

*INTELLECTUAL PROPERTY,
TECHNOLOGY TRANSFER
AND GENETIC RESOURCES*

*AN OECD SURVEY
OF CURRENT PRACTICES AND POLICIES*

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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FOREWORD

Intellectual Property, Technology Transfer and Genetic Resources is the first major OECD contribution to biotechnology related intellectual property issues since the 1985 publication, *Biotechnology and Patent Protection: An International Review*.

The report is the result of an activity first proposed by Switzerland in 1994, stimulated by the discussions preceding and accompanying the ratification of the Convention on Biological Diversity.

The Convention on Biological Diversity represents a political commitment to universally accepted objectives of conservation. However, it also addresses several objectives raising complex and controversial questions, including some relating to intellectual property. It is hoped that this report will make a constructive contribution to the international discussions on some of these matters.

The report is based on a questionnaire approved by the OECD's Working Party on Biotechnology (WPB) on 1-2 February 1995, country replies to that questionnaire, and other publications and information in the public domain.

Nineteen Member countries delivered replies: Australia, Austria, Belgium, Canada, Czech Republic, Finland, France, Germany, Ireland, Italy, Japan, Korea (member of CSTP), Mexico, the Netherlands, Norway, Spain, Switzerland, the United Kingdom and the United States. In addition, the European Commission provided comments.

The report was prepared by two international experts, Mr. R. Stephen Crespi (London) and Professor Joseph Straus (Munich) working in collaboration. Mr. Crespi was responsible in particular for Chapters 2, 3 and 4. They were supported by Mr. Salomon Wald and other members of the OECD Secretariat.

The text was approved by the WPB on 1-2 July 1996. The Working Party asked the OECD to ensure that the widest possible attention be drawn to the derestricted text, particularly in the relevant international fora such as the World Trade Organisation (WTO), the Secretariat of the Convention on Biological Diversity and the Food and Agriculture Organisation of the United Nations (FAO).

After incorporation of amendments submitted by Member countries, the OECD Committee for Scientific and Technological Policy (CSTP) agreed on 1-2 October 1996 to recommend the derestriction of the publication on the responsibility of the Secretary-General of the OECD.

The report does not necessarily represent the views of all OECD Member countries.

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SUMMARY OF MAIN POINTS

The report, *Intellectual Property, Technology Transfer and Genetic Resources: An OECD Survey of Current Practices and Policies*, reviews current practices and policies on intellectual property, technology transfer, and access to genetic resources, in an attempt to better understand the links between these topics that have recently been highlighted by the adoption of the Convention on Biological Diversity (CBD).

The analysis is based primarily on responses to an OECD Questionnaire which complemented work done in other parts of the Organisation in relation to the Convention on Biological Diversity. Account has also been taken of much published legal and scientific literature commentary in relation to genetic resources, including issues dealt with in this Convention. Nineteen countries have replied, which indicates considerable interest and commitment, even if the subject has been difficult for many respondents and required inter-agency, as well as public-private sector co-ordination. Responses are heterogeneous as to structure and detailed content. However, a number of common conclusions have emerged which points to the possibility of a common understanding of these complex issues.

INTELLECTUAL PROPERTY

In public discussion of intellectual property, there are often misunderstandings of its nature and limitations. Intellectual property protection cannot be extended or enforced with regard to naturally occurring or socially maintained genetic resources, although patent, trade secret and other forms of protection can be enjoyed in products or information derived from such genetic resources and in genetic resources themselves where there has been the intervention of human ingenuity and the national laws allow. This distinction between the subject matter of intellectual property – which is invariably value-added subject matter in relation to subject matter existing in the public domain – is often confused with interests in physical property or cultural behaviour. Seen in this manner, intellectual property systems would not appear to have a clear role to play with regard to resolving concerns related to ownership or use of naturally occurring or socially maintained materials or information in the public domain. Only novel products and processes, including

those derived from genetic resources and genetic resources themselves, where the technical intervention of humans has achieved a result which does not occur in nature, may claim some form of intellectual property protection, for a limited time.

The availability of such intellectual property protection, in both the “home” country and that to which technology is to be transferred, is seen as a fundamental prerequisite of co-operative activities that can lead to technology transfer agreements and to foreign investment in technology-importing countries. The overriding importance of strong intellectual property laws and enforcement procedures is underlined by nearly all national responses – this is one of their most emphasized areas of agreement.

GENETIC RESOURCES

The Member countries of the OECD and many other countries continue to recognise and honour the principle of unrestricted access to genetic resources (in accordance with the International Undertaking on Plant Genetic Resources for Food and Agriculture), while also accepting the need to reconcile this with the sovereign rights of States over their own resources, and the resulting authority to determine access to genetic resources, as recognised in the Convention on Biological Diversity.

Conservation is fully consistent with the scientific exploration and technological exploitation of genetic diversity for the development of new products and processes. More than this, the application of modern science and technology to genetic resources is essential to achieving the most effective conservation of biodiversity. Conservation is also fully compatible with the principles of intellectual property protection for new products and processes.

Few of the responses identify specific projects related to the discovery or development of genetic resources. It is clear, however, that private and public agencies in some OECD Member countries (and also the European Commission) are very active in their exploration, and have accumulated considerable experience, taking into account the mutual needs and expectations of all the parties involved. So far, access to genetic resources has generally been arranged case by case. No response suggested that arrangements regarding access to and use of genetic resources have proven to be difficult to conclude or have led to unsatisfactory results for any project participants.

The principle of prior informed consent, regarding the handling and use of samples of genetic resources incident to the granting of access, is now widely accepted. Consent must be arranged between the interested parties and does not necessarily require state intervention. Universities and public R&D centres are developing and using “Material Transfer Agreements” (MTAs) which are strongly favoured by public germplasm collections. So far, consent has often been given

freely, although industry expects that some sharing of benefits will be required in the future. "Codes of conduct" have been developed or are being developed.

"Access legislation" would be a more formal type of legal instrument regulating the use of genetic resources. The Biodiversity Convention provides for access to genetic resources to be subject to national legislation. So far, no OECD Member country has enacted access legislation, and only one or very few developing countries. Equally, there is no European Union legislation covering access to genetic resources in the sense of the Biodiversity Convention. No initiative towards access legislation is reported in the responses. One apparent problem would be the identification of the entity having the necessary authority to grant access, or to authorise subsequent transfer of genetic materials.

TECHNOLOGY TRANSFER

The transfer of technologies which use genetic resources, in favour of the providers of such resources, is expected to proceed on an *ad hoc* basis. No particular legal model or paradigm emerges from the responses; all traditional methods will be used, including disclosure of R&D results, licensing, information exchange, training, joint ventures, support of R&D and others.

Also, no uniform idea has emerged on how to share in a fair and equitable way the benefits arising from the use of genetic resources with the indigenous populations concerned with the conservation of those resources.

In order to give genetic resource providers due recognition and reward, various legal instruments have been mentioned. One successful example is the Letter of Collection Agreement (LOC) used by the US National Cancer Institute. A LOC is a contractual agreement providing financial reward to source countries and indigenous peoples through remuneration and technology transfer. LOCs have been negotiated with 19 developing countries.

PRIVATE SECTOR

One of the main challenges to the implementation of international genetic resource conventions is that conventions are made among governments, but it is often the private sector that seeks access to genetic resources and that creates technology that can lead to commercial and other economic benefits. The measures required to induce the private sector to transfer technology will include the creation of conditions in the recipient country that encourage voluntary technology transfer from abroad.

In spite of strong interest in principle, some specific factors may inhibit the willingness of industrial or other sectors to conclude genetic resource agreements. One factor could be high transaction costs. Another is possible underestimation of

the long time-lags before R&D on a genetic resource may yield economic benefits, *e.g.* in the pharmaceutical sector. One should also consider the longer-term potential of “combinatorial” and other types of synthetic chemistry that can create and screen at low costs large numbers of diverse molecular structures of potential biological activity. Inhibitory conditions of access to the great storehouse of natural or socially maintained genetic resources could further encourage the ongoing search for chemical techniques which might reduce dependence on bioprospecting. A critical factor is whether a private sector company will be able to protect new technologies that are developed incident to a genetic resource development agreement, whether that protection comes through effective patent, plant variety, copyright or trade secret laws in the host country, or through reliance on effective contractual arrangements to protect trade secret information.

OTHER ISSUES

Economic and financial incentives and disincentives to encourage development of genetic resources can play a significant role in the decisional process preceding investment and technology transfer decisions. However, this role appears to be secondary to intellectual property protection and to the scientific and commercial assessment of genetic resource development. Marketing restrictions on products resulting from genetic resources are a significant complication for industry, but do not necessarily inhibit projects. Financial inducements to embark on projects are an encouragement but cannot be the main motivation for industry.

The responses on the main future challenges facing the legal protection of biotechnology in general, show that there are many outstanding issues which need to be discussed in international fora. However, there is no “majority opinion” on the order of importance of these challenges. Comments are wide-ranging and extend to many fundamental issues: international harmonization, restrictions of patent protection, patents considered to be “unduly broad”, the interface between patents and plant variety rights, the impact of various lobbies, and others; a general question is the roles of bilateral and multilateral agreements and the combination thereof.

INTRODUCTION AND DEFINITIONS

The objective of the investigation which has led to this report is defined in the OECD Questionnaire (Annex I) as follows:

“Inform and co-ordinate the views of OECD Member countries with regard to intellectual property in relation to technology transfer by conducting a survey of current practices, experiences and expectations related to technology transfer in biotechnology, which will analyse, from a policy and economic perspective, issues of technology transfer incident to access to genetic resources.”

In January 1994, Switzerland proposed to include in the OECD/DSTI Programme of Work questions of intellectual property policy. Subsequently, the proposal was submitted to the first meeting of the Working Party on Biotechnology (WPB) of the Committee for Science and Technology Policy (CSTP) on 23-24 June 1994, with the comment that the activity might focus on issues associated with biological diversity.

In response to the interest expressed by other Member countries, a revised proposal was circulated in September 1994, calling for the preparation of a questionnaire in order to define the activity more clearly. On 14-15 November 1994, a meeting of intellectual property right experts from OECD Member countries was held in Bern. The experts designed a comprehensive questionnaire, with the aim of gathering data on current practices and policies related to access to genetic resources.

This draft questionnaire was revised and approved at the second meeting of the WPB (1-2 February 1995), and sent to all Member countries (15 February 1995).

Nineteen of them delivered replies: *Australia, Austria, Belgium, Canada, the Czech Republic, Finland, France, Germany, Ireland, Italy, Japan, Korea (member of CSTP), Mexico, the Netherlands, Norway, Spain, Switzerland, the United Kingdom, the United States*. In addition, the European Commission provided comments on the draft report.

In parallel to this intellectual property right activity of the CSTP's Working Party on Biotechnology, the OECD has made another, and major, effort to assist the implementation of the Biodiversity Convention. The OECD's Expert Group on Eco-

conomic Aspects of Biodiversity, under the ultimate responsibility of the Environmental Policy Committee, has recently completed a project which also began in 1994. The resulting report, *Saving Biological Diversity: Incentive Measures*, published in June 1996, examines how policy can guide human action towards the conservation and sustainable use of biodiversity, with a particular focus on the use of incentive measures. The report reviews four categories of incentives: positive incentives (monetary or non-monetary inducements); disincentives (mechanisms that internalise the costs of use of or damage to biological resources); indirect incentives (trading and other institutional arrangements); and “perverse” incentives (inducing behaviour that reduces biodiversity).

The activity of the Environment Directorate addressed Article 11 of the Convention on Biological Diversity which highlights incentive measures, and asks for “economically and socially sound measures that act as incentives for the conservation and sustainable use of components of biological diversity.”

There was agreement between the Environment Directorate and the Directorate for Science, Technology and Industry that the economic incentives study would leave the discussion of intellectual property to the WPB study on access to genetic resources. Thus, it has been possible to achieve complementarity inside the OECD, and to avoid overlap.

In this report, repeated use is made of a number of key terms. Without prejudice to formal, statutory definitions found in national and international laws, the following, less formal definitions are offered to assist the general reader:

Genetic resources are understood in accordance with definitions given in the Biodiversity Convention. Thus, genetic resources are genetic materials of actual or potential value, containing functional units of heredity, and of microbial, plant, animal, or other origin. The term therefore embraces genetic materials which have been discovered, and which may already have been utilised in practical applications, as well as those which are yet to be discovered.

Technology transfer includes, but is not limited to, the disclosure of results from research and development, the licensing or assignment of intellectual property rights related to such results, exchange of information, education and training, and joint ventures. This statement is not so much a definition as an indication of some of the means by which technology transfer, as such, is achieved. The end result, in meaningful terms, is the making available to a recipient of industrial and agricultural processes and products and the relevant enabling technology for practical realisation.

Intellectual property rights are rights granted by state authority for certain products of intellectual effort and ingenuity. These rights are the subject of specific laws (statutes) enacted by parliaments or other state authority and are generally consistent with the standards outlined in the TRIPs Agreement (see

Chapter 1), which became applicable to developed countries on 1 January 1996. **Patents** relate to inventions. **Designs** relate to shapes and configurations. **Trade marks** relate to words or symbols applied to products or services to identify source or sponsorship. **Plant varieties protection** provides *sui generis* exclusive rights in plant varieties based on the UPOV model (see Chapter 2). **Copyright** relates to literary or artistic works and also extends to engineering drawings, computer software and other areas beyond the sphere of the arts. Apart from copyright, all the other mentioned rights must be applied for to the relevant national authority according to statutory law and procedure. **Trade secret** protection protects confidential (“undisclosed”) information and does not require registration or formalities.

THE BACKGROUND: INTELLECTUAL PROPERTY AND GENETIC RESOURCES IN THE NEW INTERNATIONAL CONTEXT

GENETIC RESOURCES AS A SPECIAL CASE

Mineral ores, crude oil and genetic resources as the natural or social treasures of our planet have many characteristics in common, but they differ in many more. They share the characteristic of an uneven geographical spread, *i.e.* they are located in only some areas of the earth, to a varying extent in some developing countries.

However, whereas the increasing consumption and the reduced availability of crude oil, for instance, has become a matter of general concern and has enabled the source countries to accumulate wealth and gain access to modern technologies, as well as spurred the search for alternative energy sources, nothing similar can be observed with respect to genetic resources. Neither does the general public seem to be sufficiently concerned about the rapid extinction of biodiversity, nor have source countries been able to directly collect returns for the use of their genetic resources. They have, however, benefited significantly from the improved food security arising from the sharing of improvements in crops associated with unrestricted access to genetic resources.

Humanity has already obtained enormous economic benefits from the open access to genetic resources in the form of foods, medicines and industrial products; but concerns are now expressed, both about the risks of extinction, and about future conditions of access.

The main reason for the seemingly discriminatory economic treatment of genetic resources as compared with the treatment of other resources is at the same time their strength and their legal weakness: plants, animals, micro-organisms and other biological material as genetic resources are renewable resources, capable of self-replication or of being reproduced in a biological system. They perpetuate themselves thanks to the information embodied in their genetic constitutions, which they pass on to their progenies.

However, whereas individual plants, animals and other living organisms traditionally constitute private goods, the genetic information responsible for their

preservation does not. The capability of self-reproduction of biological material as a carrier of genetic information clearly reveals the limits of claiming property ownership; once acquired, either legally or not, it is impossible for the original owner to prove that the genetic information used was exclusively his: e.g. seeds recovered for use for further propagation, genes isolated for producing transgenic animals or plants, or for producing valuable proteins through cell culture, or for the synthetic production of valuable, active biochemical substances, and the like.

This trait of self-reproduction has rendered inventions based on self-replicating biological material particularly susceptible to copying and exploitation by parties other than the innovator. Inventions having these characteristics have proven difficult to commercialise. In this regard, the availability of intellectual property protection, and in particular, patent protection, help to establish conditions that make commercialisation feasible. Intellectual property rights provide some assurances that the innovator will be able to recoup the often extensive risks and costs of developing an invention based on a biological resource.

THE NEW INTERNATIONAL CONTEXT

The Convention on Biological Diversity, signed on 5 June 1992 in Rio de Janeiro, confirmed the principle of the sovereign rights of states over their natural resources, including the authority to determine access to genetic resources by national legislation [Article 15(1), for full text, see Annex II]. For the first time, Article 1 of the Biodiversity Convention, in which the Convention's objectives are set forth, has addressed three distinct issues in a single instrument; namely, "the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies taking into account all rights over those resources and to technologies...".

With the coming into force of this treaty, the basic principle of sovereignty over genetic resources was confirmed. Some implications of this recognition of sovereignty are addressed in general terms in Article 15 of the Convention, which provides that access to genetic resources shall be subject to prior informed consent of the party providing the resources, unless otherwise determined by the providing party, and on mutually agreed terms. These could include contracts with regard to the sharing of commercial and other benefits arising from utilisation of such resources. One benefit contemplated, as reflected in Articles 16 and 17 of the Convention, is technology transfer. This could take the form of licenses to use proprietary technology, sharing of research and development results, or technical information or training (for full text of Articles 15, 16 and 17, see Annex II).

If patented or otherwise protected technology is at stake, such access and transfer shall be provided on terms which recognise and are consistent with the adequate and effective protection of intellectual property rights. Parties are also to “take legislative, administrative and policy measures as appropriate” aimed at securing access to and transfer of technology, both in the public domain and subject to intellectual property rights. This obligation [Article 16(3)] is subject to the mutual agreement of the parties involved in the transaction. Article 16(4) addresses actions to be taken to promote participation in technology transfer activities by the private sector. And Article 16(5), which was subject to controversial discussions in the past, calls on parties to the Convention to co-operate “subject to national and international law, to ensure that” intellectual property rights are supportive and do not run counter to the objectives of the Convention. Many developed countries have emphasized their view that the various provisions in Article 16 are complementary despite the concerns that have been expressed by parties with other views.

The Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement), signed on 15 April 1994 in Marrakech, stipulates for the first time in the history of international industrial property protection the obligation of all members of the World Trade Organization (WTO) to provide patents for both product and process inventions in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. TRIPS allows several exceptions from this basic principle in respect of time and substantive aspects, yet at the same time it clarifies that, subject to these exceptions, patents are available and patent rights may be exercised without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced. It also clearly stipulates the content of the patent right, its term of at least 20 years, and the requirements which must be fulfilled in order to allow Member States to grant compulsory licences.

The Biodiversity Convention and the TRIPS Agreement are likely to influence the future exploitation of genetic resources to the benefit of the source countries as well as of co-operating and exploiting industries. The prior informed consent necessary for the access to the resources, as the corollary of the sovereign rights of the source countries over their genetic resources, can secure to those countries a fair share in the returns from their exploitation on a contractual basis. The TRIPS Agreement provides, subject to the exclusions allowed in Article 27:1 and 27:3, that patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. This provision is relevant to inventions that derive from genetic resources and may considerably improve the prospects for their commercially successful exploitation. A number of contracts, such as those between Merck (US) and INBio from Costa Rica, or between the US Massachusetts Institute

of Technology (MIT) and the Centro de Biotecnologia da Amazonia (CBA) from Brazil, or contracts between a British university-based company (Biotics Limited) with many developing countries for phytochemical screening of local flora, which were concluded in the last few years, could serve as a model for promising co-operation. They provide not only for some modest down-payments and for a fair sharing of eventual gains, but also for mandatory earmarking of a part of the returns for conservation purposes.

The following chapters will review in greater detail some of the basic concepts mentioned here and evaluate the responses of countries to the OECD Questionnaire in light of the new international context just described.

AN OUTLINE OF THE BASIC ISSUES

In an effort to simplify complex issues, this chapter analyses the basic concepts underlying the current international discussions on intellectual property, genetic resources and technology transfer. Chapter 1 has described the two main international legal developments which are the outcome of these discussions. The first of these, dealing with the question of access to and development of genetic resources, is the Biodiversity Convention enacted in 1992. Articles 15, 16 and 17 of this Convention, which are relevant to this investigation, are reprinted in Annex II. The second development dealing with intellectual property law arises from the conclusion in December 1993 of the Uruguay Round trade negotiations, creating the World Trade Organization (WTO) and introducing the TRIPS Agreement, which sets minimum standards of intellectual property protection. The relevant articles of the TRIPS Agreement, pertinent to this and to the other chapters, are reproduced in Annex III.

A. INTELLECTUAL PROPERTY

Forms of intellectual property relevant to biotechnology

In biotechnology, generally, patents are of principal interest, especially for the pharmaceutical and agro-biotechnology industries. To be patentable, an invention (e.g. a new product or process) must be *new*, involve an *inventive* step, and be *useful*, i.e. have an industrial application or other practical use. The patent application is officially and critically examined for these requirements. For agricultural research aimed primarily at the development of new plant varieties, plant breeders' rights (plant variety rights) are also crucially important. To obtain a plant breeder's right for a new variety (one not previously commercialised), it must be *distinct* from known varieties, *uniform* and *stable* (DUS). The variety is officially tested for these requirements.

Main types of biotechnology patent (relevant to genetic resources)

Naturally occurring substances, present as components of complex mixtures, can, in principle, be patented where they are isolated from their surroundings,

identified and made available for the first time, and a process developed for producing them so that they can be put to a useful purpose. This applies to inanimate substances, as well as to living materials. In appropriate circumstances, such substances are not ruled out as mere “discoveries”, but are considered as inventions by the legal authorities.

Micro-organism patents are now obtainable in most industrially developed countries, following the landmark decision of the United States Supreme Court in 1980 that the living nature of micro-organisms does not preclude them from patentability.

Plant patents are also obtainable in the United States, Europe, Japan, Australia and some other countries. To avoid legal confusion, patent law in Europe excluded plant varieties from patentability, e.g. in the prototype provision of the European Patent Convention (EPC), Article 53(b), excludes patents for “plant and animal varieties” and “essentially biological processes for the production of plants and animals”.

Animal breeds produced by traditional methods have no legal system for their protection comparable to plant breeders’ rights. US patents may in principle be obtained for non-naturally occurring non-human multi-cellular living organisms, including animals. The first transgenic animal patent was issued in 1988 to Harvard University with claims covering the “onco-mouse”, one in which an onco-gene has been introduced to make the animal more susceptible to cancer and therefore more sensitive in testing possible carcinogens. Transgenic animal patents are also available in European countries. A European patent was granted for the onco-mouse, but is now under formal opposition by various groups concerned with animal welfare.

Patents for chemical compounds corresponding to nucleotide sequences may also be obtained in industrially developed countries. “Gene patents” require more discussion than is feasible in this brief summary. The patent authorities in countries where such patents have been challenged consider that the gene, in its natural state, is unpatentable, but that a patent can be granted when the gene is isolated and made available for a practical, industrial or other useful purpose.

Apart from the necessity to comply with basic patent law requirements of novelty, inventiveness and industrial applicability or utility, the prospect of obtaining patent protection is also dependent on the disclosure (“technical teaching”) provided in the patent application. The scope of the patent, as expressed in the patent “claims” (which are verbal definitions of the invention), is largely influenced by the character and content of the disclosure. Claims are required to be supported by, and commensurate with, the disclosure, which must enable the skilled person to put the invention to use.

In the case of an active substance derived from a microbial, plant, or other biological material source, the disclosure will identify the species of organism and,

if necessary, its geographical location. If the species or strain of organism is not readily available, a deposit of the necessary biological material in a recognised culture collection may be required. The application will describe in suitable detail the method of production or extraction of the active material and the degree of purification required. The product will normally be identified by means of appropriate physical, chemical, or biological characteristics. Assigning a defined chemical structure to the compound, where possible, is considered to be the optimal form of characterisation.

In the case of an invention based on gene isolation and transfer, the methodology must also be disclosed in an enabling (repeatable) manner. The techniques of recombinant DNA technology are now well-established and can usually be adequately described for the purposes of patent applications.

Plant variety protection

Although patents for certain types of plants have been available under US law since 1930, patent law in most other countries was originally considered unsuitable for protecting new plant varieties developed by traditional breeding methods. Special national laws of plant breeders' rights (also called plant variety rights) were therefore established in the 1960s in some countries, as well as the International Union for the Protection of New Varieties of Plant (UPOV). UPOV has a current membership of 31 States. The current Convention of UPOV is that of the 1978 Act. A highly significant revision of the UPOV Agreement was concluded in 1991. Although this revision has not yet entered into force, the changes introduced through the 1991 revision have already been implemented in a number of UPOV members, and it is expected that the revision will come into force in the near future. Articles 14 and 15 of UPOV 1991 are reproduced as Annex VI.

Prior to the 1991 Act, all versions of UPOV have restricted the scope of the breeder's right primarily to the commercial marketing of the reproductive material of the protected variety. Consequently, farmers legitimately sowing seed of a protected variety are legally free to save part of the seed from the first crop of plants for sowing on their own farms to produce a second and subsequent crops (the "farm saved seed"). It was recognised that the absence of reasonable limits on the right of parties to use and sell "farm saved seed" could significantly undermine the legitimate interests of the holder of a plant breeder right. One result of this recognition was that the definition of both the plant breeders' right and the acts that constitute an infringement of that right were clarified in the 1991 revision of the UPOV. The scope of the right will henceforth subject all production/reproduction of not only propagative material but in specific circumstances the harvested material or products of the harvested material to the authorisation of the breeder. However, it is an option whether Member States include the farm saved seed in their national legisla-

tion. In practice, if farm saved seed is introduced into national legislation, royalty rates on the harvested material are expected to be lower than for bought-in seed.

Under all UPOV Conventions, breeders enjoy the so-called “breeder’s privilege” or “research exemption” which gives them the freedom to use protected plant varieties in their breeding programmes to generate other (derived) varieties. Previously, this freedom extended also to the commercialisation of the derived varieties without any royalty payment to the owner of the initial variety. UPOV 1991 now extends the scope of the breeder’s right also to include varieties “essentially derived” from the protected variety. A variety which is predominantly derived from the protected variety, but which does not differ in performances or value, can therefore be produced, *i.e.* bred, but cannot be commercialised without authorisation from the owner of the initial protected variety. It is important to note that a plant breeders’ right under the UPOV model cannot “block” in the same fashion as in patent law the right that would be granted to a derivative variety. The concept of the extension of protection provided through the references to essentially derived varieties does not alter this basic understanding but simply clarifies the boundaries of protection granted in a particular variety.

Under the 1961 and 1978 UPOV Conventions, protection of the same entity by both plant breeders’ rights and patents was forbidden (prohibition of “double protection”). This prohibition against “double protection” was not included in the UPOV Convention of 1991 as a result of the recognition that many advances in plant biotechnology and plant breeding techniques have occurred since the original UPOV treaty was developed. As a result, protection for plant innovation at the varietal level is possible through both patent and UPOV-style plant variety protection in several OECD Member countries.

The freedom of research

The freedom to carry out research is safeguarded under both patent law and plant variety rights. Under patent law, “experimental use” for research purposes is not considered to be an infringement of the rights of the patent owner. But what is purely experimental (rather than experimental for commercial purposes) is a matter of interpretation, mainly through case law, and can therefore vary according to national jurisprudence. The freedom to commercialise the resulting products of research depends on whether or not they infringe the patent claims, or are “essentially derived” or “dependent” varieties under plant variety rights. The strengthened UPOV protection will therefore go part of the way towards the strong protection given by patents. Neither system is a threat to the free use of existing or new germplasm.

The function of intellectual property

“Industrial property” systems (e.g. patents, trade secrets, trade marks, design protection, etc.) have been developed by states as a means for recognising and promoting innovation. Patents, for example, protect the innovator for a limited period against use of the protected subject matter (*i.e.* the patented invention) by third parties without his consent. Patent systems promote innovation by encouraging the early and effective public disclosure of inventions; patent systems universally involve publication of a full description of the invention upon grant or, in many systems, at 18 months after patent protection is originally sought. It must be clearly understood that a patent, for example, cannot hamper the free use of whatever is already in the public domain, but can only control the use by others of the inventor’s novel addition to the previously existing technology. This principle of providing a temporary period of legal protection encourages the climate for innovation, to the ultimate benefit of the public as a whole. This period of protection is not yet uniform in all countries, but for patents the period is most commonly set at 20 years from the patent application date, subject to the payment of official renewal fees which rise annually. Patents also encourage investment in research and development and in the production and marketing of new products and processes.

Statutory intellectual property rights provide a basic framework for voluntary technology transfer through intellectual property right licensing, supplemented and reinforced by provisions based on the supply of know-how and other factors which may be less easy to define. Patent law demands clear definition of the protected technology and thereby establishes the scope of the rights of the innovator, identifies what is transferred to a licensee, and allows for the corresponding freedoms of third parties to be assessed.

Subject to international agreements designed to improve and unify patent protection throughout the world, a country is free to develop its own policy towards legal protection systems and legal enforceability procedures. Thus, a country is free to develop and implement measures to encourage technological innovation, technology transfer and other technology-related objectives, provided these measures conform to the minimum standards of protection mandated by the TRIPS Agreement and other multilateral treaties in the field of intellectual property law. Important factors affecting national policy will be:

- the existing level of the national technology and expectations as to its future development;
- the need to encourage technology transfer from other countries; and
- the desire to induce foreign investment in the country or region; a strong patent system is more likely to attract foreign investment.

B. GENETIC RESOURCES

Access to genetic resources: The current situation

It has long been recognised that genetic materials and the valuable substances to which they give rise in living organisms can be used for the purposes of human welfare, especially through improvements in agriculture and the nutrition and health care of humans and animals. Before their full potential can be exploited to this end, genetic resources and their ultimate expression products must be identified, isolated, and developed. For this purpose, an input from science and technology is necessary. Modern chemistry and biotechnology provide wide-ranging and sophisticated means of achieving these desirable objectives, and have already led to significant improvement in both agricultural and pharmaceutical processes and products.

The voluntary international agreement dealing with access to plant genetic resources for food and agriculture, the “International Undertaking on Plant Genetic Resources for Food and Agriculture”, when first agreed, was based on the principle that plant genetic resources were the heritage of mankind. Over the years, the Undertaking was clarified through a number of interpretative annexes which *inter alia* recognised that the concept of mankind’s heritage, as applied in the Undertaking, is subject to the sovereignty of the States over their plant genetic resources (Resolution 3/91).

Some public policy declarations in this context may have been based on an incomplete appreciation of the nature of intellectual property and of its limitations. Any attempt to secure intellectual property on known and available genetic resources, either in the form of raw plant germplasm or as held in public collections, would be contrary to the fundamental principle in intellectual property law which states that what is already in the public domain cannot be removed from it and privatised. This principle is universally accepted, and in patent law, is adequately covered by the general requirement for absolute novelty of the claimed invention. To make the point explicit, the 1994 revision of the *Mexican* patent law has declared unpatentable “genetic material as found in nature”.

In spite of these considerations, which patent specialists have often widely publicised, the erroneous belief that agricultural materials, knowledge and skills, handed down through generations of rural communities, can somehow be expropriated, and that intellectual property systems can be used to effect such misappropriations, is often still expressed in public commentary.

Arrangements for access to genetic resources (Material Transfer Agreements)

From earliest times, the genetic resources of the richly biodiverse regions of the world have been explored in the search for crops and other species of potential

economic use. Scientific interest was often present, as an adjunct to commercial interest, and has continued in its own right, spurred on with increasing momentum with the development of powerful scientific techniques for manipulating genetic material.

Access to, and exchange of, genetic material in connection with scientific research has its own justification independently of direct commercial benefit. For example, cross-country collaboration between universities and other research institutes has most often been directed to the stocking of germplasm collections and a widening of the knowledge base through scientific publication, from which the collaborating scientists benefit academically. In this vein, genetic material in public gene banks has normally been freely accessible on the basis of disclosure of information as to intended use. Similarly, gene prospecting by scientists has also depended on the goodwill of local research institutes and individuals, with little emphasis placed on monetary or other return.

In recent years, as a result of renewed interest in the screening of genetic resources for potential commercial, as well as academic, purposes, the need for more formal arrangements has been considered. Agreements prepared in industrial and academic circles for the supply and exchange of biological materials in a research context have come into use in recent years. Official public collections of germplasm are considering the use of similar agreements to cater to the needs and interests of the donors of germplasm (the provider), and those individuals and organisations (the recipient) who request material from these public sources. These agreements, termed Material Transfer Agreements (MTAs), are being drafted, or are in use, in a number of variant forms by various private or public germplasm collections. An example of an MTA under consideration at present is given in Annex IV.

MTAs are viewed by some individual commentators as affording a form of intellectual property protection. However, for reasons explained above, intellectual property in the customary legal sense does not reside in the raw natural material, and may only arise when the natural material is modified in some industrially useful manner, or a component of it is isolated and applied to a utilitarian purpose. MTAs may therefore more properly be classified as contractual agreements designed to safeguard the interest of the supplier of the material in the interim, before the generation of intellectual property, from which the supplier may obtain benefit proportionate to his contribution. MTAs frequently contain provisions covering intellectual property deriving from research on the material as supplied by the official collection. Current drafts show varying attitudes to intellectual property, and a harmonized approach may take time to achieve.

The role of International Agricultural Research Centres

The Consultative Group on International Agricultural Research (CGIAR) is an informal association of 40 public and private sector donors supporting 16 international agricultural research centres. Some of these deal with genetic resources. Issues concerning terms of access and benefit sharing of the material housed in these collections are being addressed through the revision of the International Undertaking on Plant Genetic Resources for Food and Agriculture. As part of the overall process of addressing these issues, the *ex situ* collections of plant genetic resources for food and agriculture have been formally placed under the auspices of the FAO.

The International Agricultural Research Centres' gene banks are held in trust for the world community and have been available in accordance with declared CGIAR policy. Material Transfer Agreements are in use by some, but not all, International Agricultural Research Centres. Policy with regard to intellectual property rights has so far been a matter for autonomous decision by the individual centres and some variations have necessarily resulted from this. A common provision in these Agreements is that recipients will not restrict (by means of intellectual property rights) the availability of the genetic resources "in their original form" or will not "appropriate these public goods".

In the context of a voluntary International Code of Conduct for Plant Germplasm Collections and Transfer (ICCPGGT), the United Nations Food and Agriculture Organisation (FAO) and CGIAR concluded an Agreement on 26 October 1994 whereby the plant genetic resources in CGIAR gene banks will be held in trust for the international community. This Agreement [Agreement between the (name of research centre) and the Food and Agriculture Organisation of the United Nations (FAO) Placing Collections of Plant Germplasm under the Auspices of FAO] confirmed and consolidated the current CGIAR policy of "unrestricted availability of germplasm held in their (*i.e.* International Agricultural Research Centres') gene banks" and its conservation and use "in research on behalf of the international community, in particular the developing countries". Article 3(b) of the Agreement stipulates that: "The Centre shall not claim legal ownership over the designated germplasm, nor shall it seek any intellectual property rights over that germplasm or related information." It is not clear what is embraced by the term "related information". Article 10 provides that where designated germplasm or related information is transferred to any other person or institution, the Centre shall ensure that the transferee is also bound by the above conditions.

Once again, these provisions demonstrate that the erroneous idea that intellectual property rights could restrict or appropriate public domain material is clearly hard to dispel.

For their own research results, International Agricultural Research Centres' policy has tended to be in favour of not seeking intellectual property, either for income generation or to supplement operational funding. However, the Centres have to operate in a changed research and funding environment and to collaborate with organisations for which intellectual property is a necessary counterpart to their willingness to invest in development. This has long been true of industrial organisations, and academic and public sector organisations are also now taking a more positive attitude towards protecting innovations resulting from their research. The International Agricultural Research Centres may therefore wish to review their own positions in this respect.

The MTA can be adapted to facilitate equitable collaborative research with, and development on, genetic resources in ways that recognise source-country and local community rights. The parties to the agreement will be the provider of the material, the recipient, and if necessary, the national government and the consenting local community. Depending on whether the recipient is a not-for-profit or a commercial organisation, there will be variations in the typical terms of such agreements.

In the application of MTAs in the context of plant breeding and crop improvement, the strong public sector interest and involvement has influenced the climate of opinion on these matters. The use of genetic resources in the search for new pharmaceuticals and agrochemicals ("bioprospecting") is an area where public sector involvement co-exists with a major effort on the part of industry. Initiatives have been taken in recent years to access genetic resources in the more richly biodiverse countries for the express purpose of producing valuable derived products. Arrangements have been put in place, with the consent of national governments, to enable industrial or public sector scientists from developed countries to collaborate with a local facilitator organisation in the phytochemical screening of local and often exotic plants.

Bioprospecting agreements take into account the financial needs and interests of the collaborating parties and, for this reason, tend to be much more specific than the typical MTA over benefit sharing. Payment for samples collected will be made ("up-front" payments), but the major expectations of benefit will be met by royalty payments on successful commercial exploitation of derived medical and agrochemical compounds. These desirable products lie at the end of a long, expensive and uncertain road of scientific and industrial investigation. A realistic assessment of the value of these projects to the provider organisation and nation is that the benefits are likely to be long-term.

Alternatives to traditional bioprospecting

Since the early part of this century, the search for anti-microbial and other useful substances has been approached in two main ways. One approach has been

to screen natural sources such as soil samples, marine waters, insects, and tropical plants for biologically active components. In parallel, many potentially useful compounds have been synthesised chemically and screened by scientists in academia and especially in the pharmaceutical and agrochemical industries. A new method of approach is now becoming possible. Better understanding of biological mechanisms and recent advances in molecular biology have led to the identification of molecular targets underlying the pathology of many diseases. Chemical “libraries” containing millions of synthetic chemical structures which can potentially interact with biological receptors can be utilised in combination with computer-aided molecular design and the methods of solid-state chemistry to prepare compounds which interact with the target systems. This new approach is described as “combinatorial chemistry”. The hope that lies in this approach is evidenced by a number of recent acquisitions and mergers involving large companies and the smaller companies that have developed this expertise. The ability of synthetic chemistry to track through the large range of chemical structures of potential biological activity revealed by these methods may considerably extend the possibility of developing new products which are biologically more effective than the “lead” compounds found in natural sources. Although nature provides an enormous storehouse of biologically active substances, the potential of which it would be unwise to write off, combinatorial chemistry may overshadow the longer process of “look-and-see” bioprospecting used in the past. This new approach has its own science-driven momentum, but will be encouraged even more if traditional bioprospecting is impeded by inhibitory conditions.

The need for conservation of genetic resources

Understanding the importance of genetic resources to mankind carries with it recognition of the need for genetic resources to be conserved for future generations. It is important to bear in mind that the scientific exploration of the microbial, plant and animal kingdoms with a view to producing innovative processes and products of potential industrial and commercial value is in no way inconsistent with, or inimical to, the conservation of genetic resources. A distinction must be made here between the investigation of microbes, plants and animals for potential pharmaceutical products, and the investigation of genetic material itself for potential gene transfer in the context of crop improvement. In the pharmaceutical context, there is the possibility that the bioactive compounds discovered, or structures related to them, may be amenable to chemical synthesis so that commercial production will not always be dependent on the original biological source material. One notable instance of this is that of natural pyrethrum and the synthetic pyrethroids which have been developed in both public institutional and industrial research, and which have captured a large part of the agricultural pesticides market. Even more striking

examples are those of the original penicillins and cephalosporins of fungal origin and their semi-synthetic counterparts which are pre-eminent in modern medicine.

Where synthetic chemistry cannot completely take over from nature, it will be necessary to devise special measures to conserve plant populations. Similar considerations apply to the use of animals as sources of pharmacologically active compounds, *e.g.* in reptilian and arachnid venoms.

On the other hand, the study of plants and animals for the exploitation of their genetic components is less subject to this potential problem. Although there may be exceptions, it is more usually the case that relatively small amounts of genetic material are required for the investigation so that the original source material remains unchanged and undepleted. For example, the transfer of a gene from a wild grass to confer a valuable trait on a cultivated variety of wheat has no noticeable effect on the wild grass population. Once achieved, the process of transfer never requires repeating. This operation is therefore in no way comparable to the wholesale removal of the mineral wealth of a particular country or region.

The same compatibility with conservation must also be acknowledged for the intellectual property protection of such innovations. In view of widespread misunderstandings, it is necessary to stress again the fact that intellectual property extends only to the new inventions created from the gene that has been transferred from a sample of the natural material. There is, of course, the possibility that the new genetic combinations may, because of their advantages, supersede existing products. This consequence is entirely market-driven and depends as much on the purchasing choices made by the agricultural community as on the proprietor who has legal control of the improvement. In addition, the process of industrial competition will normally ensure that alternatives are available, including the older products which may continue to compete on price with the new ones. Intellectual property and competition laws contain checks and balances designed to prevent total control of what products are available on the market. It is particularly essential to dispel the common myth that intellectual property protection, standing alone, inevitably leads to monopoly power for the right-holder.

The Biodiversity Convention

The full text of Articles 15, 16 and 17 of the Convention is given in Annex II.

The Convention on Biological Diversity (CBD) sets out an internationally agreed policy framework for the conservation and sustainable utilisation of biological diversity, and for access to and the equitable sharing of the benefits arising from the utilisation of components of biological diversity.

Since its entry into force in December 1993, the CBD has covered all biological diversity, including animals, micro-organisms and plants. The CBD negotiations failed to resolve some access and benefit sharing issues in respect of plant genetic

resources for food and agriculture. At the request of the governments which negotiated the Convention, outstanding matters concerning plant genetic resources for food and agriculture are being addressed within the FAO Global System for the Conservation and Use of Plant Genetic Resources for Food and Agriculture, in particular through the revision of the International Undertaking on Plant Genetic Resources for Food and Agriculture. In contrast to the CBD, the Undertaking is non-binding in international law. The issues concerning access and benefit sharing are complex. There are different policy and technological dimensions to the issues, depending on whether they involve, for example, plant production for food and agriculture or for pharmaceuticals.

The Convention recognises the sovereign rights of states over their natural resources, from which national governments have the authority to determine access to them. The Convention provides that, in return for allowing access to its genetic resources, a donor country may benefit through any of three mechanisms:

- participation in research;
- access to and transfer of derived technology;
- sharing in the results of research and proceeds of commercial exploitation.

Access and sharing are to be dealt with “on mutually agreed terms” and “subject to prior informed consent”. Therefore, access to genetic resources must be preceded by negotiation as to the form in which benefit to the donor country is to be achieved. The Convention envisages formal arrangements for access based on the principle of prior informed consent at the official level.

Access to and transfer of technology among the contracting states is seen as necessary, both for the conservation of biological diversity, and for the use of genetic resources. Contracting parties (national governments) are given certain discretion to determine the “legislative, administrative or policy measures as appropriate” that can be taken to achieve this objective. Such measures must have the “aim that the private sector facilitates access to, joint development and transfer of technology ...for the benefit of both governmental institutions and the private sector of developing countries”.

Technology transfer may be achieved by a variety of mechanisms. It will usually include the licensing of some form of proprietary right obtained either under an established statutory form of intellectual property or deriving from the possession of secret know-how and/or proprietary biological material. The Convention recognises that the technology to be transferred may be the subject of patents and other intellectual property rights. In fact, strong intellectual property systems can more effectively serve the goal of promoting private sector efforts to provide access to and transfer of technology.

COUNTRY RESPONSES AND COMMENTS ON RESPONSES

THE OECD QUESTIONNAIRE

The OECD Questionnaire, the origin of which is explained in the Introduction to this report, is set out in full in Annex I. The questionnaire was composed of three parts. Part 1 sought information on existing projects; Part 2 was directed towards an evaluation of government policies; and Part 3 addressed consideration for future policies.

Part 1 of the questionnaire was intended to obtain basic information as to arrangements that might be in place, or in prospect, for achieving a synthesis of the four principal themes of this study, namely: access to genetic resources, development of them, transfer of technology derived from such development, and the role of intellectual property in this regard.

The preamble to the questionnaire was explicit in its terms of reference to:

- “the transfer between countries of technology in the field of biotechnology related to the development of genetic resources”;
- “access to genetic resources of one country by persons or organisations based in another country”.

The prime focus of interest in this survey was therefore upon arrangements of trans-national character as distinct from those between parties under the same national jurisdiction. The latter types of arrangement are of interest to the extent that they reflect past experience in devising agreements which may provide models for use in trans-national situations.

The questionnaire was expressly intended for transmission to “parties having practical experience in technology transfer in biotechnology incident to access to genetic resources.” Technology transfer takes many forms and is widely defined in the Background section of the questionnaire. The predominant form of technology transfer in industrially developed countries is via transfer of intellectual property rights, either of statutory form, e.g. patents and plant breeders’ rights, or by contractual arrangements based on the supply of know-how and proprietary materials. This emphasis underpins the questionnaire as a whole.

GENERAL OBSERVATIONS ON THE RESPONSES

The following features of the responses as a whole must be noted:

1. Several of the responses indicate that, of those consulted in their own country, the low proportion replying meant that the results were not statistically significant. Consequently the overall response could not in all cases be taken as a representative national view. For example, the *French* response reported that replies were received from only 28 out of 227 organisations consulted. In other countries, however, a low response rate may also indicate that only a small proportion of the industrial and public sectors is actually engaged in the types of activities surveyed.
2. There were notable differences from country to country in the range of responding parties and in their apparent degree of commitment to the task posed by the questionnaire. From some countries, relatively few agencies responded, and the views of the private sector were far from prominently represented. Even within countries, there is a lack of homogeneity of opinion on some of the issues raised in the questionnaire, which makes a national position difficult to formulate. This is not solely due to differences between industry and the public sector.
3. As noted above, the preamble to the questionnaire had placed this question in the context of a transfer of technology between countries as distinct from technology transfer from one party to another in the same country. This was emphasized by the *French* co-ordinators of the study in a note accompanying the distribution of the questionnaire to organisations in France. In the great majority of the responses, the distinction between trans-national and other types of arrangement has not been clarified or even alluded to. This may reflect the fact that most countries have relatively little experience in framing such arrangements internationally and especially at the government level.
4. Genetic resources are of interest for agriculture and the agrochemical industry. They are also important for the health care industries as a source of medical bioactive materials which are high value products. Genetic resources, particularly microbial ones, have environmental applications important to industry and to the general public. Since the financial returns from the exploitation of genetic resources will vary with the industry, attitudes to the topics of the questionnaire among these various business interests are unlikely to be uniform. In most responses, it was difficult to discern such differences from the information provided.
5. The format of the questionnaire appeared to encourage some respondents in the mere encircling or ticking of the various options without expanding, even in the general terms requested, on the types of project or arrange-

ments made under Questions 1-4. Some responses simply tabulated figures and ratings without supplying accompanying commentary; this made it difficult to draw conclusions.

6. Some of the responses were given in general summary form rather than being sub-divided by question.

In the following sections of this report, each question is set out and a summary of the relevant responses is provided. This is followed by a commentary, in which some of the individual country responses are referred to specifically. In the light of the foregoing remarks, and particularly in view of the wide range of issues involved, it was not feasible to mention the specific standpoint of every country or contributor on every point. Where individual country responses are highlighted, it is because of the distinctive manner in which the observations were made, and does not imply that the view presented was not also shared and expressed by other countries. In addition, the commentary also includes observations which do not derive from the responses, as such, but which are based on information reaching the public domain either before, or after, the responses were received.

QUESTIONNAIRE PART 1. EXISTING PROJECTS (QUESTIONS 1-4)

Please describe the types of projects that you have sponsored, or participated in, related to the discovery or development of genetic resources:

Question 1. *Describe the participants and their roles (examples of categories of arrangements):*

- a) *company/company arrangements*
- b) *university/company arrangements*
- c) *non-profit organisation/company arrangements*
- d) *government/company arrangements*
- e) *government/government arrangements*
- f) *other -----*

The object of this question was to determine what initiatives have been taken so far to collect and develop genetic resources. The emphasis was primarily on the types of projects undertaken between countries, although it was recognised that countries with abundant genetic resources of their own would present opportunities for internal initiatives in this respect.

Responses to Question 1

Few responses identified specific types of projects. The question was clearly designed to obtain information on representative, specific projects, without requir-

ing a comprehensive and unwieldy listing of such items. *Australian* respondents indicated in a general fashion the extensive activity undertaken to investigate Australian terrestrial and marine resources through collaboration between governmental institutions and both national and overseas organisations in both public and private sectors. These investigations were mainly aimed at the development of national agriculture, horticulture, and egg production. The *Belgian* response also showed active intervention and support for international agricultural research and problem solving. Five specific projects were identified which involved collaboration between *Belgian* universities and industry and institutions in African and Latin American countries, as well as with international bodies. These were aimed at crop protection and crop productivity improvements which would benefit agriculture in developed, as well as developing, countries. These projects were aimed at assisting farming communities in developing countries and providing low cost protein sources for the population.

The *Mexican* response identified specific research projects and crop improvement programmes on crops of national interest. These involve collaboration between national government departments, universities, private companies and national agricultural research institutions (CIMMYT, the International Agricultural Research Centre located in Mexico). Some projects are aimed at developing methods of conservation of national genetic resources through tissue culture.

In the response from *Norway*, one industrial contributor identified collaborative projects with national and foreign universities on crop protection and improvement. Similar references were present in individual contributions to the national responses from other countries (e.g. *Switzerland*), but not highlighted in the overall synthesis. The *Japanese* response referred to joint research projects (details not given) involving the government, industry, and other organisations directed to the conservation and sustainable use of genetic resources in South-East Asian countries, in partnership with governmental/semi-governmental organisations in those countries.

The *United States'* response dealt with the industrial experience separately from that of government agencies. The industrial replies were mediated through industrial associations reporting on behalf of their member companies. Several US companies have participated in projects to develop commercial products from genetic resources, but no specific details were provided. These projects were in collaboration with other companies, universities, non-profit research organisations and US and foreign government agencies (unspecified).

The US response stressed that the extensive funding by US government for research and evaluation of genetic resources is primarily science-oriented, related to human health, food and agriculture and in a non-commercial context. Four agencies were identified, two concerned with drug development and two with agriculture. For example, one agency (National Cancer Institute) has 40 years of experi-

ence in the search for anti-cancer drugs derived from plants of the African, Latin American and Asian continents, and has extended this to the search for anti-HIV compounds. Marine organisms are also extensively examined. Another agency (Fogarty International Center) had promoted International Co-operative Biodiversity Group programmes involving public and private sector participants from the United States and developing countries, including universities, non-profit research organisations, government laboratories and private companies. A key feature of these programmes is the involvement of at least one partner from the source country.

The US agricultural agencies reported on similar patterns of international collaboration. Sponsored projects include US company collaborations with developing countries for the micropropagation of banana and pineapple, and the development of pest-resistant potato, maize and cucurbits. A notable feature of the maize improvement programme is that the US company provides both the germplasm and the technology. Similar activities have been undertaken by Biotics Limited (based at Sussex University, United Kingdom) which, since 1986, and with European Commission support, has brokered the phytochemical screening of developing country flora by industrial and other specialised European research organisations. (Not mentioned in the *United Kingdom* response.)

To this particular question, the great majority of the other responses concentrated on the extent to which particular pairings of participant [*a*) to *l*) had taken place. Almost all combinations are cited in most of the responses, the most frequently mentioned being pairings of company/company, university/company, non-profit organisation/company. Not surprisingly, the pairing that is most mentioned is that of university to company, reflecting the fact that academic biological scientists had accumulated experience and expertise in this field of research long before commercial agriculture paid attention to its potential benefits. Other possible pairings involving universities were also mentioned (by *Belgium*).

Only in a small minority of the responses (*United States, Australia and Japan*) are there indications that government-to-government arrangements exist to allow scientists to collect, characterise and store in appropriate collections (depositories) plant and animal genetic material from other countries for potential use in agriculture. Beyond stating that they exist, no description of these arrangements was given. Similar arrangements were said to exist between governments and non-governmental (international) research institutions, and also with overseas companies.

Comments

The questions in Part 1 of the Questionnaire were specific and searching, and the information on which to found responses was no doubt distributed widely

throughout all countries and difficult to retrieve comprehensively. For some recipients, especially those of industry, matters of confidentiality may have been involved.

The responses to Question 1 were sufficient to show that some OECD Member countries have been considerably active in the exploration of genetic resources. Organisations in these countries are experienced in dealing with local institutions and official authorities in other countries to enable the potential of their genetic resources to be investigated. In the overall strategy of the investigations, the needs of the source country are important to the project, e.g. for local crop improvement, in addition to other objectives, e.g. for the improvement of cultivars in developed countries.

Question 2. *Describe in general terms the arrangements that you have made with regard to types of technology transfer:*

- a) *disclosure of results from research and development*
- b) *licensing or assignment of intellectual property rights related to such results*
- c) *exchange of information*
- d) *education and training*
- e) *joint ventures*
- f) *acquisition of one entity by another*
- g) *financial and other support of research activities*
- h) *other*

One purpose of identifying and developing genetic resources is to achieve technological innovation from which the provider may also benefit, e.g. by the transfer of derived technology. This question explored the current experiences and expectations of OECD Member countries in technology transfer through the methods by which this is commonly achieved.

Responses to Question 2

The entire context of the *United States'* response to this question was that of technology transfer between countries. The US response from the industrial sector reported that all the listed forms of technology transfer had been provided by their members but, again, no specifics were mentioned.

The *US* governmental sector emphasized the extensive technology transfer which took place incident to their participation in projects, in addition to and outside the context of intellectual property. Such would include the technical training of host country scientists, technicians and students, provision of equipment and materials, and sharing of non-proprietary information. Some agencies had experi-

ence of all the listed types of technology transfer. The Letter of Collection Agreement used by one agency (National Cancer Institute) includes provisions for technology transfer to the source country in the form of royalties and scientific exchange, but special authorisation would be necessary to license future patent rights. The same agency referred to its Co-operative Research and Development Agreements (CRADA) with host country participants, through which intellectual property rights could be transferred.

The Letter of Collection used by the National Cancer Institute is reproduced in Annex V. This is an Agreement between the NCI Division and the Source Country to investigate “the potential of natural products in drug discovery and development”. The Agreement explicitly affirms the desire “to promote the conservation of biological diversity” and recognises “the need to compensate source country organisations and peoples in the event of commercialisation of a drug developed from an organism within their (*i.e.* source country) borders”. The Agreement refers to “sincere efforts to transfer knowledge, expertise, and technology related to drug discovery and development to the appropriate Source Country Institution or Source Country Organization(s), subject to the provision of mutually acceptable guarantees for the protection of intellectual property associated with any patented technology.”

The Letter of Collection also specifies that “Should the agent (*i.e.* from a plant collected in the Source Country) eventually be licensed to a pharmaceutical company for production and marketing ... NCI will require the successful licensee to negotiate and enter into agreements with the Source Country Government, agency, or Source Country Organization(s) as appropriate.” It also addresses the concern of the Source Country Government in respect of “royalties and other forms of compensation, as appropriate”. The commitment extends even to “products structurally based on the isolated natural product (*i.e.* where the natural product provides the lead for the development of invention)”.

The special character of technology transfer between countries was not prominent in the responses received from the other countries. Indeed, the parties between which technology was transferred were rarely specified.

It may have been misleading to include (without explanation) disclosure of results from R&D as one of the listed categories of technology transfer since some of the contributors to the responses interpreted this as covering general publication of results, *e.g.* in the scientific literature. It is difficult to envisage any form of technology transfer between collaborating parties which does not involve disclosure of R&D results and exchange of information between the participants. This will in most instances be accompanied by the licensing or outright assignment of intellectual property arising from the projects. The responses are unanimous in citing these common types of technology transfer.

Most responses to this question were confined to giving a brief indication of the methods used or considered important in this respect. All the available methods were cited as relevant depending on the circumstances. For example, as noted in the *Japanese* response, the benefits of the project will normally be shared between the parties through disclosure of R&D results, and transfer of intellectual property in accordance with the project contract, e.g. by assignment of rights. Thus with projects jointly carried out by the *Japanese* government and foreign or international agencies, the resulting intellectual property rights would be transferred to one party or shared between the parties. In most cases these projects will involve exchange of information, education and training of personnel, and financial and other support of research activities. The *Italian* response (given in overall summary form) noted that different types of technology transfer tools are used according to specific targets. The *Swiss* response indicated that as far as the industrial sector is concerned, all categories of arrangements are used. For the public sector (the federal agencies dealing with technology transfer or with technical co-operation), emphasis is placed on education, training, and information exchange.

Joint ventures were less commonly cited. The *Canadian* response noted the need to avoid venture capitalists "draining small companies of their intellectual property". The *Canadian* response considered intellectual property rights licensing and assignments as essential to the orderly and effective dissemination of benefits and noted that governments, universities and not-for-profit organisations are now making increased use of these arrangements for technology transfer.

Financial and other support of research is a pre-requisite to the creation of new technology and no doubt for this reason was commonly cited. It is however not strictly speaking a method of technology transfer. Acquisitions must surely be the ultimate and extreme form of technology transfer and were rarely mentioned.

Comments

From the relatively non-specific character of the responses as a whole, one concludes that technology transfer based on genetic resources (especially between countries) is expected to proceed *ad hoc* utilising all available traditional methods and has not so far called for the devising of special models.

The responses indicate that most of the technology transfer arrangements envisaged in this question are in place in connection with actual or contemplated projects. The emphasis on particular types of transfer differs as between patents and plant variety rights and privileged access to information, depending on the industry involved.

As to benefit to source countries in terms of products, processes and enabling technology, there is little concrete information in the responses to indicate that projects are yet yielding such benefits. This underscores the conclusion that bene-

fits are unlikely to come easily and quickly, especially from the study of medicinal plants.

Question 3. *Describe in general terms the arrangements you have made with respect to access and use of genetic resources:*

- a) *consent*
- b) *compensation and other benefits*
- c) *ownership and control of genetic material*

This question assumed that access to and permission to use genetic resources would require the consent of the source, willingness to compensate the source, and some form of agreement over ownership and control of the donated material.

Responses to Question 3

Many of the answers to this question were merged with the answers to Question 4. There is little variation in the answers received. The principle of consent is universal, consent often being given freely and without expectation, as is typically the case with public gene banks. This free availability is the general rule where the material is to be used for scientific purposes. Where access is mediated through a collaborating scientist or other party in the source country the collaborator is expected to obtain consent of the relevant local authority. Universities and public research institutions are accustomed to using Material Transfer Agreements (MTAs) which are now to be found as a number of minor variants of a standard form of agreement. Public germplasm collections are developing their own versions of MTA. Industry expects that some form of agreement providing for payment will be required. As noted in the response from the *United Kingdom*, payment comes in the form of royalties on sales of products derived from the source material, the royalty level depending on whether the product is protected by intellectual property and whether the agreement is exclusive to the recipient company.

Ownership of the genetic material itself is assumed to vest in the supplier or to have been acquired by the collaborator. Individual jurisdictions of Australia have entered into research agreements which require technology transfer to other countries. Some Australian States have passed legislation providing for Crown ownership of animals and some (protected) plants, although access is generally controlled by protecting specific locations (*e.g.* national parks), and all that is found on them; protecting particular taxa (*e.g.* all indigenous mammals); and issuing licences which only allow access to specific resources, and only for a particular purpose (*e.g.* commercial or scientific purposes). The detail of the legislation varies across each jurisdiction within Australia as there is currently no nationally consistent

approach to managing access to, and benefit sharing from, indigenous biological resources.

Canadian industry also expects to use written agreements defining the terms on which consent is given to use genetic resources, but material obtained from government-controlled gene banks is normally available without restriction. In the response from *France*, while consent was a common basis for access, most arrangements were based on purchase, and recompense related to use. The response from *Switzerland* indicated that, the local collaborator having once obtained local authority consent, it was normal for industry to regulate these matters by agreements which would provide appropriate methods of compensation. Several methods of compensation were enumerated, all of which could operate without dependence upon specific intellectual property considerations.

One large *Swiss* pharmaceutical and agrochemical company (not specifically mentioned in the *Swiss* response) has made a public statement of its policy on biodiversity prospecting. This contains commitments to preserve ecosystems and endangered species, co-operation with local researchers, provision of training and support, benefit sharing through written agreements, and the search for pragmatic solutions to open questions. A prominent *Danish* company has also declared its policy of commercialising microbial diversity, with equitable sharing of resulting benefits and scientific and commercial co-operation with source countries. In a similar policy statement, a major *British* pharmaceutical company has also stated that it will approach the acquisition of natural product source samples through Material Transfer Agreements which provide for appropriate payments to the suppliers and give them benefit for commercial exploitation. However, this would not normally involve transfer or sharing of intellectual property rights.

In addition to industrial policy statements of the kind just mentioned, scientists have also made their views known. In proposing the Manila Declaration on "The Ethical Utilization of Asian Biological Resources" (February 1992), scientists from 37 countries have declared themselves in favour of the positive aspects of the Biodiversity Convention. A "Code of Ethics for Foreign Collectors" has also been developed at the Botany 2000 Herbarium Curation Workshop held in Perth, Western Australia (April 1990).

In the *United States* response, the industrial sector confirmed that all factors have been addressed, *i.e.* consent, compensation and ownership. One government agency (Fogarty International Center) reported that all participants in projects must demonstrate informed consent in the structure of their contracts and that participants in the source country must accept a consent-to-use agreement before any use is made of collected material. As indicated above under Question 2, another agency (National Cancer Institute) included in its Letter of Collection a requirement that its licensee negotiate an agreement with the source country to provide benefits back for commercial exploitation of collected material.

Comments

In view of the connection between this and the following question, a combined comment for both Questions 3 and 4 is given under Question 4.

It should be noted that some countries have difficulties with the word “compensation”, preferring the phrase “benefit sharing” as in the CBD text.

Question 4. *Describe the arrangements you have made with regard to ownership, control and protection of intellectual property rights in agreements relating to access to and use of genetic resources:*

- a) *patents*
- b) *protection of undisclosed information*
- c) *copyright*
- d) *trade marks and service marks*
- e) *plant variety protection*
- f) *other*

Responses to Question 4

The question was aimed at discovering what provisions would be commonly made in access agreements as regards ownership, control and protection of intellectual property. There appears to have been some misunderstanding of this question. Some countries considered it as referring to property in the resources, which led them to note that intellectual property resides not in the source material but only in what is derived therefrom, e.g. new plant varieties.

Some *Australian* respondents sought to distinguish between the native and the developed genetic resources, the country in which the resources were located, and the distinction between *in situ* and *ex situ* collections. An *Australian* industrial respondent emphasized that, in their experience so far, rights in the source organism remain with the collection but that rights to derived molecules are with the developer. The *Mexican* response drew the same distinction between ownership of the genetic resources and ownership of any subsequent inventions based on them.

The *Japanese* response also indicated that ownership of the genetic resource itself would not arise but that the developer of a new variety would be entitled to rights to it.

Other responses focused on ownership of the source material and indicated that the practice of retaining such ownership diverged from one institution to another.

Patents, secrecy agreements and plant variety protection are the most common types of intellectual property encountered in agreements envisaged in this question but most respondents restricted their answers to confirming this in a general way.

In the *United States* response the industry contributors confirmed that patents would be filed and the participants would pledge confidentiality in trade secrets. US government agencies require all information generated in a project to be kept secret until intellectual property has been applied for and until disclosure is mutually agreed. Reports are monitored for intellectual property right potential but oversight is applied to ensure that information flow is not impeded to the detriment of research and development. US agencies are required to seek intellectual property for inventions arising out of sponsored research but there are constraints as to ownership or sharing of legal rights. In CRADA projects (see Responses to Question 2 above) sole or joint ownership of inventions is accepted as appropriate and the US government reserves non-exclusive royalty-free licenses. The International Cooperative Biodiversity Group activities of the Fogarty International Center (see Responses to Question 1 above) are said to comply with intellectual property law and also with the Convention on Biological Diversity.

Within the US response the specific National Cancer Institute comment on this question is particularly noteworthy. This referred to the need for a “shared sense of co-operation with the source country and due consideration of the problems associated with the commercialisation of the source country’s biodiversity resources”. National Cancer Institute recognise that source countries and indigenous populations do not receive recognition under the strict canons of patent law, *e.g.* as to inventorship in derived intellectual property. Several alternative legal instruments are being developed to remedy this situation. The Letter of Collection (see Responses to Question 2 above) is seen as doing “what current patent law cannot”.

The Letter of Collection is a contractual agreement that provides the recognition and financial reward of indigenous peoples and source countries through compensation and technology transfer, guest researcher and scientific support, access to scientific data, and benefit sharing through royalties. The response lists 19 developing countries with which Letters of Collection have been negotiated and indicates that negotiations with several more countries are underway.

Comments

The question of access to genetic resources is closely bound up with issues of ownership and control of intellectual property relating to such access. The responses to Questions 3 and 4 therefore overlap to some extent. As noted earlier, some confusion was evident as between genetic resources, as such, and the results of development of these. This apart, there was no indication that access to genetic resources was especially problematical or that it required anything other than the types of negotiation that would normally be expected in such situations, especially in a trans-national context. The Letter of Collection Agreement used by the US National Cancer Institute is clearly a valuable adjunct to intellectual property and

has an important complementary legal function to perform. The subject of these questions is related also to that of Question 10 and fuller comment on it will be postponed for commentary under that Question.

QUESTIONNAIRE PART 2. EVALUATION OF GOVERNMENT POLICIES (QUESTIONS 5-10)

In this entire group of questions, recipients were asked to rate certain factors in order of importance in relation to the particular aspects of each question.

Common preamble:

Please rate the significance of each of the following factors with respect to developing agreements on research or development related to genetic resources.

(A: essential B: major importance C: minor importance D: no importance).

Questions 5, 6. *Availability of intellectual property protection (Question 5) in the country to which technology is transferred (Question 6) in your country, in the form of:*

- A B C D (a) patents
- A B C D (b) protection of undisclosed information
- A B C D (c) copyright
- A B C D (d) trade marks or service marks
- A B C D (e) plant variety protection
- A B C D (f) other

Question 7. *Your ability to enforce intellectual property rights effectively:*

- A B C D (a) in the country to which technology is transferred
- A B C D (b) in your country
- A B C D (c) in other countries

Responses to Questions 5, 6 and 7

Because Questions 5, 6 and 7 were inter-related and were treated as so in most of the responses, it is convenient to take them together for purposes of analysis. The absence of legal protection for a particular product in any country which may offer a significant market opportunity leaves a loop-hole for a competitor or for local industry to exploit the product there without legal redress. Any organisation in the business of technological innovation, be it industrial or public sector, must find a way to cope with this problem.

The responses treat all three questions as related aspects of a common theme, admitting differences of emphasis rather than of substance. As noted in the *Can-*

dian response, there is little point in obtaining intellectual property if it cannot be enforced and therefore many refrain from seeking protection in countries which lack effective enforcement procedures. In most of the responses, the availability of effective protection in the countries to which technology is transferred is rated as of the greatest importance but no-one sees this point in isolation. Protection in both home and relevant foreign country are rated as virtually of equal importance. For some, the crucial issue is the strength of their intellectual property position world-wide.

As expected from industry, patents, secrecy and plant variety rights consistently score as essential or of major importance. Strong statements in this respect came from the industrial sectoral contributions from the *United States*, *Switzerland* and many other countries. The availability of comprehensive intellectual property protection, especially patents, in both the home country and that to which technology is to be transferred, is seen as a fundamental prerequisite not only to technology transfer agreements but also to attract and maintain ancillary investment in the country receiving the technology. This is stated to be of particular importance to the smaller companies reliant on revenues from technology licensing. Plant variety protection is also seen as essential by the relevant industry. The *United States'* governmental contribution to these questions, from a non-commercial viewpoint, was consistent with that of its industrial counterpart, whilst perhaps implying that effective legal systems that govern contractual relations between parties might make up for defects in formal patent-type protection in the recipient country. The US public and private sectors both rate protection in the United States as the most essential requirement, and see strong US intellectual property protection as being instrumental in their country's success in biotechnology.

In other country responses there is some divergence between industry and the university/public sector contributors, but few now regard these matters as unimportant, which reflects the more commercially-minded approach nowadays to be found in these sources of innovation. The *Canadian* response notes that the younger research scientists are the more enthusiastic towards intellectual property. The public sector is, however, generally realistic about its difficulty in meeting the heavy cost of legal enforcement procedures without a commercial partner, and the same is true of the smaller biotechnology companies.

Comments

The dominant theme in the responses to Questions 5, 6 and 7 is the overriding importance of strong intellectual property law and enforcement procedures in the relevant countries. This requirement is stressed throughout the responses as a whole and must be assessed as a critical factor incident to any decision to embark on costly and high risk projects in this field.

Question 8. *Restrictions placed on marketing products that result from development of genetic resources:*

- A B C D (a) *in the country to which technology is transferred*
 A B C D (b) *in your country*
 A B C D (c) *in other countries*

Responses to Question 8

All the listed factors were considered significant although the precise significance was not always explained. The question was not entirely clear to some respondents. An *Australian* respondent marked them generally as of major importance while the responses from *Austria* and the *Netherlands* considered them essential. The *Belgian* industrial sector was said to be opposed to all such restrictions in whatever country. The regulatory obstacles for the placing on the market of genetically modified organisms (GMOs) was mentioned as a particularly perceived problem. However the *Canadian* response noted that regulatory systems inevitably place restrictions on the marketing of products, the problem being to strike the right balance for all concerned. The response from *Germany* showed an uneven distribution of views notable, however, for the essential or major significance this topic has for the larger companies. The *Norwegian*, *Swiss* and *United Kingdom* responses noted the major importance of restrictions only or mainly in the home and recipient countries.

The *Japanese* response considered it essential to avoid the introduction of any unnecessary restriction on the marketing of products resulting from the use of genetic resources. The current situation may be altered depending, for example, on the outcome of the discussion on biosafety protocol now underway in connection with the Convention on Biological Diversity. The response from *Finland* also considered that no special restrictions were called for apart from those imposed on products generally. The *French* response was broadly in line with these views and noted that any such restrictions might be viewed less favourably if adopted uniformly in all countries.

The industrial sectoral contribution to the US response considered the absence of such restrictions to be essential to participation, although the potential size of the market in any country would affect their willingness to persevere in the face of restrictions. The US governmental agencies were on the whole much less influenced by these factors, although concerned on the part of their commercial partners.

Comments

Questions 8 and 9 can conveniently be taken together for commentary.

Question 9. *Financial and investment conditions, particularly:*

- A B C D (a) *availability of grants or subsidies for conducting research or development of genetic resources*
- A B C D (b) *tax incentives regarding research or development of genetic resources*
- A B C D (c) *other*

Responses to Question 9

An *Australian* respondent indicated that grants and subsidies were mostly considered more important than tax incentives. However, the 150 per cent tax deductibility for industry research and development had encouraged private sector investment and the development of the national pharmaceutical industry. Funds for the large public sector breeding programmes in grains research had been essential.

These factors were rated of essential or major importance in responses from *Austria, Finland, France, Ireland, Japan, the Netherlands, Norway* and *Spain*. In the response from *Germany* these factors were especially important to small and medium-sized enterprises and public organisations. In *Belgium*, industry appreciated tax concessions while research institutions stressed the importance of grants and subsidies. One company mentioned the availability of venture capital.

The response from *Switzerland* stressed the greater significance of the general climate for private sector investment in this technology rather than fiscal intervention on the part of the state. One Swiss industrial contributor warned of unrealistic expectations of the source country, as to the level of royalties on drugs developed from genetic resources, which would militate against agreement with participants in these countries.

The *United Kingdom* response noted both the availability of grants and tax incentives as highly important. For one major company grants are an incentive if there is no obligation to share intellectual property. Tax benefits for R&D are rare in the European Union. More stress is placed in the UK response on the problem of venture capital funding and start-up cash injections.

The *United States'* governmental agencies mostly found these factors less significant to them than to commercial interests, with one exception, Fogarty International Center, which considered grants or subsidies essentially important and for which financial and investment incentives were necessary to stimulate and guide prospecting in a direction consistent with the aims of the Biodiversity Convention.

Comments

Marketing restrictions, whilst being a significant complication for the industries, will not necessarily inhibit projects for the development and exploitation of

genetic resources and are not seen as more problematical in this area than for other areas of biotechnology.

Any financial inducements to embark on projects will serve as encouragement but the main motivation comes from the scientific and/or commercial assessment of their worthwhileness.

Question 10. *Conditions placed on parties prior to gaining access to genetic resources:*

- | | | |
|---------|-----|--|
| A B C D | (a) | <i>requirement of “informed consent” as to possible future use of genetic resources</i> |
| A B C D | (b) | <i>requirement for disclosure of research results</i> |
| A B C D | (c) | <i>sharing, either through licenses or partial ownership interest, intellectual property rights to technology developed during the project</i> |
| A B C D | (d) | <i>other restrictions on the licensing of intellectual property rights</i> |
| A B C D | (e) | <i>profit sharing or royalty requirements</i> |
| A B C D | (f) | <i>up-front or fixed fee obligations as a condition of access to use of genetic resources</i> |
| A B C D | (g) | <i>other</i> |

This question was the last in the series that called for ranking. The question attempted to assess the relative importance of the listed factors in the making of R&D agreements relating to genetic resources. The listed factors clearly derive from the Biodiversity Convention, which has now been ratified by most OECD Member countries. Articles 15, 16 and 17 of this Convention, which are the most relevant to this question, are given in Annex II.

The question assumed that any factor achieving a rating of, for example, “essential or major importance” would have been viewed as a positive and desirable inducement to the making of such agreements.

Responses to Question 10

Most of the factors were assessed in the higher importance categories by *Australian* respondents, presumably implying them to be a necessary feature of the relevant agreements. Once again, whether the respondents had in mind Australian or foreign genetic resources was not totally clear. For example, one Australian respondent mentioned the need for clear policies at State and Territory level regarding access to genetic resources, this presumably being a reference to the fact that responsibility for managing access to biological resources was shared by the juris-

dictions making up the federation of Australia, though a majority of the responsibility falls to the States and Territories through responsibilities for land management.

In the *United States'* response, most of the US governmental contributors assessed informed consent as a necessary requirement, although one considered that it could also be a minor disincentive. The industrial contributors gauged most of the factors as very important or essential but, at the same time, as "a potential disincentive to reaching an agreement..." The industrial contributors were perhaps influenced by the element of restrictiveness implied in the various factors listed, as evidenced by the remark that "any conditions limiting the intellectual property rights of the company or other agent which assumes the financial and business risk of developing a new biomedical therapy based on genetic resources will severely curtail, if not eliminate, the prospects for investment and technology transfer to such a country".

The *Austrian, Korean and Spanish* responses noted most factors as very important. The *Belgian* response noted the difficulty of giving a general assessment covering a range of projects and partners of varying input and negotiating power, but mentioned most reluctance to share intellectual property rights or profits, and to a lesser degree, up-front obligations. The response from *Finland* also suggested the need for a case-by-case approach. In the *German* response, the large and smaller companies marked most factors as of high importance, as did the public-research and project-management organisations.

The *Canadian* response saw the question as implying governmental intervention in what, for the most part, are agreements between non-governmental parties, and considered that such intervention should be minimal. This response was clearly given outside the trans-national context of the Biodiversity Convention whereas the *Italian* response, while not specifically addressing this question, placed these and other issues squarely within the remit of the Convention.

The *French* response identified the need for prior informed consent and the sharing of intellectual property rights and benefits as of the greatest importance. Consent could normally be arranged between the parties and need not require state intervention. The same point was made in the *Mexican* response. The *Netherlands'* response attributed major significance to profit sharing or royalty provisions. The *Norwegian* response from the public-research institutes and ministries marked all factors as important, except up-front payments.

In the *Swiss* response, most of the listed factors are seen as highly important by the public sector but more qualified acceptance is expressed by industry. Sharing or licensing of rights is seen as of major importance by industry with one exception, which would make this dependent on the contribution made by the provider of the resources. The public sector contributors are divided on the importance of profit

sharing. One industrial contributor would restrict profit sharing to the case of joint inventorship.

The *United Kingdom* response assessed most factors as essential or of major importance, but expressed a high level of concern over informed consent.

Comments

This topic has been partly addressed in connection with the Responses to Question 4 but is given more detailed treatment here.

In seeking access to the genetic resources of any country, a foreign national individual, company or institution would expect to deal with whatever authority was appropriate to confer this privilege. Where this requires recognition or remuneration of indigenous peoples for their part in preserving and enhancing the flora and fauna of their country or region, this would be broadly acceptable to the investigating entity. As indicated in some of the responses, it might be questioned whether government intervention in these matters is necessary.

However, some time has elapsed since the Responses were formulated. During this interim, the important question of access has been the subject of ongoing consideration in connection with the Biodiversity Convention. In order to give practical effect to the Sovereignty principle and to implement Article 15 of the Convention (Annex II), the possibility of access legislation arises for consideration. No OECD Member country, nor the European Union, have yet taken this step and, with one exception (The Philippines Executive Order No. 247), neither has any developing country.

In complying with the conditions of access, one apparent problem is that of identifying the official body or other entity having the necessary authority to grant access (the "Gatekeeper"). A second problem is to devise a mechanism for obtaining consent which does not involve transaction costs that would be prohibitive for the source country and inhibitory for the investigator seeking such consent. As a partial solution of this problem, it has since been suggested that patent procedure be adapted to include a requirement to demonstrate that informed consent has been obtained. According to this scheme, patent application procedure would offer a "trigger point" for checking that the necessary consent procedure has been followed. If this suggestion were considered feasible, it would presumably have to apply also to other intellectual property procedure, e.g. under plant variety right law.

However, the whole concept of prior informed consent is that access cannot proceed until consent has been obtained, in which case no intellectual property can have been generated. The basic problem cannot therefore be side-stepped by inserting further procedural complications into intellectual property law. There are also serious practical objections to this suggestion. First, it would be totally

unprecedented in the field of intellectual property and would require substantive change in both national and international law. Secondly, the problem of identifying the gatekeeper would not be any easier for patent authorities. Thirdly, it would be seen as another point of discrimination against the biotechnology innovator and would be strongly resisted. It may also be viewed as incompatible with the anti-discriminatory provisions of TRIPS Article 27.

QUESTIONNAIRE PART 3. CONSIDERATIONS FOR FUTURE POLICIES (QUESTIONS 11 AND 12)

Question 11. *Please describe briefly measures that might be taken:*

- a) *to assist parties concerned with the conservation of genetic resources*
- b) *to improve the protection of biotechnology world-wide*

Question 11a) and b) address two different subjects, with Question 11b) being in fact more closely connected with Question 12. For this reason, the responses to Question 11b) and the comments thereon are dealt with under Question 12.

Responses to Question 11a)

In answer to Question 11a), the *Belgian* response suggested that more public funding be provided for conservation research and support of *ex situ* collections (including microbial culture collections), whereas a key contribution to the second part would be to improve public knowledge and acceptance of intellectual property rights and biotechnology itself. *Australian* respondents considered that all parties should assist in the implementation of the Biodiversity Convention, particularly as regards *in situ* and *ex situ* measures, the ecological sustainability of genetic resource development, and more effective management and knowledge of resources through inventories and taxonomic work. The Japanese response emphasized the importance of continued support to promote R&D co-operation and various other programmes with developing countries for the conservation and sustainable use of genetic resources.

The contribution of one agency to the *United States'* response agreed that ratification of the Biodiversity Convention would be a significant contribution. Source countries should comply with the objectives of collection and use, but should be assisted in dealing with multinational corporations. Source countries should be value-adders rather than mere access-providers and should be assisted in matters of technical and business training with these ends in view. The industrial component of the US response stressed that there must be a clear and tangible incentive to conserve genetic resources. If an economic value is assigned to such resources, for example, by recognising their potential for the generation of intellec-

tual property, there should be disincentives to their destruction by deforestation and in other ways.

The *Canadian* response called for the expansion of gene banks and the creation of international databases. The response noted that the developing countries are the major source of genetic resources and that incentives for conservation are necessary against competing domestic uses for land. The development of markets for innovation based on genetic resources, and assisted by intellectual property, would encourage conservation. The *Korean* response shared the view that developed countries should contribute assistance towards realisation of these goals.

These positive measures for encouraging conservation were noted in the response from *Spain* and also that from *France*, which proposed the creation of laboratories in developing countries which would collaborate with industry. The response from *Germany* followed similar lines and added the suggestion for grants to developing countries (a "biological diversity tax") for these purposes.

The views expressed above were echoed in the responses from other countries and supplemented by certain distinctive observations. The *Netherlands'* response added a view from industry to the effect that the problem lies mainly in the identification and selection of those resources that are of value for conservation. The response from *Switzerland* added an industrial view of the necessity to involve local indigenous communities in all such measures, to improve their education and socio-economic conditions, and reduce population pressures. One Swiss public sector agency supported the development of legislation appropriate to the needs of developing countries, in particular, the concept of "farmers' rights". However, the *Japanese* response could not support the concept of "farmers' rights" in terms of intellectual property rights. By nature, farmers' rights cannot be clearly defined, and therefore, cannot be enforced in practice. Also, the European Union and its member States have expressed the view that "farmers' rights" are a socio-economic concept which requires a precise legal and technical definition. The *Belgian* response referred to the issue of "farmers' rights" as an unusual form of "collective" right and noted the considerable practical problems involved in assessing a "fair" return and organising its appropriate distribution to indigenous communities.

One *Australian* public sector respondent remarked that policies to implement the provisions of the Biodiversity Convention should not unduly restrict access to genetic resources. For example high up-front payments for access would not assist either the utilisation or conservation of these resources. Granting exclusive bio-prospecting rights might bring short-term gains but could reduce competition and stifle innovation.

The *United Kingdom* response reported that a major company recommended the establishment of an international fund for the conservation of genetic resources and quoted a university view that biodiversity will be best promoted if it has

economic value from which there is a flow-back of revenue to the resource owner. Other parts of this response are addressed mainly to the need for international consensus, at least among the most industrially developed countries, on the patentability of materials of plant or animal origin.

Question 12. *What are the most important challenges facing the legal system for protection of biotechnology:*

- a) *in the near term*
- b) *in the medium term*

In many responses this question was seen as closely connected with Question 11b). Where appropriate therefore the relevant observations are merged in the following summary.

Responses to Question 11b) and Question 12

As in most responses, the summary of respondents from *Australia* called for an effective harmonized patent system covering both procurement and enforcement. Whilst being positive as to this, however, the response identified the need to resolve problems over the scope of biotechnology patents (the “unduly broad claims” issue). One public sector contributor saw conflict of interest problems as between large corporations and developed nations on the one hand, and the third-world reservoirs of genetic resources on the other. The summary of Australian respondents noted the lack of international consistency in the legal relationship between plant breeders’ rights and patents. This is the one response in which public-sector contributors call for a legal system for the protection of animal varieties comparable with plant breeders’ rights. An industrial contribution to this response called for more general recognition of the principle that intellectual property resides with those who develop inventions from genetic materials rather than those who supply the source material.

In the *United States’* response the industrial contribution summarised the problem, in both the short and long term, as one of eliminating restrictions on the availability of patent protection for biotechnology products. The public-sector contributors also called for co-ordinated systems for plant variety protection, and expressed views very similar to those of *Australian* respondents as regards patent protection. The burdensome cost of obtaining and enforcing intellectual property rights world-wide was noted, especially in the light of the many over-lapping patent claims. Adaptation to the TRIPS Agreement (see Chapter 1) was also called for.

The *Belgian* response called for improved public knowledge on intellectual property and biotechnology in all countries and the development of legal systems adapted to the needs of developing countries. Global harmonization of law was

desirable, starting at the European level, extending to all OECD Member countries, the newly industrialising countries, and finally to the remaining countries. A specific separate law for the protection of biotechnological inventions was not to be recommended. Ethical questions should be directed to the exploitation rather than to the protection of inventions. The *Belgian* response also considered that the situation would be helped by the training of experts in developing countries towards a realisation of the role of intellectual property rights as aids to development. The *Canadian* response emphasized the same points but noted that a decision on whether to grant patents on higher life forms was still awaited in Canada. The *Italian* response referred to ongoing European attempts to harmonize patent law in this field.

The response from *France* identified four themes relevant to this question in the short term. One is the recurring idea of legislation specific for biotechnology, which has its supporters and its opponents. The need for world-wide extension of systems for plant variety protection is another consistent theme. Third is the fear of appropriation of genetic resources. Finally, attention is drawn to the difficulty of apportioning value to the respective contributions made toward the exploitation of genetic resources. In the longer term the abolition of the distinction between patents and plant variety rights could be contemplated. The fear that excessive financial demands of source countries may stifle research into the development of genetic resources is seen as a significant factor for the smaller biotechnology companies. The *German* response notes the major problems of harmonization and public acceptance of patenting, and the adaptation to TRIPS and the Biodiversity Convention. Reconciling the need to encourage the private sector and ensure third world access to techniques and products is seen as a major challenge.

The *Netherlands'* response also supports the development and harmonization of patent law on the basis of the traditional established criteria of novelty, inventive step and industrial applicability (utility). Unclear and unfounded restrictions on patentability should be removed, and greater clarity is necessary on patent scope and exhaustion of rights in relation to living material. Ethical considerations and the concerns of special interest groups should be dealt with outside patent legislation.

The *Norwegian* response was somewhat indefinite as to its own national position on this question but noted the standpoint of developing countries which have traditionally been against strong legal protection systems.

The *Swiss* response called for the wider acceptance of biotechnology and a more harmonized and positive acceptance of the need for equal treatment of this technology under intellectual property law. On some points the response from Switzerland showed an element of polarisation between one part of the public sector and industry. The patentability of plants is one area of such disagreement. For example, for industry, patents for plants and animals are indispensable. The

industry view is that efforts to promote public understanding and acceptance of the legitimate use of these legal instruments is also necessary at the political level.

The *United Kingdom* response to this question listed a range of views from various contributors which cannot conveniently be synthesised into a single theme: the gene patenting issue; harmony on patentability and scope; and the activities of anti-biotechnology patent lobbies.

A warning note concerning intellectual property law is sounded in the response from *Korea*. Innovation in biotechnology is seen as a most important potential contribution to the improvement of human life in the next century. To achieve this, technology transfer has to spread to all countries without excessively high cost. The strengthening of intellectual property law should not erect barriers between developed and developing countries but should be more flexible and morally orientated if it is to achieve these objectives.

Comments

The wide-ranging responses to this question, although given in the specific context of the questionnaire, extended to many fundamental issues of general concern to intellectual property affecting biotechnology as a whole. These pertain to the problems of international harmonization, restrictions on patent protection for certain types of product, the paradoxical issue of unduly broad patents in some jurisdictions, and the interface between patents and plant variety rights, which is still confused in some countries. Perhaps there is also a need to counter the effects of the anti-biotechnology lobbies on public opinion and to promote greater understanding of biotechnology and the role of legal protection in bringing its benefits to society.

CONCLUSIONS

At this early stage in the international discussion of these issues, the demanding nature of this investigation helps to explain the incompleteness of the response from many OECD Member countries. It appears that more investigation would be necessary to do justice to the standpoints of all the key potential contributors to this debate, especially from the industrial sector. There may be divergence of opinion and attitude within both the public as well as the private sectors which remain to be resolved in many countries. The conclusions which can be drawn at this stage, therefore, while firm and clear, could well be modified in the light of further information.

Whether or not linkages can be made between access to genetic resources, technology transfer and intellectual property has been a topic of keen debate for some years now, but has been brought into more definite focus by the Convention on Biological Diversity and its implementation. In requesting information from OECD Member countries, the questionnaire was aimed at determining whether any models had been developed by or in Member countries which relate conditions of access to genetic resources to a commitment to return to the source country a share in the benefit gained by the recipient as a result of the development of these resources. The main type of benefit addressed in the questionnaire was that resulting from improved industrial or agricultural technology.

The responses almost invariably state that all the factors listed in the questionnaire have been addressed by governments and by public- and private-sector organisations within their countries. However, in view of the relatively short time since the Biodiversity Convention was adopted, it is not surprising that few instances, if any, have been described demonstrating concrete results from the development of genetic resources which have already enabled donor countries to be "compensated" in a formalized manner, either by monetary payments or by enrichment of their own national technology through technology transfer. The great achievements of the past through plant breeding to make improved cultivars available to developed and developing countries have not required formalized procedures. The public-sector effort in this direction has made these improvements freely

available to agricultural communities (the “Green Revolution”) and the commercial breeders have marketed the proprietary products they have themselves developed.

There is no indication in the responses that any OECD Member country is at present developing access legislation which could form a model for implementing the Biodiversity Convention on these issues. If developing countries decide to introduce access legislation, considerable expertise will be necessary to address constructively the interests of all parties involved, including indigenous communities. Measures which involve high transaction costs would almost certainly be counterproductive, not only to the interests of the parties but also to the conservation of genetic resources. Voluntary agreements and the establishment of codes of practice which commend themselves to prospectors seem to be the best way forward for the present. Such voluntary agreements and the establishment of codes of practices would also be not detrimental to the adequate and effective implementation of intellectual property law by the relevant administrative bodies.

In the area of crop improvement, there is already an abundance of germplasm for plant breeders to exploit, either in the public collections or in commercially available breeders’ lines from which desirable traits can be transferred. It is only through realistic estimates of the demand for genetic resources, further characterisation of stored germplasm, and correspondingly realistic conditions of access, that the objectives of the Convention will be achieved.

Most respondents found Part 1 of the Questionnaire the most searching and the most difficult to handle in a general way. No paradigm appears yet to exist for the coupling together in a legal framework of access to genetic resources and technology transfer. In spite of this, there is a wide underlying degree of consensus as to the importance of intellectual property to its possessor as well as for its role in bringing about the desired ends (of technology transfer, sustainable exploitation of genetic resources, etc.). It is assumed that intellectual property rights can fulfil these diverse roles even though the necessary mechanisms remain to be worked out.

Technology transfer, in the most meaningful sense, is much more than the assignment or licensing of intellectual property rights. The transfer of legal rights avails little unless the recipient has the technological capacity to put industrial processes into operation. International conventions are made between governments, but governments alone do not create technology (although the purchase of rights by developed countries and their transfer to developing countries may be a useful element of development co-operation policies). Devising measures to induce private-sector owners of technology to transfer this technology to foreign organisations to the extent envisaged in Article 16 of the Biodiversity Convention will require considerable co-operation among all parties concerned. This is unlikely to be achieved unless all the parties see that real and substantial benefits are to be gained.

The exploitation of genetic resources is an undertaking which, as in all areas of the life sciences, will have its share of failures at the research, development or commercialisation stage. For this reason it is recognised as doubtful that the demands for benefit sharing and technology transfer will alone generate the level of international funding necessary to achieve the primary objective of the Biodiversity Convention. The Global Environment Facility is clearly of central importance in this context.

This report takes a step towards a better understanding of the issues involved and of the positive role of intellectual property rights in the establishment of workable solutions. To make further progress, improved co-ordination among OECD Member countries would be desirable. Such co-ordination was stated at the beginning of the questionnaire as the objective of this OECD activity.

Annex I

**STUDY OF INTELLECTUAL PROPERTY POLICY
IN THE FIELD OF BIOTECHNOLOGY
WITH REGARD TO TECHNOLOGY TRANSFER**

QUESTIONNAIRE

Background

Objective of the activity

Inform and co-ordinate the views of OECD Member countries with regard to intellectual property in relation to technology transfer

by conducting a survey of current practices, experiences and expectations related to technology transfer in biotechnology,

which will analyse, from a policy and economic perspective, issues of technology transfer incident to access to genetic resources.

Scope of the activity

The questionnaire relates to laws, agreements, contracts and practices, including those in and between OECD Member countries as well as with other countries, that involve either or both:

- the transfer between countries of technology in the field of biotechnology related to the development of genetic resources;
- access to the genetic resources of one country by persons or organisations based in another country.

Use of terms

For the purposes of this questionnaire, the following terms shall have the following meanings:

“Biotechnology” is the application of scientific and engineering principles to the processing of materials by biological agents to provide goods and services.*

“Genetic material” is any material of plant, animal, microbial or other origin containing functional units of heredity.**

“Genetic resources” is genetic material of actual or potential value.***

“Transfer of technology” includes, but is not limited to, the disclosure of results from research and development, the licensing or assignment of intellectual property rights related to such results, exchange of information, education and training, and joint ventures.

Questions

I. Existing Projects

Please describe the types of projects that you have sponsored, or participated in, related to the discovery or development of genetic resources:

1. Describe the **participants and their roles** (examples of categories of arrangements):

- a) company/company arrangements
- b) university/company arrangements
- c) non-profit organisation/company arrangements
- d) government/company arrangements
- e) government/government arrangements
- f) other -----

2. Describe in general terms the arrangements that you have made with regard to **types of technology transfer**:

- a) disclosure of results from research and development
- b) licensing or assignment of intellectual property rights related to such results
- c) exchange of information
- d) education and training
- e) joint ventures

* *Biotechnology – International Trends and Perspectives*, OECD, 1982.

** Convention on Biological Diversity.

*** Convention on Biological Diversity.

- f) acquisition of one entity by another
- g) financial and other support of research activities
- h) other -----

3. Describe in general terms the arrangements that you have made with regard to **access to and use of genetic resources:**

- a) consent
- b) compensation and other benefits
- c) ownership and control of genetic material

4. Describe the arrangements that you have made with regard to **ownership, control and protection of intellectual property rights** in agreements relating to access to and use of genetic resources:

- a) patents
- b) protection of undisclosed information
- c) copyright
- d) trade marks or service marks
- e) plant variety protection
- f) other -----

II. Evaluation of Government Policies

Please rate the significance of each of the following factors with respect to developing agreements on research or development related to genetic resources.

(A: essential B: major importance C: minor importance D: no importance)

5. Availability of intellectual property protection in the country to which technology is transferred, in the form of:

- A B C D (a) patents
- A B C D (b) protection of undisclosed information
- A B C D (c) copyright
- A B C D (d) trade marks or service marks
- A B C D (e) plant variety protection
- A B C D (f) other -----

6. Availability of intellectual property protection in your country, in the form of:

- A B C D (a) patents
- A B C D (b) protection of undisclosed information
- A B C D (c) copyright
- A B C D (d) trade marks or service marks
- A B C D (e) plant variety protection
- A B C D (f) other -----

7. Your ability to enforce intellectual property rights effectively:
- A B C D (a) in the country to which technology is transferred
 - A B C D (b) in your country
 - A B C D (c) in other countries
8. Restrictions placed on marketing products that result from development of genetic resources:
- A B C D (a) in the country to which technology is transferred
 - A B C D (b) in your country
 - A B C D (c) in other countries
9. Financial and investment conditions, particularly:
- A B C D (a) availability of grants or subsidies for conducting research or development of genetic resources
 - A B C D (b) tax incentives regarding research or development of genetic resources
 - A B C D (c) other -----
10. Conditions placed on parties prior to gaining access to genetic* resources:
- A B C D (a) requirement of "informed consent" as to possible future use of genetic resources
 - A B C D (b) requirement for disclosure of research results
 - A B C D (c) sharing, either through licenses or partial ownership interest, intellectual property rights to technology developed during the project
 - A B C D (d) other restrictions on the licensing of intellectual property rights
 - A B C D (e) profit-sharing or royalty requirements
 - A B C D (f) up-front or fixed-fee obligations as a condition of access to use of genetic resources
 - A B C D (g) other -----

III. Considerations for Future Policies

11. Please describe briefly measures that might be taken:
- a) to assist parties concerned with the conservation of genetic resources;
 - b) to improve the protection of biotechnology world-wide.

12. What are the most important challenges facing the legal system for protection of biotechnology:
- a) in the near term?
 - b) in the medium term?

Annex II

**ARTICLES 15, 16 AND 17 OF THE CONVENTION
ON BIOLOGICAL DIVERSITY**

The following articles are of relevance to this report.

Article 15: Access to genetic resources

1. 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.
2. Each Contracting Party shall endeavour 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.
3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.
4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.
5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.
6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.
7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 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 utiliza-

tion of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

Article 16: Access to and transfer of technology

1. Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.

2. Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. The application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below.

3. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.

4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above.

5. The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

Article 17: Exchange of information

1. The Contracting Parties shall facilitate the exchange of information, from all publicly available sources, relevant to the conservation and sustainable use of biological diversity, taking into account the special needs of developing countries.
2. Such exchange of information shall include exchange of results of technical, scientific and socio-economic research, as well as information on training and surveying programmes, specialized knowledge, indigenous and traditional knowledge as such and in combination with the technologies referred to in Article 16, paragraph 1. It shall also, where feasible, include repatriation of information.

*Annex III***AGREEMENT ON TRADE-RELATED ASPECTS
OF INTELLECTUAL PROPERTY RIGHTS
(TRIPS AGREEMENT)**

The following articles contained in the TRIPS Agreement are among those which are particularly relevant to this report:

Section 5: Patents*Article 27: Patentable subject matter*

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.* Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
3. Members may also exclude from patentability:
 - a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
 - b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-

* For the purposes of this Article, the terms “inventive step” and “capable of industrial application” may be deemed by a Member to be synonymous with the terms “non-obvious” and “useful” respectively.

biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 33: Term of protection

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.*

Article 34: Process patents: burden of proof

1. For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

- a) if the product obtained by the patented process is new;
- b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.

2. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.

3. In the adduction of proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account.

* It is understood that those Members which do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant.

Section 7: Protection of undisclosed information*Article 39*

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

Part VI: Transitional arrangements*Article 65: Transitional arrangements*

1. Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.

2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.

3. Any other Member which is in the process of transformation from a centrally-planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws and regulations, may also benefit from a period of delay as foreseen in paragraph 2.

4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.

5. A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

Article 66: Least-developed country members

1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their

need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

Article 67: Technical cooperation

In order to facilitate the implementation of this Agreement, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members. Such cooperation shall include assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel.

Part VII: Institutional arrangements; final provisions

Article 70: Protection of existing subject matter

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

- a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;
- b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and
- c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this

Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

9. Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.

*Annex IV***MATERIAL TRANSFER AGREEMENTS**

A type of Material Transfer Agreement and a Standard Order Form under consideration by an International Agricultural Research Centre (referred to below as “the Centre”) are given below:

MATERIAL TRANSFER AGREEMENT

The material contained herein is being furnished by (the Centre) under the following conditions:

1. (The Centre) is making the material described in the attached list available as part of its policy of maximising the utilisation of genetic material for research. The material was either developed by (the Centre); or it was acquired prior to the entry into force of the United Nations Convention on Biological Diversity; or if it was acquired after the entering into force of the Biodiversity Convention, it was obtained with the understanding that it could be made freely available for any agricultural research or breeding purposes.
2. The recipient may reproduce the seed and use the material for agricultural research and breeding purposes and may distribute it to other parties provided that any recipient is willing to accept the conditions of this agreement.
3. If the seed packet is labelled “FAO Designated Germplasm” the material is held in trust under the terms of an agreement between (the Centre) and FAO, and the recipient has no rights to obtain intellectual property rights.
4. Recipients are free to release for commercialisation (the Centre) research products in the form they are provided. If released without obtaining Intellectual property rights, (the Centre) requests notification and acknowledgement. Recipients are not to apply for any form of Intellectual property rights of (the Centre) research products without the written permission of (the Centre). Moreover, while (the Centre) recognises the validity of Intellectual property rights, it reserves the right to distribute all material in accordance with paragraph 1 above.

5. (The Centre) makes no warranties as to the safety or title of the material, nor as to the accuracy or correctness of any passport or other data provided with the material. Neither does it make any warranties as to the quality, viability, or purity (genetic or mechanical) of the material being furnished. The phytosanitary condition of the material is warranted only as described in the attached phytosanitary certificate. The recipient assumes full responsibility for complying with the recipient nation's biosafety regulations and rules as to import or release of genetic material.

6. Upon request (the Centre) will furnish information that may be available in addition to whatever is furnished with the seed. Recipients are requested to furnish (the Centre) performance data collected during evaluation.

7. The material is supplied expressly conditional on acceptance of the term of this agreement. The recipient's retention of the material constitutes such acceptance.

Standard Order Form

I/We order the following material:

see attached list

Insofar as this material is "FAO Designated Germplasm" under the Agreement between (the Centre) and the Food and Agriculture Organization of the United Nations (FAO) Placing Collections of Plant Germplasm under the Auspices of FAO dated 26 October 1994, I/We agree

- a) not to claim ownership over the material received, nor to seek intellectual property rights over the germplasm or related information,
- b) to ensure that any subsequent person or institution to whom I/We make samples of the germplasm available, is bound by the same provision.

Name of person or institution
requesting the germplasm: _____

Address: _____

Shipping address: _____

Authorised signature: _____

Date: _____

Annex V

LETTER OF COLLECTION

**AGREEMENT BETWEEN SOURCE COUNTRY
AND DEVELOPMENTAL THERAPEUTICS PROGRAM
DIVISION OF CANCER TREATMENT
NATIONAL CANCER INSTITUTE, UNITED STATES**

1. The Developmental Therapeutics Program (DTP), Division of Cancer Treatment (DCT), National Cancer Institute (NCI) is currently investigating plants, marine macro-organisms and microbes as potential sources of novel anticancer and AIDS-antiviral drugs. The DTP is the drug discovery program of the NCI which is an Institute of the National Institutes of Health (NIH), and arm of the Department of Health and Human Services of the United States Government. While investigating the potential of natural products in drug discovery and development, NCI wishes to promote the conservation of biological diversity, and recognizes the need to compensate source country organizations and peoples in the event of commercialization of a drug developed from an organism collected within their borders.

2. As part of the drug discovery program, DTP has contracts with various organizations for the collection of plants and marine macro-organisms worldwide. DTP has an interest in investigating plants from Source Country, and wishes to collaborate with the Source Country Government ("SCG") or Source Country Organization(s) ("SGO") as appropriate in this investigation. The collection of plants will be within the framework of the collection contract between the NCI and the NCI Contractor (Contractor) which will collaborate with the appropriate agency in the Source Country Government ("SCG") or the Source Country Organization(s) ("SCO"). The NCI will make sincere efforts to transfer knowledge, expertise, and technology related to drug discovery and development to the appropriate Source Country Institution ("SCI") in Source Country as the agent appointed by the Source Country Government ("SCG") or Source Country Organization(s) ("SCO"), subject to the provision of mutually acceptable guarantees for the protection of intellectual property associated with any patented technology. The Source Country Government ("SCG") or Source Country Organization(s) ("SCO"), in turn, desires to collaborate closely with

the DTP/NCI in pursuit of the investigation of its plants, subject to the conditions and stipulations of this agreement.

3. The role of DTP, DCT, NCI in the collaboration will include the following:
 1. DTP/NCI will screen the extracts of all plants provided from Source Country for anticancer and AIDS-antiviral activity, and will provide the test results to SCI on a quarterly basis. Such results will be channelled via Contractor.
 2. The test results will be kept confidential by all parties, with any publication delayed until DTP/NCI has an opportunity to file a patent application in the United States of America on any active agents isolated. Such application will be made according to the terms stated in clause 6.
 3. Any extracts exhibiting significant activity will be further studied by bioassay-guided fractionation in order to isolate the pure compound(s) responsible for the observed activity. Since the relevant bioassays are only available at DTP/NCI, such fractionation will be carried out in DTP/NCI laboratories. A suitably qualified scientist designated by SCI may participate in this process subject to the terms stated in clause 4. In addition, in the course of the contract period, DTP/NCI will assist the Source Country Government ("SCG") or Source Country Organization(s) ("SCO"), in conjunction with SCI, to develop the capacity to undertake drug discovery and development, including capabilities for the screening and isolation of active compounds from plants and marine organisms.
 4. Subject to the provision that suitable laboratory space and other necessary resources are available, DTP/NCI agrees to invite a senior technician or scientist designated by SCI to work in the laboratories of DTP/NCI or, if the parties agree, in laboratories using technology which would be useful in furthering work under this agreement. The duration of such a visit would not exceed one year except by prior agreement between SCI and DTP/NCI. The designated Guest Researcher will be subject to provisions usually governing Guest Researchers at NIH, except when carrying out research on materials provided through collections in Source Country. Salary and other conditions of exchange will be negotiated in good faith.
 5. In the event of the isolation of a promising agent from a plant collected in Source Country, further development of the agent will be undertaken by DTP/NCI in collaboration with SCI. Once an active agent is approved by the DTP/NCI for preclinical development, SCI and the DTP/NCI will discuss participation by SCI scientists in the development of the specific agent. The DTP/NCI will make a sincere effort to transfer any knowledge, expertise, and technology developed during such collaboration in the discovery and development process to SCI, subject to the provision of mutually acceptable guarantees for the protection of intellectual property associated with any patented technology.

6. DTP/NCI will, as appropriate, seek patent protection on all inventions developed under this agreement by DTP/NCI employees alone or by DTP/NCI and Source Country Government ("SCG") or Source Country Organization(s) ("SCO") employees jointly, and will seek appropriate protection abroad, including in Source Country, if appropriate.
7. All licenses granted on any patents arising from this collaboration shall contain a clause referring to this agreement and shall indicate that the licensee has been apprised of this agreement.
8. Should the agent eventually be licensed to a pharmaceutical company for production and marketing, DTP/NCI will require the successful licensee to negotiate and enter into agreement(s) with the Source Country Government ("SCG") agency(ies) or Source Country Organization(s) ("SCO") as appropriate. This agreement(s) will address the concern on the part of the Source Country Government ("SCG") or Source Country Organization(s) ("SCO"), that pertinent agencies, institutions and/or persons receive royalties and other forms of compensation, as appropriate.
9. Such terms shall apply equally to instances where the invention is the actual isolated natural product, or, where the invention is a product structurally based on the isolated natural product (*i.e.* where the natural product provides the lead for the development of invention), though the percentage of royalties negotiated as payment might vary depending upon the relationship of the marketed drug to the originally isolated product. It is understood that the eventual development of a drug to the stage of marketing is a long-term process which may require 10-15 years.
10. In obtaining licensees, the DTP/NCI will require the applicant for license to seek as its first source of supply the natural products from Source Country. If no appropriate licensee is found who will use natural products available from Source Country, or if the Source Country Government ("SCG") or Source Country Organization(s) ("SCO") as appropriate, or its suppliers cannot provide adequate amounts of raw materials at a mutually agreeable fair price, the licensee will be required to pay to Source Country Government ("SCG") or Source Country Organization(s) ("SCO") as appropriate, an amount of money (to be negotiated) to be used for expenses associated with cultivation of medicinal plant species that are endangered by deforestation, or for other appropriate conservation measures. Such terms will also apply to instances where the active agent is prepared by total synthesis.
11. Section 10 shall not apply to organisms which are freely available from different countries (*i.e.* common weeds, agricultural crops, ornamental plants, fouling organisms) unless information indicating a particular use of the organism (*e.g.* medicinal, pesticidal) was provided by local residents to guide the collection of such an organism from Source Country, or unless

other justification acceptable to both the Source Country Government (“SCG”) or Source Country Organization(s) (“SCO”) and the DTP/NCI is provided. In the case where an organism is freely available from different countries, but a genotype producing an active agent is found only in the Source Country, Section 10 shall apply.

12. DTP/NCI will test any pure compounds submitted by the Source Country Government (“SCG”) or Source Country Organization(s) (“SCO”) as appropriate and SCI scientists for antitumor and AIDS-antiviral activity, provided such compounds have not been tested previously in the DTP/NCI screens. If significant antitumor or AIDS-antiviral activity is detected, further development of the compound and investigation of patent rights will, as appropriate, be undertaken by DTP/NCI in consultation with SCI and the Source Country Government (“SCG”) or Source Country Organization(s) (“SCO”).
13. Should the agent eventually be licensed to a pharmaceutical company for production and marketing, DTP/NCI will require the successful licensee to negotiate and enter into agreement(s) with the appropriate Source Country Government (“SCG”) agency(ies) or Source Country Organization(s) (“SCO”). This agreement will address the concern on the part of the Source Country Government (“SCG”) or Source Country Organization(s) (“SCO”) that pertinent agencies, institutions and/or persons receive royalties and other forms of compensation, as appropriate.
14. DTP/NCI may send selected samples to other organizations for investigation of their anticancer, anti-HIV or other therapeutic potential. Such samples will be restricted to those collected by NCI contractors unless specifically authorized by the Source Country Government (“SGO”) or Source Country Organization(s) (“SCO”). Any organization receiving samples must agree to compensate the Source Country Government (“SCG”) or Source Country Organization(s) (“SCO”) and individuals, as appropriate, in the same fashion as described in Sections 8-10 above, notwithstanding anything to the contrary in Section 11.

The role of the Source Country Government (“SCG”) or Source Country Organization(s) (“SCO”) in the collaboration will include the following:

1. The appropriate agency in Source Country Government (“SCG”) or the Source Country Organization(s) (“SCO”) will collaborate with Contractor in the collection of plants, and will work with Contractor to arrange the necessary permits to ensure the timely collection and export of materials to DTP/NCI.
2. Should the appropriate agency in Source Country Government (“SCG”) or the Source Country Organization(s) (“SCO”) have any knowledge of the medicinal use of any plants by the local population or traditional healers, this information will be used to guide the collection of plants on a priority basis where possible. Details of the methods of adminis-

tration (e.g. hot fusion, etc.) used by the traditional healers will be provided where applicable to enable suitable extracts to be made. All such information will be kept confidential by DTP/NCI until both parties agree to publication.

The permission of the traditional healer or community will be sought before publication of their information, and proper acknowledgement will be made of their contribution.

3. The appropriate agency in Source Country Government ("SCG") or Source Country Organization(s) ("SCO") and Contractor will collaborate in the provision of further quantities of active raw material if required for development studies.
4. In the event of large amounts of raw material being required for production, the appropriate agency in Source Country Government ("SCG") or Source Country Organization(s) ("SCO") and Contractor will investigate the mass propagation of the material in Source Country. Consideration should also be given to sustainable harvest of the material while conserving the biological diversity of the region, and involvement of the local population in the planning and implementation stages.
5. Source Country Government ("SCG") or Source Country Organization(s) ("SCO") and SCI scientists and their collaborators may screen additional samples of the same raw materials for other biological activities and develop them for such purposes independently of this agreement.

This agreement may be amended at any time subject to the written agreement of both parties.

Name (Signature)

Name (Print or type)

Institution or Agency

Institution or Agency

Director,
National Cancer Institute

Address

Date

Date

Annex VI

**INTERNATIONAL UNION FOR THE PROTECTION OF
NEW VARIETIES OF PLANT (UPOV), 1991
THE RIGHTS OF THE BREEDER**

The following articles contained in the 1991 Revision of the UPOV International Convention are among those which are particularly relevant to this report. This revision requires ratification by UPOV Member States.

Article 14: Scope of the breeder's right

1. [Acts in respect of the propagating material]
 - a) Subject to Articles 15 and 16, the following acts in respect of the propagating material of the protected variety shall require the authorization of the breeder:
 - i) production or reproduction (multiplication),
 - ii) conditioning for the purpose of propagation,
 - iii) offering for sale,
 - iv) selling or other marketing,
 - v) exporting,
 - vi) importing,
 - vii) stocking for any of the purposes mentioned in (i) to (vi) above.
 - b) The breeder may make his authorization subject to conditions and limitations.
2. [Acts in respect of the harvested material] Subject to Articles 15 and 16, the acts referred to in items (i) to (vii) of paragraph (1)(a) in respect of harvested material, including entire plants and parts of plants, obtained through the unauthorized use of propagating material of the protected variety shall require the authorization of the breeder, unless the breeder has had reasonable opportunity to exercise his right in relation to the said propagating material.
3. [Acts in respect of certain products] Each Contracting Party may provide that, subject to Articles 15 and 16, the acts referred to in items (i) to (vii) of paragraph (1)(a) in respect of products made directly from harvested material

of the protected variety falling within the provisions of paragraph (2) through the unauthorized use of the said harvested material shall require the authorization of the breeder unless the breeder has had reasonable opportunity to exercise his right in relation to the said harvested material.

4. [Possible additional acts] Each Contracting Party may provide that, subject to Articles 15 and 16, acts other than those referred to in items (i) to (vii) of paragraph (1)(a) shall also require the authorization of the breeder.

5. [Essentially derived and certain other varieties]

- a) The provisions of paragraphs (1) to (4) shall also apply in relation to:
 - i) varieties which are essentially derived from the protected variety, where the protected variety is not itself an essentially derived variety,
 - ii) varieties which are not clearly distinguishable in accordance with Article 7 from the protected variety and
 - iii) varieties whose production requires the repeated use of the protected variety.
- b) For the purposes of sub-paragraph (a)(i), a variety shall be deemed to be essentially derived from another variety (“the initial variety”) when
 - i) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety,
 - ii) it is clearly distinguishable from the initial variety and
 - iii) except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.
- c) Essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, back-crossing, or transformation by genetic engineering.

Article 15: Exceptions to the breeder’s right

1. [Compulsory exceptions] The breeder’s right shall not extend to
 - i) acts done privately and for non-commercial purposes,
 - ii) acts done for experimental purposes and

iii) acts done for the purpose of breeding other varieties, and, except where the provisions of Article 14(5) apply, acts referred to in Article 14(1) to (4) in respect of such other varieties.

2. [Optional exception] Notwithstanding Article 14, each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or a variety covered by Article 14(5)(a)(i) or (ii).

Article 16: Exhaustion of the breeder's right

1. [Exhaustion of right] The breeder's right shall not extend to acts concerning any material of the protected variety, or of a variety covered by the provisions of Article 14(5), which has been sold or otherwise marketed by the breeder or with his consent in the territory of the Contracting Party concerned, or any material derived from the said material, unless such acts

- i*) involve further propagation of the variety in question or
- ii*) involve an export of material of the variety, which enables the propagation of the variety, into a country which does not protect varieties of the plant genus or species to which the variety belongs, except where the exported material is for final consumption purposes.

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