria National Parks Act

- 1993 Food and Agriculture Organisation drafting instructions for legislation for Seychelles
- Second Draft Eritrean Proclamation on Conservation of Biological Diversity 1996
- Mexico Environment Act 1996
- Peru Law for the Conservation and Sustainable Use of Biodiversity 1997
- The Gambia National Environmental Management Act 1995
- Kenya Draft Environmental Management and Coordination Bill 1995
- Malawi Environmental Management Bill 1996
- Republic of Korea National Environmental Preservation Act 1991, as amended in 1994
- Uganda National Environmental Statute 1995 (Glowka 1998).

The basis of almost all access regimes is a contract permitting access on specified terms and conditions. These agreements are sometimes called research agreements, and sometimes materials transfer agreements (both might be used for different purposes). They can be secured by a law that prohibits access without a permit or licence, or they may be imposed simply as a result of government policy. Where foreigners are concerned, it is usually possible to impose requirements simply through immigration restrictions as a condition of visas, for example. If there is concern that citizens within a country are involved in bioprospecting, then a separate law will be needed to enforce the requirement for contracts prior to accessing genetic resources.

Codes of conduct for collection

Codes of conduct are a useful way of setting a common framework for an activity, particularly where the persons or bodies to be bound by it are already in a relationship with one another, and there is a general desire to do the right thing. The exchange of germplasm between Pacific island country governments has been occurring for some time. Agencies involved in tree and food crop improvement programs regularly undertake such exchanges, with mutually beneficial aims. In recognition of the growing sensitivity about these exchanges, a number of programs have developed codes of conduct that regulate the process of collection. Most of them provide that intellectual property in the genetic material remains with the donor country, and there are restrictions on the transfer of material to third parties.

Other codes of conduct for collection are also available and might be adopted for use. These include the Food and Agriculture Organisation Draft International Code of Conduct for Plant Germplasm Collecting and Transfer, and the provisions of the Manila Declaration on the Ethical Utilisation of Asian Biological Resources, adopted at the seventh meeting of the Asian Symposium on Medicinal Plants and Spices. It includes suggested minimum standards for contracts between collecting organisations and their developing country hosts. A number of codes of conduct are available on the Working Group on Traditional Resource Rights website.⁸ Many provide similar comprehensive lists of possible conditions for an access regime.

Elements of an access regime

Scope

An access law or policy should specify the scope of coverage of the activities that are permitted and that should be undertaken in accordance with the scheme. The scope of an access regime will be governed mainly by the way key concepts are defined. Genetic resources and biodiversity might be defined widely (to include knowledge about genetic resources, for example) if there are concerns that prospecting activities may take place without samples actually being removed. Reference to the definitions in the Convention on Biological Diversity would be useful. Bio-prospecting should also be carefully defined, since many activities involve the taking of small amounts of vegetative material (harvesting tea, for example) that should not be accidentally captured by the scheme.

There should be provision to limit the scope of application to particular species or habitats, depending on rarity, ecosystem fragility, danger of genetic erosion or risk of adverse social impacts. The harvesting of human genetic material should be excluded from the scheme. In addition, most access regimes exclude customary transfers of material from permit requirements. In some cases it may be appropriate to extend this to customary transfers between countries.

Competent national authority

An essential element of an access regime is a national body with whom research agreements or materials transfer agreements should be negotiated. Multiagency groups (involving representatives from a

number of interested departments) are a common choice, but these sometimes have the disadvantage of being slow to make decisions, and they can be too cumbersome in some situations to negotiate adequately. Legislation may be needed to give a body of this kind the legal status to enter into binding contracts with bioprospectors, or the body may act in an advisory capacity to another authority, such as a minister, who ultimately signs contracts.

In some cases it may be more appropriate to use existing sectoral bodies operating within a clear framework and with an independent agency (such as the Attorney-General's office) involved in overseeing compliance. If existing agencies are used, it may be more appropriate to amend their existing legislation than to develop a new Act (if legislation is desired). However, the dangers of duplicating licensing requirements should be borne in mind.

In the absence of national policy or legislation, research organisations in Pacific island countries are taking on the role of negotiating the terms on which access occurs. While these organisations have considerable knowledge about these issues, they cannot assume the role of granting consent to access genetic resources on behalf of a nation state, unless they have been specifically authorised to do so by legislation. In any case, local research institutions may not be the appropriate bodies to act as the competent national authority, given that they usually stand to gain financially from the proposed bioprospecting projects.

Regulatory system

Bioprospecting activities will often involve as many as four discrete organisations working together: a pharmaceutical company; the overseas research institution that it engages to undertake the research work; a local partner institution, and sometimes a body representing the government and/or local communities.

The regulatory system should be effective in controlling the use of genetic material after it has left the country, and is in the hands of third parties who may not have been directly involved in the collection of the material. While permits issued within a country allow the state to exercise a gatekeeper role, and provide a basis for challenging collecting activities that are not in accordance with it, they do not provide a basis for challenging unauthorised use of material once it has left the country. Collateral contract arrangements are needed to ensure that there is

control over the use of material after it has been collected and the results of tests are passed on to the clients of the research organisation.

It may be appropriate for the access regime to provide for framework agreements setting out in broad terms the relationship between the bioprospector and the host country; for example, partnerships between local research or collecting bodies, and overseas companies seeking to benefit from the bioprospecting activities. Within the framework of these agreements, much simpler individual materials transfer agreements could be negotiated.

Basis for access

The national law or policy should set out the basic minimum terms for access but should not be too prescriptive. The process for applying for access permission should be transparent, effective and efficient. Licensing administrative systems can easily develop a life of their own and sometimes create more problems than they solve. Minimum terms might include the following.

Application processes

- Requirement for full disclosure of information about the proposed activity (including the locality, the nature of the activity, the species to be harvested and sampling techniques to be used) and the end use to which the material will be put (in other words, a complete project proposal and plan).
- Requirement to demonstrate adequate skill and knowledge to carry out the work.
- Where it is considered viable to develop a local industry, a requirement for collaboration with a local research body may be required.
- Limits on the duration of exclusive materials transfer agreements.

Collection

- Requirement to carry out research in an environmentally sound manner and comply with environmental laws, and not to deplete local populations.
- Requirement to observe all other laws of the country in relation to collection and export, including quarantine laws.
- Requirement to enter into collecting agreements with local and indigenous communities.

After collection

- Requirements for deposit of voucher specimens with the national herbarium.
- Requirement for academic citation in relation to published research findings.
- Access to research information (this might not realistically be required in the case of commercial agreements, but could be required of academic agreements).
- Circumstances in which information provided to the national authority can be kept confidential, and any limit on the duration of confidentiality provisions.

Academic research agreements

Academic access and intergovernmental transfer proposals are likely to involve different considerations from commercial bioprospecting ones. It may be appropriate to have a different set of requirements applying to these situations. For example, academic agreements might contain

- a prohibition on obtaining any intellectual property over the material
- restrictions on disposal of material and/or information to third parties.

Given that there is no direct monetary benefit arising from the exchange, it may also be appropriate to limit fees so that only collectors fees (paid to local communities) are required.

Research agreements/materials transfer agreements

Within the framework provided by the access regime, research agreements or materials transfer agreements are likely to form the basis of the individual arrangements applying to specific collecting proposals. Agreements may contain a range of standard provisions including

- transfer of materials collected into custody of collector
- limitations on transfer to third parties
- whether destructive harvesting (for example, involving whole plants and bark) is permitted
- maximum volume limitations per species or overall, and provisions for extending these
- limitations on assertion of ownership over materials and genetic information
- requirements for agreement to be reached with local or indigenous communities

- basis for entry onto private or government land
- benefit sharing, including disposition of intellectual property rights, collecting fees and royalty sharing
- term of the agreement
- whether access, either generally or to a particular area, is exclusive
- return of remaining materials on conclusion of contract
- confidentiality of information and duration of confidentiality
- mechanisms for ongoing review and monitoring of agreement
- contact persons for each party
- dispute resolution, and whether arbitration is to be used in lieu of litigation
- applicable law
- confidentiality of terms of agreement
- termination.

Prior informed consent of local communities and benefit sharing

Access regimes are a means by which nations can ensure that access to the genetic resources within their sovereign territory occurs only with their prior informed consent and on mutually agreed terms, as required by the Convention on Biological Diversity.

However, the Convention on Biological Diversity also requires states to provide a prior informed consent regime for the indigenous people who are the owners of these resources. It is important to have a common policy on the means by which the prior informed consent of indigenous and local communities is to be sought. In many cases, a collateral materials or information transfer agreement is entered into with the group or persons who are supplying either samples or knowledge.

Sometimes an intermediary organisation will enter into collecting agreements with indigenous people on behalf of the research body which is to receive the samples. The terms of the agreement will usually include respect for local customs, procedures for obtaining consent, agreed rates for samples and/or knowledge. In some cases companies have entered into more complex arrangements that involve funding sustainable use activities by communities. It may be appropriate to limit the term of the agreement to a fixed exploration period and to provide for collateral development phase contracts if ongoing supply of a particular material is required.

Other mechanisms can be used to gain a wider range of views on a proposal. These include public notification requirements and holding research proposals in a public register. However, these systems are expensive to operate and should not be adopted without careful consideration of the resource implications.

Possible monetary benefits

Monetary benefits payable under an agreement will vary from case to case. Some of the kinds of monetary benefits that are typically included in agreements are

- upfront payments
- collection fees
- share of royalties in event of commercialisation
- know-how licence fees
- support for in-country researchers or institutions.

Sample fees are usually paid to indigenous communities. Typical amounts for collection payments are reportedly between US\$50–200 per kilogram of raw material, depending on the difficulty involved in collection (Laird 1993:108–9).

An issue for serious consideration in the access regime is the proportion and mechanisms for distribution of royalty shares in the event of a marketable discovery. While those groups who have provided the initial sample may assume that they are entitled to receive royalties, this may not be an equitable outcome, in particular if the species has a widespread distribution. The identification of all the range of owners of a particular species is probably an impossible task. It may be more appropriate to consider mechanisms that give all resource owners in the country access to a pool of these funds for specific purposes, for example, activities that support and reward biodiversity conservation.

Possible non-monetary benefits

A review of existing access arrangements suggests that non-monetary benefits are the most important form of compensation flowing from access to genetic resources. These include

- mutual exchange of material
- improvement of genetic stock
- information exchange

- joint research
- technology transfer and training
- institutional capacity building
- joint venture
- deposit and identification of specimens.

Benefit sharing

Some of the most important negotiations that will occur under any access regime relate to the benefits that flow back to the country which provided the material. There are a number of possible beneficiaries including

- the competent national authority—to cover the costs of administration
- any intermediary organisation, such as a university—to cover the costs of their involvement and promote research
- conservation activities—to maintain the resource that is generating the income
- (depending on the constitutional structure) sub-national government
- resource owners and local communities (Para 3, Contract Guidelines: Appendix 2).

The Manila Declaration provides some guidance about suggested division of proceeds between different bodies involved in a collection process. It suggests that

- ‘60 per cent of any income arising from supply of extracts to commercial organisations should be returned to the appropriate country organisation’
- the country organisation should receive ‘51 per cent of any royalties arising from external collaboration that results in marketable products’ (a fair royalty is suggested to be of the order of 3–5 per cent) (Para 4, Contract Guidelines: Appendix 2).

Benefits, and the arrangements for their distribution, are likely to vary considerably between different agreements.

Mechanisms for distributing benefits

Distribution of benefits to resource owners is a difficult issue in any context. Where payments are made for samples collected, the issues are comparatively simple. Individuals and families who supply material are paid at the agreed rate. Where communal knowledge is accessed, or where royalty shares are being distributed, the arrangements for

distribution are likely to be more complex. Incorporated land groups or agency arrangements may be an appropriate mechanisms. Trust arrangements could also be used, although at least one commentator has criticised the use of trusts on the basis that they are a culturally foreign concept for indigenous people (Simpson 1997:157).

Future directions

Countries that are looking to develop a more formal approach to allowing access to their genetic diversity have a wide range of information available to them. Unfortunately, not much information is collected together in an accessible form. Websites, publications in technical journals and a handful of text books are available. A number of international and regional bodies are developing an expertise in this area. They include the International Union for the Conservation of Nature, World Wildlife Fund, Working Group on Traditional Resource Rights and the Malaysian-based Third World Network. A substantial amount of work has also been done by the African Centre for Technology Studies, based in Nairobi.

The range of examples of other countries' experience in developing access regimes should be carefully evaluated. Many of the countries who have enacted access laws already have quite sophisticated administrative systems and more resources than small Pacific island nations. The suitability of their models should not be automatically presumed. However, they may offer a useful basis for developing a simpler, more streamlined and cost-effective approach.

Within and outside government there are a wide array of stakeholders whose interests need to be accommodated in developing a system for regulating access. These include

- biologists and biological research bodies
- forestry regulatory authorities and research bodies
- forest industry representatives
- environment protection and conservation authorities
- agricultural research bodies and industry representatives
- organisations working in the non-government sector with an interest in conservation and rural development
- local and indigenous communities and sub-national governments.

All these stakeholders will be required to participate in effective implementation and their acceptance of its suitability to their needs is essential.

A strategic plan for the establishment of an access regime (including the development of model access agreements, establishment of a competent national authority and so on) should be developed. A strategic plan should help to identify the cost implications of the proposal and ensure that it will possible to implement it.

The importance of regional coordination of efforts to establish access regimes cannot be underestimated. Some of the possible benefits of regional cooperation are

- economies of scale in terms of researching and evaluating different models
- developing a respository of regional expertise
- adoption of complementary systems to clarify and simplify access for prospective prospectors and encourage compliance
- the provision of a mechanism for regional cooperation in relation to access to regional endemic species.

Conclusion

The debate in Papua New Guinea about how to protect sovereign interests in genetic resources has so far concentrated mainly on intellectual property rights. Some of the discussion is misinformed. For example, the suggestion that a wide variety of species of animals and plants could be patented is unrealistic in view of the cost of obtaining patents. In any case patents of this kind would not conform to the international standards for patent law because products of nature are not patentable unless they are a new variety produced through artificial breeding. Rather than whole species, the issues about intellectual property rights relate to processes and products that have been developed on the basis of information obtained from genetic material.

Intellectual property law is a complex and highly specialised area. Its application to biotechnology and pharmacology is even more complicated and specialised. It is important that the debate in Papua New Guinea be informed by those who are knowledgeable about these areas so that the issues are understood in their proper context.

This chapter has considered the issues involved in establishing a system for protection that does not rely on intellectual property rights. Instead, it works on the basis of a gatekeeper mechanism. Quite simply, access to biological resources would not be allowed except on certain terms and conditions dictated by government, including terms relating

to the intellectual property (and benefits from its use) arising from any discovery made in Papua New Guinea.

Instituting a system of controlling access is a relatively simple matter legally, but has significant resource implications. It is probably beyond the capacity of existing government agencies to operate such a system effectively. Furthermore, the task of regulation becomes more complicated when issues of indigenous rights are considered.

The mechanisms by which indigenous owners of biological resources (not just in the location where they are accessed, but everywhere in Papua New Guinea) are involved in decision making, and share in benefits, are likely to involve a substantial infrastructure. These issues challenge Papua New Guinea's community and policymakers to think creatively and laterally about how to do much more with much less, perhaps through the involvement of agencies outside government in partnerships to implement the new regulatory mechanisms.

In the thick of this debate, it is important not to lose sight of the final goal (in the words of Papua New Guinea's Fourth National Goal): 'to secure the conservation of natural resources and the environment for the collective benefit of future generations'. One thing is certain: without some intervention, however inadequate, the current generation will fail in its challenge to secure the future for its children.

Notes

- 1 An earlier version of this paper was presented to the Conference on Plant Genetic Resources, Apia, Samoa, April 1999. The author wishes to thank Clark Peteru for his comments on the earlier version. Errors and omissions are the author's responsibility alone.
- 2 Prior informed consent provisions are used in a number of other international conventions, including the Basel Convention on the Transboundary Movement of Hazardous Wastes. It has been suggested that a prior informed consent regime would require full disclosure of the reasons for the activity, the specific procedures involved, potential risks and the full implications that can reasonably be foreseen (Fourmile 1998:15 and note 11).
- 3 447 US 303 (1980) (Huft n.9 and Peet).

- 4 In the early 1990s the National Institute of Health filed a patent application for copy DNA sequences resulting from research conducted by its biochemist as part of the Human Genome Project. The sequences included some obtained from Hagahai people in the Highlands of Papua New Guinea. See Moufang (1994) for a full discussion of the ethical issues.
- 5 The Code of Conduct appended to the Manila Declaration suggests that a maximum of 500 grams of dry weight should be provided initially, although Laird (1993:108) suggests that more is now usually required.