Study unit 5

Biodiversity and genetic resources

Overview

In this study unit you will be introduced to the concepts 'biodiversity' and 'genetic resources'. You will also be introduced to the importance of the protection of biodiversity, and to the relationship between biodiversity and traditional knowledge. You will also briefly explore the protection of biodiversity and genetic resources at international, regional, and national levels.

Learning outcomes

After completion of this study unit, you should be able to —

- ❏ appreciate the meaning and content of concepts such as 'biodiversity', 'genetic resources', 'access', 'prior informed consent', 'transfer of technology', and 'benefit sharing'
- ❏ justify the legal protection of biodiversity
- ❏ understand the problems faced by countries that host genetic resources
- ❏ acknowledge the attempts at international, regional, and national levels to protect biodiversity and traditional knowledge

Setting the scene

- ❏ The bark and leaves of the *Acacia nilotica* tree in Kenya were collected by pharmaceutical companies in developed countries which later used such bark and leaves in the development of patentable products.

- ❏ The Amazonian Indians in Ecuador have used a tomato from the jungle called 'tamate' (a small and cylindrical tomato) because of its cancer fighting properties. A multi-national pharmaceutical company went to Ecuador, isolated the active ingredient, patented it, and now sells it as a cutting-edge product to treat cancer.

- ❏ In 1991, the pharmaceutical company Merck & Co entered into an agreement with Costa Rica's Instituto Nacional de Biodiversidad (INBio), a non-profit

organization. In terms of this agreement, over a two-year period, Merck received some 10 000 plant samples. They were supplied with information about their traditional use. Merck has paid a reported $1.35 million to INBio for these samples, and have agreed to pay a royalty of between 2 and 3 per cent. If one of the samples becomes a billion dollar drug, Merck has agreed to pay INBio between and $20 million and $30 million in royalties. Conceivably, the royalties from these samples could earn INBio more than $100 million every year.

Discussion

Introduction

developing countries

In the context of biodiversity and genetic resources, nature favours developing countries. It is estimated that about 90 per cent of the world's genetic resources are situated in developing countries. Latin America is reported to have the largest concentration of plant species: Colombia, Peru, and Ecuador between them have some 40 000 species on just 2 per cent of the earth's surface. At the same time, more than 90 per cent of the world's research and development activity takes place in the developed countries. So the international picture is one of a gene-rich but technology-poor South and a technology-rich but gene-deficient North. Ideally, this should create the potential for mutually beneficial bargains between these two groups.

gene-rich South

technology-rich North

economic & ecological interests

Developed countries have a strong economic and ecological interest in the preservation of genetic resources. Developments in biotechnology increase the prospects for better harnessing of the gene pool of the developing countries by corporations in the North. So a number of research and other institutions in developed countries have entered into contracts with developing countries for the prospecting of genetic resources (*bioprospecting*).

bioprospecting

global loss of biodiversity

At the same time, there are serious concerns about the loss in global biodiversity with potentially catastrophic consequences. While estimates vary, there seems to be increasing agreement that there is a large-scale, ongoing destruction of biodiversity with potentially very serious consequences. For example:

rain forests

- It is estimated that the biodiversity rich tropical rain forests and moist forests are being cleared at the rate of 1.8 per cent each year (this equals the size of the American state of Florida each year).

deforestation

- It has been estimated that deforestation leads to a loss of about 2.7 per cent of the species per decade in these forests. With the rate of deforestation accelerating, the biodiversity loss could be enormous.

extinction of species

- A median estimate is that there are about 10 million species in the world, and that the current extinction rate of species is about 5 per cent per decade. On this basis, about 50 000 species could be lost each year. Only 70 000 would have been recognized and named. This also means that about two-thirds of living species would be lost during this century.

wheat varieties

- China had more than 10 000 wheat varieties in 1945, of which today fewer than 1 000 remain.

rice varieties

- Farmers in India today work with less than twenty rice varieties, although there were more than 30 000 at the beginning of the twentieth century.

common heritage of mankind

Traditionally, genetic resources were considered as part of the 'common heritage of mankind'. (For example, until 2001, the International Undertaking on Plant Genetic Resources, of the United Nation Food and Agriculture Organization (FAO), defined plant genetic resources as the 'heritage of mankind ... which should be available without restriction'.) This concept is also used in other contexts (such as with reference to Antarctica, outer space, and the deep sea bed). It connotes the power, exercised jointly by different states, to exploit and use resources. This made it possible for users in developed countries freely to take advantage of genetic resources.

no economic return to host countries

These users usually did not return any economic benefit to the countries or communities that provided and conserved the resources. As there was no obligation to share any profits, and as the communities that lived near the genetic resources and associated biological resources used in such inventions generally did not participate in the advanced research that led to inventions protected by intellectual property, the economic consequence of biological diversity had no relation with its host country. In intellectual property terminology, genetic resources were in the public domain. As a consequence, third persons could freely utilize genetic resources as common heritage from the public domain, which then gave rise to

public domain

intellectual property rights.

genetic resource collections

The notion of the common heritage of mankind has also led to genetic resources being used, modified, and stored in centres around the world. Scientific institutions around the world hold substantial collections of microbial genetic resources (culture collections), and plant and animal genetic resources. These are, especially, the plant collections of the International Agricultural Research Centres, the Microbial Resource Centres, microbe collections, botanical gardens collections, and the private collections of breeding companies and biotechnology firms. The collections are referred to as ex situ collections.

ex situ collections

biopiracy

In a series of prominent incidents, corporations in developed countries were involved in the use – without remuneration – of genetic plant material found in developing countries. So the term *biopiracy* was coined. Consider these examples:

turmeric

- ❏ Turmeric is an Indian plant that has been used for thousands of years for controlling pests and healing wounds and rashes. The United States Patent Office granted a patent for turmeric to be used to heal wounds (US Patent 5.40.504). The patent was assigned to University of Mississippi Medical Centre. It claimed that the administration of an effective amount of turmeric through local and oral route enhances the wound healing process. This patent was revoked after the Indian Council for Scientific and Industrial Research presented ancient documents that witnessed the traditional use of the plant. So the patent failed to meet the novelty criterion for patentability.

neem tree

- ❏ The Neem tree grows in India and other parts of South-East Asia. Neem extracts can be used as a pesticide against pests (such as the white fly) and fungus diseases. Besides, the oil extracted from its seeds can be used to relieve various human diseases, such as malaria, skin diseases, and even meningitis. The European Patent Office revoked the patent granted to an American corporation, mainly due to the lack of novelty and inventive step. The Examining Division stated that the technique used had already been well known to local farmers. So the invention lacked any inventive step and could not be patented.

- ❏ Another patent that failed to meet the criteria for patentability was granted on Ayahuasca

Ayahuasca

(*Banisteriopsis caapi*). It is an Amazonian plant used for medicinal and ritual purposes. Ayahuasca is the vernacular name among the Amazon Quichua people, for whom it always has been a sacred plant. In 1986, after research in Ecuadorian Amazonia, an American scientist was granted a patent for Ayahuasca. Later the Coordinating Body for the Indigenous Organizations of the Amazon Basin (COICA), the Coalition for Amazonian Peoples and Their Environment, and lawyers at the Centre for International Environmental Law asked for a re-examination of the patent by the Patent and Trademark Office. The office revoked the patent. Its decision was based on the fact that publications describing the plant and its effects had been known prior to the filing of the patent application.

❑ A little less clear is the rosy periwinkle (*Catharantus roseus*) case. This plant had been used through the ages by Malagasy healers to treat diabetes. As early as 1757, French explorers had introduced the plant to the world. It was used to cure sore throat, pleurisy, dysentery, and diabetes. The plant now grows all over the tropics and it was used by many indigenous groups throughout the world. In the fifties and sixties, the United States National Cancer Institute and Eli Lilly, an American pharmaceutical firm, on a large scale screened plants for their anti-cancer properties. Scientists from Eli Lilly separated a large amount alkaloids from the leaves of the rosy periwinkle and produced two compounds –vincristine and vinblastine – that were discovered to be powerful anti-cancer drugs. Although the plant had long been used by indigenous groups all over the world, none of them had used it to treat cancer. Vincristine is now used to treat leukemia, while vinblastine is effective in treating testicular cancer. Whilst childhood leukemia before 1957 was fatal for 95 per cent of its victims, with the aid of vincristine, the survival rate now reaches 84 per cent. Eli Lilly earns about $100 million annually from the sales of these drugs, under the trade names Velban and Oncovin. But the local populations – especially in Madagascar, the original home of the rosy periwinkle – do not share in these benefits.

rosy periwinkle

Note that although this case relates to traditional knowledge and indigenous practices, the application of the relevant genetic resource is new. There is no

misappropriation

misappropriation of pre-existing human information – apparently the scientists from Eli Lilly were the first to discover the anti-cancer properties of rosy periwinkle. The only misappropriation, then, can concern the resource as such.

disadvantages for developing countries

So the perception was created that developing countries were doubly disadvantaged:

- ❏ their resources were used without remuneration; and
- ❏ the patented product came with a higher price tag because of the patent monopoly.

Seattle Ministerial

Finally, at the Seattle Ministerial Meeting of Trade Ministers in 1999, a number of developing countries raised the issue of the protection of traditional knowledge. Bolivia, Colombia, Ecuador, and Nicaragua specifically proposed that the Seattle Ministerial Conference establish a mandate for the next round of trade negotiations to –

- ❏ carry out studies, with other relevant international organizations, to make recommendations on the most appropriate means of recognizing and protecting traditional knowledge as the subject matter of intellectual property rights;
- ❏ on the basis of these recommendations, to initiate negotiations with a view to establish a multilateral legal framework that will grant effective protection to the expressions and manifestations of traditional knowledge; and
- ❏ to complete the envisaged legal framework in time for it to be included as part of the results of next round of trade negotiations (WT/GS/W/362).

What is 'biodiversity'?

biodiversity and genetic resources

Although the terms 'genetic resources' and 'biodiversity' are often used interchangeably, they are not identical. Biodiversity is a measure of the genetic variation contained within the earth's biological resources (plants, animals, fish, bacteria, insects, and so on). It increases with the number of distinct species. Many species have thresholds – once their population falls below a critical number they are doomed to extinction. So biodiversity does not simply relate to the quantity of biological resources but also to their distribution relative to the threshold levels. Beyond these levels, additional quantities of resources contribute little to biodiversity.

Traditional knowledge and biodiversity

traditional knowledge

Developing countries usually seek to protect traditional knowledge, on the one hand, and genetic resources (like seeds, endoplasm, rare animal and plant species, and parts of plants and animals), on the other. A distinguishing characteristic of genetic resources is that they are not the product of human invention or creativity. Instead, they typically exist in nature. The real importance of genetic resources lies in the encoded genetic information that is valuable in the development of medicines and pharmaceutical products to cure human diseases and in raising agricultural productivity.

public goods

Traditional knowledge and genetic resources share certain characteristics of public goods:

non-rivalrous in consumption

- ❏ Once created (traditional knowledge) or once preserved (genetic resources), they can be used be used by any number of people. So they are non-rivalrous in consumption – one person's enjoyment of the value of traditional knowledge and genetic resources does not diminish another's.

non-exclusionary

- ❏ They are non-exclusionary – once they are created or preserved, it is difficult to prevent them being used by everyone. With genetic resources access to a very small (even an infinitesimal) quantity may be enough to enjoy their benefits.

distinction

But it should be clear that it is important to distinguish between traditional knowledge and genetic resources. Traditional knowledge is the product of human invention and creation, whereas genetic resources are in some sense given by nature.

Why should genetic resources be protected?

These main reasons have been advanced:

medicines

- ❏ Economic benefit: a large part of the world population in China, India, and Brazil depend on plants for their medicines. Even the drug industry is founded on genetic resources. It is estimated that more than 100 drugs in international commerce derive from plants.

drug industry

For example, of the top twenty drugs sold (with a market value of $6 billion) in the United States in 1988, two were taken directly from natural resources, three were semi-synthetic, eight were synthetics with their chemical structure modelled on previously natural compounds, and seven had their pharmacological activity defined by natural products research (PH Raven & JA McNeely *Biological Extinction: Its Scope and Meaning for Us*, WTO Council for Trade in Services (S/C/W/94 of 9 February 1999)). For example, Artemisin, the only effective drug against all strains of malaria, was discovered because the Chinese use it to treat fever. Advances in biotechnology, especially the possibility of using genetic information and transferring genes from one species to another, enhances the potential economic value of genetic resources.

ecological functions

❑ Biodiversity has important ecological functions that sustain plant and human life. It provides a variety of services such as protecting watersheds, regulating local climates, maintaining atmospheric quality, absorbing pollutants, and generating and maintaining soils. Also, a properly functioning ecosystem is necessary to maintain the basic photosynthetic processes that sustain life on earth.

intrinsic value

❑ Genetic resources may have an intrinsic value, a value to exist in and of themselves and independent of their use to us. Many ecologists and environmentalists maintain that we have an absolute moral responsibility to protect plants and animals.

cultural & aesthetic value

❑ Biodiversity may have cultural and aesthetic value. For example, in certain societies, plants and animals are revered and have symbolic value, such as elephants in Hinduism, the bald eagle in the United States, the lily in France, and so on.

Protection of genetic resources by intellectual property law

intellectual property protection

Intellectual property law may be used to a limited extent to protect biodiversity and genetic resources. These forms are most often used:

❑ patents;

- ❏ plant breeders' rights (including the International Union for the Protection of New Varieties of Plants (UPOV));
- ❏ trade secrets.

sui generis protection

These forms of protection are dealt with in other modules and so will not be canvassed here. Instead, we will survey sui generis legal protection available for biodiversity and genetic resources at three levels:

- ❏ international level, with specific reference to the Convention on Biological Diversity;
- ❏ regional level, with specific reference to the Andean Community and the Organization for African Unity; and
- ❏ national level, with specific reference to legislation adopted in Costa Rica.

Convention on Biodiversity

Rio Earth Summit

The Convention on Biological Diversity (CBD) was adopted at the United Nations Conference on Environment and Development in Rio de Janeiro (the 'Rio Earth Summit') in June 1992. It entered into force on 29 December 1993. As of January 2002, the CBD had 182 Contracting Parties.

Objectives

objectives

The CBD has three main objectives:

- ❏ the conservation of biological diversity,
- ❏ the sustainable use of its components, and
- ❏ the equitable sharing of benefits arising from the use of these genetic resources.

preamble

According to its preamble, these goals are based on the conviction 'conservation and sustainable use of biological diversity is of critical importance for meeting the food, health and other needs of the growing world population, for which purpose access to and sharing of both genetic resources and technologies are essential'.

Definitions

Article 2 defines certain keys terms:

biological diversity

- ❏ 'Biological diversity' connotes 'the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and

the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems'.

biological resources

- ❏ 'Biological resources' connotes genetic resources, organisms or parts of them, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity.

genetic resources

- ❏ 'Genetic resources', as a part of biological resources, connotes 'genetic material of actual or potential value'.

Access

The CBD recognizes that genetic resources are subject to the sovereign rights of Contracting Parties as states. Article 15.1 states:

sovereign right

> 'Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.'

absolute right

control bioprospecting

From this provision flows the rights of states to determine the conditions under which access to genetic resources is granted or facilitated. This sovereign right to create and freely dispose of natural resources is absolute. So a Contracting Party can control, for example, bioprospecting and regulate how its natural resources should be exploited. The latter includes developing legal processes, levying duties, and controlling external influences on the exploitation of its biological diversity.

control access

legal basis for compensation

This is important to developing countries – the right of a country or origin to control access to genetic resources has now been codified in international law. So host countries are now in a stronger bargaining position to negotiate bioprospecting and material transfer agreements. They now have a legal basis on which to receive compensation for access to genetic material and to benefit directly by sharing in the profits from any commercial use of those resources. Developing nations accordingly see the emerging access regime in the CBD as an opportunity to improve their position in global politics, and to obtain capital needed for development.

Note, though, that all those ex situ collections referred to

limited scope - ex situ collections

above fall outside the ambit of the CBD – the convention does not apply to such collections existing prior to its coming into force. Even if a plant held in an ex situ collection originates from a determinable country that may the only place that provides such a resource, there is still no national sovereign right over it, not any obligation to regulate terms for access or equitable benefit sharing. This restricted scope of the CBD has been criticized, since these collections operate beyond the scope of international law, yet they house extremely valuable genetic resources from around the world.

not intellectual property right

What is the nature of this sovereign right conferred by the CBD? It is an absolute right to tangible goods, *not* an intellectual property right. The CBD concerns access to the phenotype of genetic resources, and so states rules relating to tangible goods – genetic resources such as plants and animals. The TRIPS Agreement, by contrast, deals with international standards for intellectual property rights, including those intellectual property rights that relate to genetic information which may derive from biological diversity. It is for this reason that the exclusion of ex situ collections from the sovereign right of the originating host states under the CBD is significant – if such sovereign right were an intellectual property right, ex situ collections would had to have been subject to it.

obligation to provide access

At the same time that the CBD confers such sovereign right on states, it also obliges them to facilitate access to genetic resources. Section 15.2 states:

> 'Each Contracting Party shall endeavor to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.'

prerogative

The details of the manner of access remain to the prerogative of a Contracting Party. These details may involve –

- ❏ obligation to inform the Contracting Party;
- ❏ documentation required;
- ❏ the preservation of duplicates;
- ❏ an obligation to report the collection of a genetic resource; and
- ❏ the control of exportation of a genetic resource.

contractual terms

But the CBD does require that access be given on contractual terms. Article 15.4 states:

> 'Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.'

prior informed consent

Article 15.5 then introduces the notion of prior informed consent:

> 'Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.'

Bonn Guidelines

In October 2001, the Ad Hoc Open-ended Working Group on Access and Benefit-sharing of the CBD met in Bonn. One outcome of the meeting was the draft of the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization (*Report of the ad hoc Open-Ended Working Group on Access and Benefit-Sharing* (UNEP/CBD/COP/6/6 of 31 October 2001). These guidelines are intended as guidance to users and providers of genetic resources. They will be reviewed continually, and revised and improved as the international experience with access and benefit-sharing expands. The guidelines intend to provide stakeholders with a transparent framework –

- ❏ to facilitate access to genetic resources;
- ❏ to ensure fair and equitable sharing of benefits; and
- ❏ to promote the effective transfer of technology to providing Contracting Parties, stakeholders, and indigenous and local communities.

stakeholders

The guidelines stipulate that procedures legally regulated on a national level should facilitate the involvement of all relevant stakeholders from the community to the government level, which includes indigenous peoples and local communities. Also, such consent should include information about the specific uses for which consent is to be granted. So users of genetic resources and related knowledge will need to seek such consent not only from the government (as represented by a designated authority) but also from an indigenous or local community, or an authority nominated or established by the community to represent it.

Transfer of technology

developed countries to transfer technology

Developed countries are obliged to facilitate access for other Contracting Parties to technologies relevant to the conservation of biological diversity (article 16). The intended transfer of technologies from developed countries to Contracting Parties hosting genetic resources may be seen as some sort of quid pro quo for access to biodiversity. So, for the first time international law, a relationship between the appropriate access to genetic resources and the appropriate transfer of technology is established. This represents a truce in the ongoing battle between developing and developed countries.

costs of maintaining biodiversity

From an economic perspective, article 16 acknowledges that the conservation of biodiversity inflicts costs on biodiversity-rich countries that does not control the adequate and necessary technology to achieve the Convention's objective – the conservation and sustainable use of biodiversity for the benefit of present and future generations.

favourable and preferential terms

Article 16 recognizes that 'access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives'. So Contracting Parties undertake to 'provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant' to those objectives, or that 'make use of genetic resources and do not cause significant damage to the environment'. Accordingly, 'access to and transfer of technology ... to developing countries shall be provided and/or facilitated under fair and most favorable terms, including on preferential terms where mutually agreed.'

conservation or sustainable use

in situ conservation and sustainable use technologies

This obligation is limited to listed technologies directly linked to the conservation or sustainable use of genetic resources or their exploitation. A Note by the Secretariat of the CBD to the second meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) refers to in situ and ex situ conservation technologies, and sustainable use technologies (CBD (Subsidiary Body on Scientific, Technical and Technological Advice) *Ways and Means to Promote Access to, and Transfer and Development of Technology, Including Biotechnology* (UNEP/CBD/SBSTTA/2/6 of 12 August 1996)). According to

this Note (at 8), in situ conservation and sustainable use technologies include –

- ❏ aerial survey equipment,
- ❏ geographical information systems,
- ❏ fencing equipment, and
- ❏ technologies associated with low-external input agriculture, integrated pest management, re-vegetation, and other on-farm management techniques.

soft technologies

Soft technologies may take the form of 'know-how, management routines, and behavioral patterns and attitudes'.

ex situ conservation and sustainable use technologies

By contrast, the Note describes ex situ conservation and sustainable use technologies as 'tissue culture, field-based propagation, protoplast fusion, and cryopreservation' (at 8). Common mechanisms for transferring such technologies include –

- ❏ joint research and development,
- ❏ the training of nationals in foreign universities and other institutions, and
- ❏ technology partnerships undertaken under biological diversity-prospecting arrangements (at 12).

private sector

Note that the CBD addresses its Contracting Parties. They are members of the United Nations. But technology is held mainly by the private sector. So the influence of the CBD on the transfer of technology is remote.

relationship to TRIPS Agreement

The most contentious issue in the context of the transfer of technology is the role of the protection of intellectual property rights. This brings us to the relationship between the CBD and the TRIPS Agreement. Many of the relevant technologies may be in the public domain. But if they are subject to patent or other intellectual property rights, their transfer must occur on terms that are consistent with the "adequate and effective" protection of intellectual property rights (article 16.2). This provision confirms a close link with the TRIPS Agreement. It

close link

may well be, then, that the CBD, even though it does not focus on intellectual property rights as such, will lead its Contracting Parties to raise their level of protection of intellectual property right to the level of protection mandated by the TRIPS Agreement.

no agreement on extent of impact

But questions remain. For example, what is the impact of article 16.5? It states that Contracting Parties recognize that patents and other intellectual property rights 'may have an influence on the implementation of this Convention'. The use of the term 'may' illustrates that the negotiators could not agree on whether intellectual property rights have any effect on the achievement of the objectives of the CBD, or even if it has, on the extent of such effect. The provision also states that Contracting Parties must cooperate to ensure that intellectual property rights promote and do not run counter to the objectives of the CBD. This provision represents an attempt to resolve the conflict between the intellectual property protection mandated in the TRIPS Agreement and the protection of tangible property over genetic resources under the CBD.

Benefit sharing

flow of benefits

The CBD seeks to redefine the flow of benefits generated by genetic resources. So the provisions regarding the sharing of benefits are crucial in the context of articles 15 and 16. Legislative, administrative, or policy measures should be established to share in a fair and equitable way the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party that has provided such resources. Such sharing should be upon mutually agreed terms that recognize and are consistent with the adequate and effective protection of intellectual property rights. Each Contracting Party should take measures 'with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Party providing such resources' (article 15.7).

mutual agreement

participation in research

Also, article 19 obliges Contracting Parties to take measures to provide for the effective participation in biotechnological research by Contracting Parties, especially developing countries, that provide the genetic resources for such research. Contracting Parties are required to 'take all practicable measures to promote and advance priority access on a fair and equitable basis' for Contracting Parties that provide genetic resources, especially developing countries to 'the results and benefits arising from biotechnologies based

upon those genetic resources ... on mutually agreed terms' (article 19.2). Also, Contracting Parties should realize scientific research based on genetic resources with the full participation and, as far as possible, inside the states holding the relevant resources (article 15.6).

allocation of benefits

The proper allocation of benefits is complicated – benefits should be shared with all those stakeholders in the host country who have contributed to the resource management and scientific process. This may include governmental or academic institutions, and local and indigenous populations. It is important that benefits help to promote conservation and sustainable use of biological diversity. This can be achieved only if at least parts of them are directed to the local populations. National legislation has to take these considerations into account.

broad meaning of term 'benefits'

The term 'benefits' has to be interpreted in broadly, as the wording of articles 15 and 19 illustrates. Most benefits will be non-monetary. Typical rewards for access to genetic resources are capacity building, transfer of technology, joint research, and training. These rewards may also address conservation goals.

national examples

Examples of benefits specified in national legislation include –

- ❏ the participation of nationals in research activities,
- ❏ the sharing of research results, including discoveries, and
- ❏ the obligation to leave complete sets of voucher specimens in national institutions.

other relevant benefits

Other benefits that might be relevant are –

- ❏ training in collecting and preparing specimens;
- ❏ resource management;
- ❏ joint research and development;
- ❏ capacity building of institutions and indigenous and local communities;
- ❏ support for research in the field of conservation and sustainable use of biological diversity;
- ❏ access for nationals to all national specimens deposited in international ex situ collection;
- ❏ the receipt by Providers, without payment of a royalty, of all technologies developed from research on endemic species; and

- ❏ fees, royalties, and financial benefits, and donations to national institutions of equipment used as part of research.

examples from India

In India, for example, such benefits include –

- ❏ joint-ownership of intellectual property rights,
- ❏ the transfer of technology,
- ❏ the location of research and development,
- ❏ the association of Indian scientists and local people with research and development, biosurvey, and bio-utilization,
- ❏ the location of production units,
- ❏ setting up Venture Capital Funds,
- ❏ direct monetary compensation, and
- ❏ other non-monetary benefits appropriate to the entity from where the resource has been accessed.

Andean Community

Andean Community

In July 1996, the Commission of the Andean Community introduced a regional measure on access and sharing of benefits. It is effective in Bolivia, Colombia, Ecuador, Peru, and Venezuela. Decision 391 introduces 'The Common System on Access to Genetic Resources' to regulate 'access to the genetic resources of the Member Countries and their derivatives'.

objectives

The objectives of Decision 391 are –

- ❏ to create the conditions for fair and equitable sharing of the benefits accruing from the access to genetic resources;
- ❏ to establish a basis for the recognition and appreciation of genetic resources, their derivatives, and related intangible components, particularly where indigenous, Afro-American, and local communities are involved;
- ❏ to encourage the conservation of biological diversity and sustainable use of biological resources containing genetic resources;
- ❏ to promote the consolidation and development of scientific, technological, and technical capacities at local, national, and subregional level; and
- ❏ to strengthen the negotiating capacity of the Member

Countries shall be strengthened (article 2).

only Bolivia

Until now, the Decision has barely been operational at the level of the member states. Only Bolivia has passed implementing regulations, but they have not yet been put into effect. Colombia and Venezuela have opted not to produce implementing regulations, but to apply Decision 391 directly.

genetic resources

The regime covers genetic resources provided by the Member Countries where they originate, and the genetic resources of migratory species found for natural reasons in their territories. Article 1 defines genetic resources as 'any

definition

biological material containing genetic information of actual or potential value'. The country of origin is defined as the country that has the genetic resources in in situ conditions.

Common System

The Common System sets out the details of –

- ❏ a system of consent;
- ❏ a requirement of public notification;
- ❏ the participation of nationals in research;
- ❏ support for conservation and sustainable use;
- ❏ technology transfer;
- ❏ scientific reporting requirements; and
- ❏ the deposit of voucher specimens.

prior informed consent

Applicants seeking access have to obtain the prior informed consent of (and share benefits with) both the Competent National Authority and indigenous, Afro-American, and local communities. Granting access is determined by the legally correct, complete, and trustworthy information provided by the applicant (article 22). So the applicant is obliged to present the information concerning the genetic resource that he is in a position to know at the time of presenting his application. This information has to include –

- ❏ the actual and potential uses of the resource, its derivatives, or intangible components,
- ❏ its sustainability, and
- ❏ risks that could arise from accessing it.

resource and derivatives

The sovereign right of the source country extends not only to the genetic resource as such, but also the derivatives of such resource. Article 5 states:

'The Member Countries have sovereign rights over their

definition of derivatives

genetic resources and derivatives thereof and therefore determine the conditions of access to said resources, pursuant to the contents of this decision. The conservation and sustainable use of genetic resources and their derivatives shall be regulated by each Member Country, according to the principles and provisions enshrined in the Convention on Biological Diversity and in the present decision.'

wider than CBD

A derivative, in turn, is defined as a 'molecule or combination or mixture of natural molecules, including raw extracts of living or dead organisms of biological origin, derived from the metabolism of living organisms' (article 1). By including derivatives within its ambit, Decision 391 goes beyond the CBD. Unlike genetic resources, derivatives may not always contain functional units of heredity. So it is possible that isolated biocompounds may become subject to the aims of the Member States of the Andean Community, even if those compounds have been patented by a corporation outside the Andean region. Such an extension is unlikely to be compatible with the TRIPS Agreement.

unlikely to be compatible with TRIPS

rights not recognized

So Decision 391 states beyond its 'Complementary Measures' that any rights, including intellectual property rights, to genetic resources, derivatives, synthesized products, or related intangible components obtained or developed through non-compliance with the Common Access System, shall not be recognized by the Member States of the Community. Also, the competent authorities dealing with intellectual property rights are empowered to require applicants to submit a copy of their access contract (prior informed consent) as a condition for granting a patent. These provisions assume a distant position on intellectual property rights. It seems that in the Andean Community Decision, provisions of the TRIPS Agreement have been subordinated to the CBD. Since the TRIPS Agreement does not provide for similar exclusions from patentability, the compliance of the Andean Community regime with the TRIPS Agreement is highly doubtful.

copy of access contract

TRIPS Agreement subordinated to CBD

regulate access & equitable distribution of benefits

Decision 391 was intended as an instrument to regulate access to genetic resources and help guarantee the conservation, sustainable use, and equitable distribution of the benefits derived from those resources. Still, its implementation has seemingly been problematic for a variety

of reasons. It has had the effect of hindering foreign, and even most domestic access to Andean genetic resources rather than to promote it.

contrary to intentions

This lack of access has resulted in a reduction in both national and international projects promoting research, conservation, and use of Andean plant genetic resources. This seems contrary to what the Member States originally had intended. To address the problems arising from over-restrictive legislation, the Andean countries are now seeking ways to implement Decision 391, also in view of the International Treaty on Plant Genetic Resources. The goal will be to develop a mechanism that facilitates regulated international access and exchange of genetic resources, instead of complicating any measures of bioprospecting.

Organization of African Unity

OAU model legislation

One of the most far-reaching and controversial measures is the 'Model Legislation for the Recognition and Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources', drafted by the Organization of African Unity (OAU) in 2000.

prior informed consent

deposit duplicate specimens

informed about research findings

Like the Andean system, the Model Legislation requires prior informed consent of not just the State, but also of the local communities that which would be granting access to biological resources (article 5). Also, the Model Legislation requires the applicant to deposit duplicates of each specimen of the biological resource, or the records of community innovation, practice, knowledge, or technology collected with the duly designated governmental agencies, and, if so required, with local community organizations. Besides, national authorities and concerned communities have to be informed of all the findings that result from research and development of the resource (article 8)

information required

The information obligations of the applicant seeking access go further than in other instruments. The applicant has to inform not only about himself and the planned bioprospecting project, but also about –

- ❏ the resource to which access is sought, including the sites from which it will be collected, its present and

potential uses, its sustainability, and the risks that may arise from access to it;

- ❏ whether any collection of the resource endangers any component of biological diversity; and
- ❏ the risks which may arise from the access; and
- ❏ the purpose for which access to the resource is sought, including the type and extent of research, teaching, or commercial use expected to flow from it.

local & national collaboration

Also, bioprospectors must submit descriptions of the manner and extent of local and national collaboration in the research and development of the biological resource concerned.

Further information duties relate to –

further information required

- ❏ the identification of the national institution (or institutions) that will participate in the research and be in charge of the monitoring process;
- ❏ the identity of the location where the research and development will be carried out;
- ❏ the primary destination of the resource and its probable subsequent destinations;
- ❏ the economic, social, technical, biotechnological, scientific, environmental, or any other benefits that are intended, or may be likely, to accrue to the country and local communities;
- ❏ the biological resource;
- ❏ the collector and the country (or countries) in which he operates; and
- ❏ the proposed mechanisms and arrangements for sharing of benefits.

Finally, the applicant has to submit –

description of innovation

- ❏ a description of the innovation, practice, knowledge, or technology associated with the biological resource; and

environmental & socio-economic impact assessment

- ❏ an environmental and socio-economic impact assessment that covers at least the next three generations, in cases where the collection is in large quantities (article 3).

may not transfer resource without consent

Subsequently, the applicant is not allowed to transfer the biological resource or any of its derivatives, or the community innovation, practice, knowledge, or technology to any third party without the authorization of the National Competent

may withdraw consent

Authority and the concerned local community or communities (article 8).

inalienable right

Local communities are entitled to withdraw their consent, or restrict the activities relating to access where such activities are likely to be detrimental to their socio-economic life, or their natural or cultural heritage (article 21). They should also exercise their inalienable right to access, use, exchange, or share their biological resources to sustain their livelihood systems as regulated by their customary practices and laws. No legal barriers may be placed on the traditional exchange system of the local communities in the exercise of these rights.

patents & plant breeders' rights

Regarding patents and plant breeders' rights, bioprospectors are obliged not to apply for any form of intellectual property protection over the biological resource, or parts or derivatives of it, and not to apply for intellectual property rights protection over a community innovation, practice, knowledge, or technology without the prior informed consent of the original providers. The language is clear about patent rights (article 9):

patent rights

> 'Patents over life forms and biological processes are not recognized and cannot be applied for. The collector shall, therefore, not apply for patents over life forms and biological processes under this legislation or under any other legislation relevant to the regulation of access and use of a biological resource, community innovation, practice, knowledge and technology, and the protection of rights therein.'

benefit sharing

Where the applicant obtains intellectual property protection, the applicant has to provide for the sharing of benefits. The state must ensure that at least fifty percent of the benefits obtained from the commercial use of a biological resource and/or community innovation, practice, knowledge, or technology is channelled to the relevant local community or communities (article 23). It must enter into a written contract with the collector that ensures those benefits are to be derived on behalf of the local community or communities concerned. Any such written contract must be entered into by the state and the collector, with the full participation and approval of the relevant local community or communities (article 23.3).

written contract

Biological Diversity Law

In May 1998, Law 7788 (Biological Diversity Law) was enacted in Costa Rica. It is one of the most elaborate national laws regarding access to genetic resources and benefit sharing. Its general objectives are –

objectives

- ❏ to conserve biological diversity,
- ❏ to generate the sustainable use of resources, and
- ❏ to distribute fairly the derived benefits and costs.

Its more than 100 provisions deal with issues such as –

issues covered

- ❏ biosafety,
- ❏ conservation and sustainable use of biological diversity,
- ❏ access to its genetic and biochemical elements,
- ❏ prior informed consent,
- ❏ protection of scientific and traditional biological diversity-related knowledge,
- ❏ education and public awareness,
- ❏ technology transfer, and
- ❏ incentives for the preservation of biological diversity.

includes intangible elements

The Law contains a broad definition of 'biological diversity'. It includes 'intangible elements', such as traditional, individual, or collective knowledge, innovation, and practice with real or potential value associated with biochemical and genetic resources, irrespective of whether it is by intellectual property law or a sui generis register system (article 7). These intangible elements represent the same content as the intangible component in the Andean Community's Decision 391.

prior informed consent

A basic condition for the access to genetic resources and bioprospecting is the prior informed consent of the regional councils of Conservation Areas, the owners of farms, or indigenous authorities. Applicants have to submit

- ❏ the terms of technology transfer and equitable distribution of benefits, as agreed in the permits, agreements, and concessions,
- ❏ the type of protection of associated knowledge demanded by the representatives of the place where the access will occur, and
- ❏ a description of the ways in which their activities will

contribute to the conservation of species and ecosystems (article 63).

applications

Applications for access are submitted to the Technical Office. They must be accompanied by the prior informed consent of the appropriate stakeholder group (article 65).

access

Article 65 concerns prior informed consent with reference to obtaining access to elements of biological diversity. In cases involving access to resources on private property, the Technical Office of the National Commission for Environmental Management must be given documentary proof of the land owner's prior informed consent. If indigenous lands are involved, prior informed consent must be obtained from the authority of the indigenous community and the Director of the Conservation Area.

opposition

Article 66 recognizes the right of local and indigenous communities to oppose the access to resources and associated knowledge for cultural, spiritual, social, or economic reasons, or for any other reason. Consent is required from representatives of the place from where access is sought. They may include the regional councils of Conservation Areas, landowners, and indigenous communities.

link between prior informed consent and IPRs

Like the Andean Decision, the Law connects prior informed consent and intellectual property rights. Article 78 lists exceptions to intellectual property protection. The most important are –

- ❏ DNA sequences as such, and
- ❏ inventions derived from knowledge associated with traditional or cultural biological practices in the public domain (article 78.1 and 78.6).

sui generis community IPRs

Article 82, on sui generis community intellectual property rights, similarly states that the State expressly recognizes and protects the practices and innovations of indigenous peoples and local communities. The purpose of this provisions is to prevent any form of protection of intellectual or industrial property rights from affecting historical practices (article 82.2).

Articles 83 and 84 call for the examination and registration of sui generis community intellectual property rights through a

participatory process

participatory process. Article 85 deals with how such rights will be used, and who will hold their title and identify the recipients of any benefit derived from them.

prior consultation

The Nation Seed Office and the Registry of Intellectual and Industrial Property should be consulted prior to establishing intellectual property protection for industrial innovations (article 80). The original certificate of origin and proof of prior informed consent must submitted with the documentation.

similar to Andean Decision and OAU model legislation

So prior informed consent forms an additional requirement for the granting of intellectual property rights. In this regard, the Costa Rica Biodiversity Law is similar to the Andean Decision and the OAU model legislation. Note that these laws and proposal refer only to national access provisions and to genetic resources held inside the territory where the provisions apply. There is no general requirement, for example, that the subject matter of patents applications filed in Costa Rica must have been obtained according to the access provisions of other host countries.

unique position

Merck agreement

Note that the position in Costa Rica is special. Only one entity may carry out bioprospecting inside the country – the American corporation Merck & Co. The exclusive bioprospecting contract between the Costa Rica National Biological Diversity Institute (INBio) and Merck & Co was signed in 1991, long time before the enactment of the Biodiversity law. So there are no patent applications that can conflict with the access and benefit sharing provisions in Costa Rica, as long as this exclusive contract remains in force.

Although Costa Rica seems to make more use of its biodiversity and share more benefits than the other members of the Andean Community, it should be noted that this is a consequence not of the Law (which is very little different from the Andean Decision) but of the contract that had been signed earlier.

Conclusion	You should now appreciate the meaning and content of the concepts ‘biodiversity’, ‘genetic resources’, ‘access’, ‘prior informed consent’, ‘transfer of technology’, and ‘benefit sharing’.

	You should also be able to advance an economic and a social justification for the legal protection of biodiversity, and understand the problems faced by developing countries that are rich in genetic resources. Finally, you should be able to explain attempts at international, regional, and national levels to protect biodiversity and traditional knowledge. In particular, you should be familiar with the contents of the Convention on Biological Diversity, and with developments in the Andean Community and Africa, and in Costa Rica.