Intermediary Biotechnology Service

A Biotechnology Research Management Study

Jeroen van Wijk
Joel I. Cohen
John Komen

Intellectual Property Rights for Agricultural Biotechnology

Options and Implications for Developing Countries

Research Report NUMBER 3

The mandate of the International Service for National Agricultural Research (ISNAR) is to assist developing countries in bringing about lasting improvements in the performance of their national agricultural research systems and organizations. It does this by promoting appropriate agricultural research policies, sustainable research institutions, and improved research management. ISNAR's services to national research are ultimately intended to benefit producers and consumers in developing countries and to safeguard the natural environment for future generations.

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Intermediary Biotechnology Service

This report is the second publication in a series of interrelated research-management reports from the Intermediary Biotechnology Service. A forthcoming report will provide a tool for the decision-making process involved in establishing national biotechnology programs, by analyzing this process at three levels: program scientists, sectoral leaders, and national policymakers. Another report will give a detailed overview of international initiatives that have as a common goal the application of biotechnology to tropical agriculture, and reviews the possibilities for national institutions in developing countries to collaborate on these activities.

The Intermediary Biotechnology Service

The Intermediary Biotechnology Service (IBS) was established by an international group of donor agencies to act as an independent advisor to national programs in developing countries on matters of biotechnology research management and policy. The IBS is headquartered at ISNAR, where it represents a continuation of activities begun in 1988 under a four-year program of ISNAR, the World Bank, and the Australian government, titled Agricultural Biotechnology: Opportunities for International Development.

The establishment of the IBS resulted from a recommendation from the Biotechnology Task Force (BIOTASK) of the Consultative Group on International Agricultural Research (CGIAR). BIOTASK conducted an extensive investigation into the problems and potential benefits of applying biotechnology to agricultural research in developing countries. It recommended that a demand-driven, problem-oriented advisory service be established to make available the expertise of advanced biotechnology institutes to the developing countries. The Government of the Netherlands provided funding to implement this recommendation in late 1992.

The IBS is guided by a Steering Committee composed of representatives from client countries, contributing donors, and the implementing agency, ISNAR.

Functions

The current program of the IBS has three main functions:

- **to assist national agricultural research systems in developing countries with biotechnology research program management and policy formulation;**
- **to carry out country studies to identify priority problems amenable to solution through biotechnology;**
- **to identify international biotechnology expertise and enhance its availability to national programs in developing countries.**

The IBS also advises bilateral and multilateral development agencies on biotechnology issues affecting developing countries.

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The origin of this report lies, to a large extent, in a study commissioned by the United Nations University Institute for New Technologies (UNU-INTECH), titled *Intellectual Property Protection of Advanced Technology*, by Jeroen van Wijk and Gerd Junne. The support from UNU-INTECH and its director, Professor Charles Cooper, is gratefully acknowledged. The report has since been expanded and updated. A number of specialists have contributed significantly to the new format and to the development of the options and implications for IPR which we present in this IBS publication. Their names are listed in Annex 3. In addition, the authors wish to thank Barry Nestel, Howard Elliott, and Cesar Falconi of ISNAR, and Hans Wessels of the Directorate General for International Cooperation of The Netherlands' Ministry of Foreign Affairs, for their valuable comments on the contents and style of the report. John Barton's assistance is appreciated for supplying the information contained in Annex 2. Special thanks to Isabelle Hand, Carmel van der Heijden, and Fionnuala Hawes for their professional secretarial, proof-reading, and type-setting support.

J.v.W, J.I.C, and J.K.
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ABSTRACT

Policymakers in developing countries responsible for national agricultural research are considering the implications of adopting intellectual property rights for biotechnology. The impetus for these deliberations comes from many factors, including the desire of developing countries to acquire and use new technologies in agricultural research, and the pressure exerted on developing countries in international negotiations to strengthen their intellectual property legislation. In this report, the introductory chapters summarize the increasing significance of intellectual property rights for agricultural biotechnology and current international trade- and development-related debates on IPR and developing-country responses to these issues. An analysis is then provided of the complexities, options and implications regarding intellectual property rights in relation to three national technology objectives: acquiring either public or proprietary biotechnologies, developing and protecting national innovations, and choices for technology transfer and licensing.

ARBEGE

Les responsables des systPmes nationaux de recherche agricole (SNRA) et les décideurs des pays en développement se doivent de réfléchir aux conséquences que peut avoir pour la biotechnologie agricole, l'adoption de droits de propriété intellectuelle (DPI). Un grand nombre de facteurs se combinent pour donner l'impulsion à ces délibérations. Citons, entre autres, le désir des pays en développement d'acqéurir et d'utiliser des technologies nouvelles relatives à la recherche agricole et la pression exercée sur ces pays dans le cadre de négociations internationales pour qu'ils renforcent leur législation en matière de propriété intellectuelle. Les chapitres qui introduisent le présent rapport font le point sur l'importance croissante des droits de propriété intellectuelle pour la recherche biotechnologique et résument les débats sur les DPI actuellement en cours dans les mondes du commerce et du développement internationaux. Cette introduction est suivie par une analyse des choix possibles et de leurs implications pour les SNRA et ce, par rapport à trois objectifs spécifiques : l'acquisition de biotechnologies soit publiques, soit breveétes, les motifs pour développer et protéger des innovations nationales, et les choix intervenant dans le transfert de technologies et les brevets à accorder.

RESUMEN

Los ejecutivos y formuladores de políticas de los Sistemas Nacionales de Investigación Agrícola (SNIAs) de países en desarrollo deben considerar las consecuencias de establecer derechos de propiedad intelectual (DPI) para la biotecnología agrícola. La motivacóin de estas deliberaciones proviene de varios factores como el deseo de los países en desarrollo de adquirir y usar nuevas tecnoloígas en la investigacóin agrícola y la presión sobre las países en desarrollo en las negociaciones internacionales para intensificar su legislación de propiedad intelectual. En este estudio, los capítulos introductorios resumen la creciente importancia de los derechos de propiedad intelectual para la biotecnología agrícola y los recientes debates del comercio y desarrollo internacional relacionados a los DPI. Luego se analiza los alternativas e implicaciones para los SNIAs con respecto a los derechos de propiedad intelectual en relación a tres objetivos: la adquisición de biotecnoloígas de dominio público o patentadas, consideraciones para desarrollar y proteger innovaciones nacionales, y opciones para la transferencia de tecnología y licencias.

ACRONYMS

AUTM	Association of University Technology Managers
CCPA	Court of Customs and Appeals (USA)
EC	European Community
EPC	European Patent Convention
EPO	European Patent Office
FAO	Food and Agricultural Organization (UN)
FDA	Food and Drug Administration (USA)
GATT	General Agreement on Tariffs and Trade
INPADOC	International Patent Documentation Centre
IPR	intellectual property rights
NAFTA	North American Free Trade Agreement
NARS	national agricultural research systems
NGO	non-governmental organization
NIC	newly industrializing country
OECD	Organization for Economic Co-operation and Development
OTA	Office of Technology Assessment (USA)
PBR	plant breeders' rights
PPA	Plant Patent Act (USA)
PVPA	Plant Variety Protection Act (USA)
R&D	research and development
TRIPs	Trade-Related Aspects of Intellectual Property Rights (GATT)
UN	United Nations
UNCED	United Nations Conference on Environment and Development
UNCTC	United Nations Centre for Transnational Corporations
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Program
UNEP	United Nations Environment Program
UNU-INTECH	United Nations University Institute for New Technology
UPOV	Union Internationale pour la Protection des Obtentions VJgJtales
USPTO	United States Patent and Trademark Office
USTR	United States Trade Representative
WIPO	World Intellectual Property Organization (UN)

EXECUTIVE SUMMARY

National decision makers and directors of national agricultural research systems (NARS) are presented with a number of options to help equalize opportunities between the industrialized and developing countries regarding biotechnology innovation in agricultural research. One of these options is the use of legislation to protect intellectual property rights (IPR) for products and processes of biotechnology. Choosing from among these options raises a number of issues which are currently the subject of widespread international debate. The issues include the types of protection available and their respective exemption clauses, the appropriateness of using IPR for living material, the attempts to harmonize international IPR regulations, and the relation of IPR to international trade and development.

This report covers these topics in reference to this growing debate, with special attention to the possible effects of IPR on national agricultural research systems in developing countries. Thus, the audience for this report includes decision makers and directors of research in various ministries, including Agriculture, Justice, Policy and Planning, and Science and Technology, as national policies on intellectual property rights are not formulated for the agricultural sector alone.

The subject is introduced by first describing the nature of intellectual property mechanisms applied to agriculture, followed by an analysis of the increasing significance of IPR, and their relation to the pressing economic, trade and technology realities emerging for the agricultural sector, particularly in developing countries. Decisions regarding patents and plant breeders' rights should be appropriate to specific national and institutional technology objectives. These policies and their implications are discussed in reference to three national technology objectives:

- acquiring and using new biotechnology innovations, from either public or proprietary domains;
- developing and protecting national biotechnology innovations;
- technology transfer mechanisms.

With regard to technology acquisition, several options are presented for obtaining and using public-domain technologies in agricultural research. The importance of these is often overlooked by national programs because of the focus on protected or proprietary technologies. The acquisition of protected technologies, which can be considered if public-domain technologies are not adequate, can present problems to developing-country NARS. However, there are several ways in which these may be overcome, depending on the nature of the protection involved and the intent of the property owner.

Developing and protecting biotechnology innovations is discussed from the perspective both of national systems lacking IPR policies and of those with some form of IPR. Options for protection are limited for systems without IPR, although options for the use of material transfer agreements and trade secrets are presented. However, lack of IPR presents less of a problem to NARS where innovation is considered to be a public good and not appropriate for any type of IPR protection.

Regardless of whether NARS use public- or proprietary-domain technologies, consideration must be given to how innovations in biotechnology are transferred to reach farmers, growers or consumers. In this context, licensing (non-exclusive or exclusive) is discussed. The potential role of an Office of Intellectual Property to provide NARS with guidance for making these decisions, for ensuring a consistent policy regarding the protection of innova-

tions generated by NARS and for collaborating with public and private sectors is also reviewed.

1. INTRODUCTION

The last decade has seen a significant increase in the importance of biotechnology as a component of the agricultural technology system in both developed and developing countries. This has raised a number of new and specific problems to be addressed by both national policymakers and managers of national agricultural research systems (NARS)[1] in developing countries. One of the important problem areas is intellectual property rights (IPR) protection. Developing countries are increasingly being confronted with the need to define policies for intellectual property rights as a result of: (1) changing objectives of national research programs, (2) international IPR and trade negotiations, and (3) the changing attitudes towards intellectual property protection of biotechnology. NARS managers are also faced with examining the impact of adopting some type of IPR, either as a result of activities at the level of their own institute or because of initiatives at the national level.

In most developing countries, policies for the application of IPR to products arising from biotechnology are still under formulation. The patentability of plants and animals is in dispute in major OECD countries, and the lack of an established practice in patenting living material contributes significantly to uncertainties related to IPR for biotechnology.

The situation regarding the adoption of IPR among developing countries differs widely. Some countries have never explicitly excluded living material from patent protection. Others have recently adopted IPR for biotechnology, or are discussing IPR legislation in which the explicit inclusion of living material is envisaged. Many more countries are likely to consider changes in their IPR legislation as regards biotechnology when the Uruguay Round of multilateral trade negotiations under the aegis of the General Agreement on Tariffs and Trade (GATT) is concluded. If the new GATT is concluded, it is expected to define some form of legal protection of microorganisms and plant varieties. This could have a significant impact on the way in which national IPR policies are defined.

Against this background, developing countries are faced with establishing intellectual property policies for agricultural research which will guide them between two extremes, one being the absence of sufficient legal protection and the other being the insistence on excessive protection of IPR (Cottier 1991).

This report is designed to assist national policymakers and directors of research in developing countries who must determine whether or not IPR protection should be strengthened for agricultural research. As such, the report focuses on options and implications for the agricultural research system in relation to national IPR policy decisions on biotechnology.

The *second* chapter outlines the main legal developments in IPR for biotechnology in the past decade. The chapter deals with the changes in the patent laws of the USA and European countries concerning living material, and further includes a description of the recent revision of the international convention on plant breeders' rights.

The *third* chapter focuses on the increasing importance of IPR in relation to the fundamental changes in the global technology system that are stimulating private companies, public institutes, and national authorities of industrialized and developing countries to reconsider IPR policies.

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1 A national agricultural research system is defined to be: all of a country's entities responsible for organizing, coordinating, or executing research that contributes to the development of its agriculture and the maintenance of its natural resource base. For the purpose of clarification, in this report this includes both public and private sector institutions and universities.

The *fourth* chapter looks at the complexities of national decisions regarding IPR and the relation of these decisions to the diverse needs, issues and responses which are likely to arise in developing countries.

In the *fifth* chapter, the international dimension of the legal protection of biotechnology is outlined. The various fora where international negotiations on IPR have taken place are discussed, and the main outcomes reviewed.

The *sixth* chapter comprises three parts, each discussing options for NARS regarding IPR. The first part deals with options for the acquisition and use of biotechnology from either the public or proprietary domains. The second part discusses the options available to a NARS for defining an IPR policy for the protection of its own biotechnology innovations. In the final part, the chapter reviews the alternatives available for transferring technology into production practices.

The *final* chapter synthesizes the conclusions presented in Chapter 6.

2. INTELLECTUAL PROPERTY PROTECTION OF BIOTECHNOLOGY

The legal protection of biotechnological innovations has now been under consideration for more than a decade. New bioprocesses and manufactured living organisms did not fit in existing systems for the protection of intellectual property rights and raised many questions with respect to their legal protection. Except for plant varieties, living material was generally not within the purview of any IPR system until the 1970s. In many industrialized countries this situation changed with the extension of patent coverage to microorganisms which, by the beginning of the 1980s, were major vehicles for pharmaceutical innovation. Patent protection of higher organisms, including plants, animals and human tissue and cell cultures followed.

With respect to agricultural biotechnology, two IPR mechanisms are relevant: patents and plant breeders' rights. A *patent* is a right granted by the government to inventors to exclude others from imitating, manufacturing, using or selling a specific invention for commercial use during a certain period. In industrialized countries this is usually 17-20 years. In order to be eligible for patent protection, the subject matter has to be:

- novel and inventive;
- not obvious to a person skilled in the art; and
- industrially applicable and useful.

Final receipt of a patent in turn requires that the inventor disclose his invention to the public. Once awarded, patents are *territorial*, which means that they can only be honored in countries where the patent is awarded. It is the patent claim itself that defines the actual scope of the patent.

Plant breeders' rights (PBR) are rights granted by the government to plant breeders to exclude others from producing or commercializing material of a specific plant variety for a period of, minimally, 15-20 years. In order to be eligible for PBR, the variety must be novel, distinct from existing varieties, and uniform and stable in its essential characteristics.

The legislation for both patent and PBR systems contains provisions for limited unauthorized use of the protected matter. Patent legislation includes a *research exemption* which allows others to study the protected subject matter without reproducing or multiplying it for commercial purposes. Under PBR law, the use of material of a protected variety for creating new varieties, and the commercial exploitation of these new varieties remains, to a certain extent, free. This so-called *breeders' exemption* is the core principle of the PBR system. Furthermore, under the PBR system, governmental authorities often leave farmers the freedom to use their own harvested material of protected varieties for the next production cycle on their farm. This privilege is referred to as the *farmers' privilege.*

International harmonization of patent laws has taken place in the *Paris Convention for the Protection of Industrial Property*. This Convention, first signed in 1883, established the right to equal protection of industrial property rights under the laws of member countries for both nationals and residents of its member countries. At present, over 100 countries are members of this Convention. International harmonization of PBR laws has taken place

Box 1. Presumed advantages of providing adequate protection of IPR

An OECD publication concluded that, "society derives satisfactory compensation for the rights it temporarily confers on certain individuals since this exclusivity generates benefits, especially in the long run, that adequately offset any economic disadvantages or risks which "exclusive rights" might possibly entail."

A number of arguments are provided in favor of IPR:

- Encouraging and safeguarding intellectual and artistic creation;
- Disseminating new ideas and technologies quickly and widely;
- Promoting investment;
- Providing consumers with the results of creation and invention;
- Providing increased opportunities for the distribution of the above effects across countries in a manner proportionate to national levels of economic and industrial development.

Source: OECD 1989a.

through the *Union Internationale Pour la Protection des Obtentions Végétales*, or UPOV. The UPOV Convention was first signed in 1961 and presently has 24 member states.[2]

The advantages generally ascribed to patents and other forms of IPR by industrial organizations are listed in Box 1.

2.1 Patenting Life Forms

Early on, the *US Patent and Trademark Office* (USPTO) regarded natural products and organisms as "products of nature" and not covered by the U.S. patent laws. In 1977, however, the *Court of Customs and Appeals* (CCPA) made it clear that, although a patent could not be claimed for a natural product *per se*, one could be claimed for any *new* form or composition. This decision resulted in the recognition that purified natural products could be considered as *new* and thus patentable (Armitage 1989).

Following this decision, patents on living material were granted. In 1980, the American Supreme Court, in the landmark *Diamond v. Chakrabarty case*, held that the first patent on genetically engineered bacteria capable of cleaning oil spills should be honored. The Court held that a live, human-made micro organism can be patented under the American patent law as a "manufacture", or "composition of matter". This decision provided a judicial framework for subsequent USPTO decisions to issue patents for both plants and non-human animals (OTA 1989).

In 1985, a patent was awarded for a maize variety containing an increased level of the amino acid tryptophan. In 1988, the first patent was granted for genetically engineered mice with a uniform susceptibility to cancer to be used in cancer research, the so-called "oncomouse".

2 As of September 1993, the 24 UPOV member states are: Australia, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Hungary, Ireland, Israel, Italy, Japan, the Netherlands, New Zealand, Norway, Poland, Slovakia, South Africa, Spain, Sweden, Switzerland, the United Kingdom, and the United States.

In Europe, the patent laws of the 17 member countries of the European Patent Organization[3] follow Article 53 of the *European Patent Convention* (EPC). Article 53(a) states that European patents shall not be granted for inventions which would be contrary to the public order or morality. Article 53(b) excludes from patent protection (1) plant or animal varieties, and (2) essential biological processes for the production of plants or animals. This provision does not apply to microbiological processes or their products and the *European Patent Office* (EPO), set up under the European Patent Convention, granted its first patent for a micro-organism in 1981.

Despite the provisions of Article 53(b), the first patent on a plant was issued in 1989. It was decided to award this patent as the plant in question was not considered to be a *variety*, defined by the Technical Board of Appeal of the EPO as a multiplicity of plants which are largely homogeneous in their characteristics that remain stable after every propagation. Genetically engineered mice were patented in 1992 on similar grounds. The EPO did not consider the "oncomice" an animal variety which would be excluded under Article 53(b). The EPO also ruled that Article 53(a) of the convention was not applicable as the benefits to mankind outweighed the suffering of the mice (Bizley 1992).

The European biotechnology industry strongly favors the removal of the exclusions under Article 53(b) of the EPC. Difficulties in securing patents for inventions based on living material is considered to hinder biotechnological innovation in Europe, as compared to Japan and the USA.

To adapt the patent laws of EC member countries, the European Commission has proposed a *Council Directive on the Legal Protection of Biotechnological Inventions* (Commission of the EC 1988, 1992a). With respect to agricultural biotechnology, this directive envisages protection for biological material, including plants and animals, microbiological processes, and subsequent generations derived from patented biological material. However, plant and animal *varieties*, as well as essential biological processes, are to be excluded from patent protection. Furthermore, because of heavy pressure on the part of the European Parliament, the proposed directive includes a *farmers' privilege*: farmers may use seeds of patented plants to resow their land and may rear patented livestock to renew their stock on their own farm. The proposed directive, first published in 1988, is still under debate.

2.2 The Patentability of Life Forms Debated

Ethical and political considerations provide considerable input to the public debate about whether or not life forms should be patentable. For example, the small number of patents granted for plants and for an animal under the European Patent Convention have all been officially opposed by various organizations. More than 80 NGOs have collectively filed a legal objection to the issuance of a patent on the "oncomouse". The debate in Europe has had two effects. Firstly, it has led to the expectation that it will take years of litigation before a final decision on plant and animal patents is reached. Secondly, the efforts of the EC Commission to harmonize the patent laws of member countries with respect to biotechnology, through an EC directive, have been significantly delayed.

Uncertainty also exists in the USA where the granting of patents on life forms other than microorganisms may have preceded existing controversies. The US patent law does

3 The European Patent Organization members comprise all EC countries, including Belgium, Denmark, Germany, France, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain, and the United Kingdom, as well as the non-EC countries: Austria, Liechtenstein, Monaco, Sweden, and Switzerland.

not contain specific exclusions and the extension of its scope does not require the enactment of a new law. As a consequence, the patent holder may long remain uncertain about the final validity of his patent. So far, only one case, that regarding microorganisms (in 1980), was extensively reviewed for validity by the American Supreme Court.

The other leading American cases involving patenting in biotechnology were administrative rather than judicial decisions. Both the US Court of Appeals for the Federal Circuit and the Supreme Court have yet to speak specifically on patenting life forms other than microorganisms (Nies 1990).

Moreover, the US patent system is designed so that the issuance of a patent is based on face validity, which can be challenged in a court of law. This will almost certainly happen when broad-based patents are issued. For example, at the beginning of 1993, the American company Agracetus was granted a patent on *all* transgenic cotton products, regardless of the engineering technique used. Because of the large number of other patented inventions that the Agracetus patent may conflict with, it is safe to assume that it will be challenged.

A severe backlog in the number of patent applications waiting to be processed in the US has contributed to extensive litigation over biotechnology patents. In 1990, 8200 biotechnology applications remained unexamined at the US Patent and Trademark Office. Claims often overlap and they contain increasingly complex details. But, as most biotechnology patents take three to five years to process, companies have to start marketing before patent disputes are settled (Cookson and Clayton 1992).

Although these examples are derived from industrialized countries, they may represent a foretaste of what is to be expected in developing countries as they acquire greater expertise in biotechnology and more capacity for biotechnological innovation with a commercial potential or which raises ethical sensitivities.

2.3 Strengthening Plant Breeders' Rights in UPOV

Broadening patent coverage to include plants has been strongly opposed by farming and plant breeding circles, especially in Europe. Traditionally, plant varieties could only be protected through the *plant breeders' rights* (PBR) system. As has been outlined above, PBR provide breeders and farmers with privileges for the unauthorized use of protected varieties for specific purposes.

The plant biotechnology industry is increasingly resorting to patent law because this offers stronger protection than PBR. This increase in the use of patents was an important reason for UPOV to revise its Convention. In 1991, UPOV strengthened the position of the PBR holder by eliminating the *breeders' exemption* for an "essentially derived variety". This is defined as a variety predominantly derived from another (initial) variety which retains the expression of the essential characteristics from the genotype or combination of genotypes of the initial variety (UPOV 1991). One consequence of the change is that a breeder who inserts a single new disease-resistance gene into a PBR-protected variety will now have to obtain permission from the holder of the original rights before marketing the new variety (Barton and Siebeck 1992).

The *farmers' privilege* was contested during the negotiations on the preparation of the 1991 Convention. From the outset of UPOV, in 1961, farmers have been allowed to use their own harvested material of protected varieties for the next production cycle on their own farm. American farmers are even allowed to sell part of the on-farm produced propagating material of a protected variety directly "over the fence" to their neighbors (DGIS 1991). On-farm seed saving is still a common practice in UPOV countries. Due to a lack of

consensus among the UPOV members, no minimum standard could be adopted as regards farmers' re-use of harvested seed. The 1991 Convention contains an "optional exception," which provides that it is up to a national government whether to permit farmers to use the seed of a PBR-protected variety for propagation purposes on their own holdings (UPOV 1991, Article 15(2)).

At present, most member states have signed the UPOV 1991 Convention. However, none of them have yet ratified it. The main differences between patent law and the two UPOV PBR acts of the Convention are summarized in Table 2.1.

Table 2.1 Comparison of main provisions of PBR under the UPOV Convention and Patent Law

Provisions	UPOV 1978 Act	UPOV 1991 Act	Patent law
Protection coverage	Plant varieties of nationally defined species	Plant varieties of all genera and species	Inventions
Requirements	* Distinctness * Uniformity * Stability	* Novelty * Distinctness * Uniformity * Stability	* Novelty * Inventiveness * Nonobviousness * Industrial application and usefulness
Protection term	Min. 15 years	Min. 20 years	17-20 years (OECD)
Protection scope	Commercial use of *reproductive material* of the variety	Commercial use of *all material* of the variety	Commercial use of protected matter
Breeders' exemption	Yes	Not for *essentially derived* varieties	No
Farmers' privilege	In practice: yes	Up to national laws	No
Prohibition of double protection	Any species eligible for PBR protection can not be patented	——-	——-

3. THE GLOBAL TECHNOLOGY SYSTEM AND IPR PROTECTION

Recent efforts to strengthen IPR worldwide largely reflect the general changes in the global technology system. This helps to explain the increasing pressure exercised by highly industrialized countries on developing countries to introduce or strengthen IPR.

The role of technology as a determinant of economic growth and competitiveness is currently much larger than it was twenty years ago. All parts of what we may call "the world technology system," i.e. the production, diffusion, application, and protection of technology, have undergone profound change. The rise of new *generic technologies*[4] with a wide applicability throughout almost all sectors of the economy has speeded up technological development, made a number of economic sectors research-intensive which hitherto were not, and changed the patterns of international competition.

The purpose of this chapter is to describe some of these changes. It provides information on the global trends regarding intellectual property rights (IPR) that national policies will have to take into account.

3.1 A Changing Global Technology System

A number of fundamental innovations, especially in microelectronics, but increasingly also in the field of biotechnology and new materials, have changed the technological basis of the global economy. In many sectors of the economy, this has led to large-scale investments in new types of plant and equipment and to a change in the skill profile of the labor force (OECD 1989b). The changes have already had a far-reaching effect on the institutional base of the economy and have profound implications for the regulatory system which governs economic relations. The introduction of generic technologies is intensifying the drive towards stronger IPR for the following reasons:

- There is more to protect because of higher investments in R&D;
- There are more actors against whom intellectual property has to be protected;
- The protection of a specific process at the beginning of a new technological cycle may protect a whole area of research with a broad range of applications;
- Research may become more collaborative, involving a number of institutions, each wanting clear rules to apportion resulting benefits.

3.1.1 Increasing Investment in R&D and the Use of Patents

Policy makers and corporate executives alike have realized that new technologies have a far-reaching impact on the competitiveness of their countries and companies. As a result, government and business expenditure on research and development has increased considerably in most OECD countries since 1975. Many companies currently spend more annu-

4 Biotechnology, information and microelectronic technologies, and new materials technologies are often defined as "generic technologies". These are basic technologies with a wide application in new products and production processes across many sectors. They are "key technologies" in the sense that they open up large new spheres of investment and have a pervading impact on the productivity of an economy.

ally on R&D than they do on replacing buildings and machinery. Consequently, interest in protecting the results of R&D investments against copying and counterfeiting is greater than before.

Another important factor related to this intensified investment has been the potential scope of basic patents taken out in the early phase of the development of new technologies. Innovations differ in importance, and so do the IPR accorded to the respective innovators. In the early phase of the development of new technologies, a number of break-through innovations are normally necessary to lay the basis for further development. The basic process allowing DNA-transfer into foreign organisms patented by Stanford University in 1973 (the Boyer/Cohen patent) is a case in point. A more commercially-oriented patent holder than Stanford University could have exercised considerable control over the development of biotechnology, at least in the USA. Since basic patents of specific processes could close off entire areas of application to potential competitors but not to collaborating developers, there has been a scramble to register patents in the early phases of development.

3.1.2 New Competitors

The pervasive character of the new technologies has resulted in the entry of many new participants in the world technology system. For any individual company, competition intensifies as the result of three parallel developments:

- internationalization of the economy;
- the blurring of sector boundaries; and,
- a worldwide proliferation of actors contributing to the pool of knowledge of commercial interest.

Internationalization of the economy

The internationalization of the economy in the 1980s was closely linked to the rise of new technologies. Given the large amounts of capital necessary to develop new products on the one hand, and the shortening of the life cycle of most technology-intensive products on the other, companies were forced to market their products as quickly as possible, especially in the countries of North America, Western Europe and Japan. This has boosted foreign investment globally and created a large number of strategic alliances. Consequently, firms in any of these markets face new competitors from other advanced industrialized countries.

As a result, companies now seek protection through IPR in more countries than they did in the past in order to: (i) expand their market share, (ii) prevent competitors from becoming active in those countries, or (iii) as a bargaining tool to negotiate favorable local agreements. Foreign patent applications in the OECD countries, i.e. applications made by non-residents, almost doubled between 1983 and 1989. A similar increase can be seen for external patent applications by the residents of the countries concerned, i.e. applications made abroad.

Blurring of sector boundaries

The wave of new generic technologies has profoundly changed the relationship between different branches of the research economy. New patterns of competition arise as technology developers, formerly in different research sectors, become part of similar technological groups with competing products. For example, the emergence of biotechnology has enabled chemical companies to expand their research base to include plant genetics, thus facilitating

their entry into seed production. The chemical industry has traditionally relied on the patent system and has therefore become a strong advocate of patent protection for plant material.

Increasing number of institutions carrying out R&D

Companies and countries which did not spend much on research and development in the past have become important new entrants to the R&D scene. In the food processing industry, for example, the share of R&D expenditure was traditionally very low in proportion to total sales. Biotechnology is being used to develop new methods to conserve and process foodstuff, and so R&D efforts in this field are expanding. Not only are new companies emerging as competitors, but governments, including those of the Newly Industrialized Countries (NICs), have also increased their R&D efforts. Although the relative share of developing countries as a whole in world R&D expenditures has declined as a result of the recent increase of expenditures in the highly industrialized countries, the NICs have been able to expand their own R&D systems at a much faster pace than the older industrialized countries. The past record of these countries in successfully absorbing foreign technologies, hence increasing competition, has led to the industrialized countries stressing IPR even more strongly.

3.1.3 Organizing Collaborative R&D Ventures

The introduction of new technologies, coupled with the growing internationalization of global economies, has prompted research-based institutions to explore multiple avenues when assessing prospects for commercial use. While large amounts of capital may be necessary to achieve a critical mass for research in a given field, the investment may be too risky for companies to finance all of it as in-house research. In such circumstances, there is a tendency to seek the cooperation of partners to shorten product and process development, to take advantage of complementary research developments, and to formulate alternative paths for risk-sharing. Options pursued here include:

- strategic alliances;
- contract research;
- greater company-university cooperation.

Strategic alliances

Independent firms producing comparable products are increasingly cooperating in order to bring together complementary experience, to reduce the risks involved in research and development, and to share costs. Such alliances can be between more or less equal partners, or between small and large companies with the larger company often benefitting from the innovative skills and entrepreneurship of the smaller one, while the partnership gives the smaller company better access to capital, marketing channels, technologies and scaling-up facilities. A good patent portfolio can be a valuable asset to attract alliance partners.

Contract research

Contract research can take many different forms. For example, the development of biotechnology in the USA has given rise to the creation of several hundred start-up firms, sometimes called *bioresearch boutiques*. These derive the main part of their income from

licensing their research results. Adequate IPR enforcement is absolutely essential for the survival of this type of enterprise.

Increasing company-university cooperation

Companies not only cooperate with each other but also with universities and public research organizations. Universities are attractive partners because of the long-term, basic research they carry out. Many research developments are so uncertain that companies do not want to engage in areas which may not turn out to be commercially viable. University research often suffers from financial constraints so that research funding from the private sector is usually very welcome.

4. DEVELOPING COUNTRY RESPONSES, ASSESSING COMPLEXITIES

Intellectual property rights are just one of the policy issues facing developing countries as they examine national scientific and technology objectives. Besides the factors summarized in the previous chapter, other broad changes are occurring, such as the liberalization of national economies and a growing awareness of the need to enhance participation in international agricultural markets. These changes increase the need for developing countries to analyze the costs and benefits associated with intellectual property rights systems.

4.1 Challenges Ahead for Developing Countries

The surge of R&D investment in the highly industrialized countries tends to:

- increase the technology gap between industrialized and developing countries, undermining the latter's position in the world market;
- change the manner in which foreign companies become engaged and invest in developing countries; and,
- intensify the pressure on developing countries to accept stricter IPR norms.

All of these points present both opportunities and challenges to the national agricultural research systems of developing countries and are discussed in this context in the rest of the paper.

The increasing technology gap

Only a small part of the world's research and development takes place in developing countries. Even among the OECD countries, there has been a tendency for R&D expenditures to be concentrated in the most advanced countries. The new emphasis on technological development is, therefore, likely to increase the gap between highly industrialized and developing countries. It may undermine the developing countries' export-oriented development strategies, and increase their dependence on the import of technology.

Changing character of foreign engagement and investment

The involvement of foreign enterprises in developing countries often takes the form of *non-equity engagements*. However, the high political and economic risks of operating in many developing countries have had a cautionary effect on many multinational enterprises. As a consequence, a number of them have adopted a strategy which limits their capital risk but nevertheless provides them with effective partial or total control over a project or enterprise. In this context, technological superiority is a crucial asset for a foreign company in that a domestic company can become so dependent on the foreign supplier that the latter can exercise control from the outside, even without equity participation. The new wave of technology development has increased the chances of such types of control. The same processes that can make developing countries more dependent on the import of new technologies may cause redistribution of direct investment away from developing countries.

Stronger demands for effective IPR

While the use of technology transferred to a wholly owned subsidiary can easily be controlled, such control is more difficult in the case of a formally independent enterprise. The only sanction in a case of misuse of technology transferred to a partner that is not wholly owned is to cut off further transfers. Strong IPR legislation, where it exists, can also help to enforce technology transfer agreements. The spread of new forms of investment, therefore, contributes to the pressure to strengthen IPR. In countries without IPR legislation, however, certain sectors of domestic industry could be adversely affected if IPR were to be introduced and enforced.

4.2 Open Market Economies and Changing Opinions Regarding IPR

Changes in the global technology system, and the function of IPR, should be seen in relation to the increasing trend in many developing countries towards having less interventionist and more open market economies. ***This shift has raised increasing doubts as to whether traditional permissive IPR policies are conducive to social and economic development in the Third World*** (Cottier 1991). As developing countries move towards a more open market approach, they may need to provide adequate IPR protection to increase the flow of imported technology.

In their effort to gain access to advanced information and technology to accelerate economic development, developing countries have traditionally been reluctant to enforce any form of IPR, particularly patent rights. They argued that their nations are on the periphery of the patent system and are opposed to practices by multinational companies which limit technology transfer. Developing countries have taken the stand that the patent environment has kept their industries from catching up with the industrialized countries. IPR standards in developing countries were, therefore, generally weaker than those in industrialized countries; in fact, proposals to strengthen IPR protection were often interpreted as an attempt to deprive developing countries of the benefits of new technologies (UN 1975).

However, without adequate IPR protection the holders of proprietary rights in products of biotechnology face the risk of having their technologies appropriated without compensation. These technologies may be exceptionally costly to develop, yet relatively cheap to duplicate or reverse-engineer (Burk et al. 1993).

Rather than lowering IPR standards, it may become necessary to strengthen them to help reduce the technology gap, increase private sector participation in the national and international markets and attract foreign investment. For these reasons, despite domestic opposition, many developing countries are increasingly agreeing to accept upgraded, international IPR standards. International negotiations on IPR have been instrumental in this area (see Chapter 5).

The extent to which the changes in IPR legislation of developing countries will in fact lead to accelerated technology transfer and to greater domestic innovation in advanced technology remains to be seen. Only limited evidence exists with regard to IPR in developing countries and their relationship to welfare and development. A review of the literature on IPR in developing countries underlines that “knowledge of the scope, standards and effectiveness of IPR in developing countries is seriously inadequate. There is little evidence on the question as to whether and to what extent IPR in developing countries affects technology imports or stimulates domestic R&D” (Siebeck 1990).

4.3 Different Needs and Responses Among Developing Countries

Developing countries have traditionally relied on public-sector institutions and their collaboration with the international agricultural research system to provide inputs necessary for agricultural growth. In fact, returns from investments in public-sector agricultural research have been found to be higher than for investments in industrial R&D. However, despite these high returns, the relation between agricultural investment and the presence or absence of IPR is difficult to determine (Evenson 1990).

Such evidence illustrates the difficulties facing developing countries as they decide whether to adopt or strengthen national policies for IPR, particularly for countries where: (i) agricultural research remains primarily a public-sector responsibility, and (ii) innovation is seen as more of a public than a private good. Consideration of stronger intellectual property protection will entail an analysis of both costs and benefits. Among the costs to be considered are:

- **Introducing and enforcing an intellectual property system**. The costs of implementing an intellectual property system include an administrative component for establishing and maintaining a national patent office, as well as an enforcement component, to ensure that national courts make well-informed decisions;
- **Possible higher royalty payments**. Many developing countries are net importers of technology, and strengthening their IPR systems would tend to increase the amount of payments abroad for proprietary knowledge;
- **Displacement of "illegal" manufacturing activities**. Developing country industries imitating products or processes by infringing intellectual property rights may suffer when a stronger IPR system is introduced;
- **Increasing prices of consumer goods**. The loss of counterfeit industrial goods and the monopoly effects that stronger IPR protection may entail, can increase prices to consumers and impair the process of technological diffusion.

These cost considerations have to be weighed against the potential benefits of domestic research efforts with greater access to foreign technology and foreign investment, and increased opportunities for technology transfer. It should be noted that neither the costs nor the benefits of strengthening IPR systems have been empirically established.

The introduction of IPR will be only one of the policy mechanisms that developing countries may consider that affects national capabilities to engage in advanced research. Other initiatives could include building indigenous research capacity, providing opportunities to purchase advanced technologies and removing regulatory constraints. In fact, these may be of more immediate importance than implementing national IPR policies.

Policymakers in developing countries will take these factors into account as they consider biotechnology and IPR in relation to their own country's technological needs and capabilities. In part, their decisions will be guided by the extent to which generating innovative capacity is an objective of national scientific and technology policy. This means assessing the need to protect indigenous biotechnological innovation, gaining access to protected technology from abroad and the degree of orientation towards foreign markets. The more outward-oriented the national industrial and agricultural sector, and the greater the level of technological development, the more there is to be gained from stronger IPR legislation.

The role of the private research sector will also differ among developing countries as national agricultural systems respond to more open-market economies and the growing diversification of research (See Chapter 3). The private sector will be important for introduc-

ing and making available new technologies. If national IPR policies and legislation favor development of the private sector alongside the public sector, then greater competition will occur for the provision of agricultural products and services as well as for providing alternative sources for varieties released from the national seed industry or from other NARS institutions. Taken together, these developments will ensure greater variety in agricultural inputs for local farmers and consumers.

While technology and germplasm acquisition, whether public or private, is one matter, the ability to use this material in various phases of biotechnology development, is another. In nations where the local technology base is weak, stronger IPR are hardly likely to increase indigenous technological development. IPR considerations will differ for NARS which have only recently established their capabilities in biotechnology as they will initially lack institutional abilities to develop innovations which merit the additional time and costs required to justify IPR. However, as capabilities in biotechnology and local innovative capacity strengthen, opinions regarding the value of IPR may change.

4.4 Impact on Seed Production and Farmers' Rights

Seed production in developing countries is predominantly the domain of farmers and public institutions. This system relies on the international free exchange of plant genetic material, and on-farm seed saving practices. It may face restrictions when plant varieties are protected under patent or PBR law.

Under patent law, all unauthorized use of patented material is prohibited. This means that the use of patented material in breeding programs, for other than research purposes, may be restricted by the patent holder, and will raise the costs of seed production. Patent protection of biological material covers all its subsequent generations as long as the patent lasts. On-farm seed saving of patented plant varieties may entail an infringement of the patent.

Under the 1991 UPOV Convention, PBR protect against commercial use of all material of plant varieties for a minimum of 20 years. As in the case of patent protection, the inclusion in breeding programs of plant varieties protected under PBR conforming to UPOV 1991, requires authorization and the payment of royalties if the new improved variety is considered to be essentially derived from the protected variety. The new UPOV Convention may also lead to restrictions on on-farm seed production (see Chapter 2).

The concern over the possible negative effects on seed production is intensified by the fact that so-called "landraces" cannot be protected by IPR. These are often regarded as the product of rural-community improvement, but are freely available to, for instance, commercial breeders. The concept of *farmers' rights* was put forward in FAO in the early 1980s as one means of compensating farmers for their prior selection and improvement efforts. FAO then established an International Fund for the Conservation and Utilization of Plant Genetic Resources in 1987, to be funded from a tax on seed sales, as a way of implementing farmers' rights. The fund was to be used to promote breeding and conservation programs in developing countries. To date, however, no contributions to the fund have been made.

5. TOWARDS AN INTERNATIONAL AGREEMENT ON THE LEGAL PROTECTION OF BIOTECHNOLOGICAL INNOVATIONS

International negotiations regarding IPR have been initiated to:

- harmonize IPR legislation within industrialized countries; and,
- extend the stronger provisions of industrialized countries for protecting new technologies to other parts of the world.

Currently, the level of IPR differs widely among nations. In many (developing) countries the duration of protection is much shorter than it is in industrialized countries (WIPO 1990a). Even in the latter group of countries, some exclude specific processes and products from patent protection. For example, half of the signatories of the *Paris Convention for the Protection of Industrial Property*, including most Western European countries, exclude plant or animal varieties, and biological processes for the production of plants and animals. Many developing countries also exclude pharmaceuticals, food products and processes for pharmaceutical and food production from their patent legislation (WIPO 1990b).

The reason for this situation is that the Paris Convention does not provide for minimum standards, in terms of patent coverage or duration, that the laws of member countries should meet. The Convention is based on the so-called 'national treatment' principle, which requires signatories to offer equal protection to both foreign and national applicants.

While over 100 countries have acceded to the Paris Convention, only 24 (industrialized) countries are members of UPOV. Under international law, countries that do not adhere to either of these conventions have no obligations with respect to IPR for biotechnological innovations.

Two routes have been used to try to harmonize IPR legislation: a) multilateral negotiations in the *World Intellectual Property Organization* (WIPO) and in the Uruguay Round of multilateral trade negotiations under the aegis of the *General Agreement on Tariffs and Trade* (GATT); and b) bilateral negotiations initiated by the USA, and to a lesser extent by the EC and Japan. To the extent that they are related to biotechnology, these negotiations are discussed below.

5.1 Protection of Biotechnology in WIPO

WIPO is the United Nations' specialized agency which administers most IPR conventions. WIPO's role in the debate on IPR in biotechnology has been twofold. First, the International Bureau of WIPO has undertaken several initiatives to discuss proper protection mechanisms for biotechnology, and second, WIPO has been the main forum for talks on the international harmonization of patent laws.

Expert committee on biotechnology

The aptness of patent laws with respect to the protection of biotechnological inventions has been discussed by a WIPO Committee of Experts that was first convened in 1984 (WIPO 1988a). This committee discussed reports prepared by the International Bureau of WIPO,

containing *Suggested Solutions* for the patent protection of, among other things, plants and animals or parts thereof, and processes for the production of plants and animals. The Committee of Experts, consisting mainly of non-agricultural specialists from highly industrialized countries, advocated inclusion of living material in patent laws.

Harmonization of patent laws

Since 1984, WIPO has been working on a *Treaty on the Harmonization of Certain Provisions in Laws for the Protection of Inventions*. However, the Treaty, should it be concluded, is not expected to deal with the issue of patenting living organisms. The original aim of the treaty was to harmonize the American, European, and Japanese patent laws, particularly in two respects:

- the *grace period* (the period required for public disclosure of an invention prior to filing an application); and
- the question of to whom a patent should be granted: the inventor (the USA approach) or the first applicant (the approach in Europe and Japan) (WIPO 1990c).

During the preparatory meetings on this treaty, the participation of developing countries was increased and the scope of the proposed treaty widened. Industrialized countries proposed provisions to raise the minimum standard of patent protection under the Paris Convention.

5.2 Protection of Biotechnology in GATT

When the Uruguay Round commenced in the mid-1980s, the USA, supported by Japan and the EC, successfully insisted that intellectual property rights should be included in the GATT negotiations. Their reasons were twofold. Firstly, developed and developing countries had not been able to reach agreement in the WIPO negotiations. In GATT, however, negotiations on IPR were linked to international trade negotiations, making developing countries' access to export markets in industrialized countries contingent upon advances on IPR. Secondly, GATT contains an effective dispute-settlement mechanism, the use of which would facilitate relatively quick, enforceable action against countries violating any GATT agreement on intellectual property.

IPR have been discussed in the GATT negotiations on *Trade-Related Aspects of Intellectual Property, including Trade in Counterfeit Goods* (TRIPs). The industrialized countries brought forward proposals which would lead to a new international IPR standard for advanced technology, including biotechnology. They also proposed provisions for enforcement and the settlement of disputes between states concerning international trade in protected matter. Dispute settlement was perceived as taking place under the authority of an envisaged *Council on Trade- Related Aspects of Intellectual Property Rights* as part of the proposed *Multilateral Trade Organization* of GATT.

Because of the linkage between trade and IPR in the GATT forum, the TRIPs negotiations have been used by developed countries to put pressure on developing countries to accede to proposed legislation giving stronger legal protection to the products of advanced technology. A TRIPs agreement was also considered desirable to facilitate agreement on the current patent harmonization talks in WIPO.

The latest GATT draft agreement, issued December 1991, on the results of the Uruguay Round includes a draft accord on TRIPs. There appears to be a high degree of consen-

sus on this draft agreement, and it is unlikely to be subject to extensive revision. It can, therefore, be considered to be the new international (minimum) IPR standard, irrespective of the final outcome of the Uruguay Round. Its most important provisions concerning biotechnological innovations are presented in Table 5.1

Table 5.1 Selected provisions of the final draft TRIPs agreement under GATT having impacts on biotechnological innovations

- Biotechnological inventions are to be protected under patent law. Excluded from patent protection may be: plants and animals other than microorganisms, and essentially biological processes for the production of plants and animals, other than non-biological and microbiological processes. Plant varieties should be protected either by patents and/or by an effective *sui generis* system. This provision shall be reviewed four years after the entry into force of the new GATT;
- A minimum patent duration of 20 years from filing;
- Extension of the protection of a patented process to the products directly obtained by that process. No discrimination against certain fields of technology or against foreign inventions;
- Reversal of the burden of proof in case of alleged infringement of a process patent.
- Use of compulsory license only under specific conditions;
- Developing countries are not required to apply the provisions of the agreement within a period of five years, except for general provision of non-discrimination. For product patents on pharmaceuticals, and foodstuffs, including biotechnology, developing countries may benefit from a transitional period of ten years. Least developed countries benefit from renewable open-ended periods. The transition period is restricted for the protection of pharmaceutical and agrochemical products. Patent applications can be filed for these product categories, but are pending until the expiration of the transitional period. Instead, for the products covered by these pending patent applications, there will be *a five-year marketing exclusivity period.*

5.3 Biotechnology in Bilateral IPR Talks

Apart from the multilateral route, the USA, and to a lesser extent the EC, have put bilateral political pressure on individual countries to strengthen the legal protection of advanced technologies, including biotechnology. The *Special 301* provisions of the US Omnibus Trade Act of 1988 provide that the US Administration must take retaliatory measures against alleged shortcomings in foreign IPR legislation. For this reason, about 40 countries have been targeted by the US Trade Representative in the past few years, and some have had sanctions imposed on them.

For example, the renewal of the 10-year-old Sino-American Science and Technology Agreement, in early 1989, acted as a leverage to stimulate China to improve, among other things, its patent system. Controversies between India and the USA about IPR gave rise to difficulties in the Indo-US Vaccine Action Program, leading twice to a postponement of the continuation of the Indo-US Science and Technology Initiative, in force since 1982.

The EC has also exerted pressure on several developing countries to adjust their IPR legislation both through diplomatic initiatives and commercial policy measures linked to its *New Trade Policy Instrument.*

The threat of trade sanctions and suspension of technological cooperation in bilateral negotiations have had a much greater impact than the IPR negotiations in WIPO or GATT.

From the point of view of industrialized countries, the advantages of the bilateral route over the multilateral framework are threefold. First, IPR legislation in developing countries has been upgraded as quickly as possible when agreed to bilaterally. Many countries have accepted the US and EC demands while the talks in GATT and WIPO have still to be concluded. Second, changes in IPR which have been agreed to bilaterally take effect almost immediately, without transition periods as envisaged in the draft TRIPs agreement. Third, the level of IPR which has been agreed upon is higher than is envisaged in GATT or WIPO. In the case of Mexico, for example, patent protection has been granted for plant varieties. ***From the standpoint of the developing countries, the trade pressures being applied by the industrialized countries are sometimes seen as leading to infringements on national sovereignty.***

6. DEVELOPING COUNTRY RESPONSES, ASSESSING THE OPTIONS

Many NARS have experienced the changing international climate towards IPR for biotechnological innovation. The protection of technology or genetic material may have been a condition for collaboration with foreign institutes or companies. National IPR policy may have changed as a result of changes in national science and technology policy, or as a result of international negotiations. Some institutes may have developed plant material or technologies warranting protection of IPR for potential income generation from royalties or licensing.

Whether or not NARS have already experienced the effects of the growing importance of IPR, it is safe to assume that most of them will do so in the near future. In this chapter we discuss some of the options available to NARS in relation to IPR and the consequences of adopting different options.

The principal options available are discussed below in relation to three technology objectives:

- acquiring and using public and proprietary technologies (Section 6.1);
- developing and protecting national institutional inventions (Section 6.2); and,
- exploring alternatives for technology transfer (Section 6.3).

The decision as to which of these options to exploit will be heavily influenced by the institutional and/or system-wide technology objectives and national IPR legislation. The latter may differ widely from country to country. Some countries have never explicitly excluded living material from IPR, others have recently adopted IPR for biotechnology and plant breeding, or are discussing IPR legislation in which the explicit inclusion of living material is envisaged (Annex 1). Basically, two different IPR situations can be distinguished, each of which may have a specific impact on technology policy:

- the first refers to countries that do not provide for IPR to living material. In this situation it is assumed that no plant breeders' rights exist and living material is also not patentable;
- the second presumes the availability of some form of legal protection of rights to living material, such as an effective PBR system, comparable with the UPOV system, or patent laws whose scope includes plant or animal material.

Each of these situations will be examined in this chapter with regard to the three technology objectives mentioned above.

6.1 Acquiring Technologies

As discussed in Chapter 4, there are costs and benefits to be considered for either providing or not providing national IPR and their effect on the three technology objectives. Regarding technology acquisition, the provision of IPR is beneficial in helping to increase access to advanced technologies, but may involve increased costs in terms of royalty payments and administration and enforcement of IPR.

If IPR are **not** available, the benefits of acquiring technology may be seen as avoiding royalty payments, using a "free-rider" status, and promoting general technology diffusion.

However, the absence of IPR may present difficulties for accessing advanced technologies which can be regarded as a cost. Various methods of acquiring either public- or proprietary-domain technologies are discussed below.

6.1.1 Acquiring and Using Public-Domain Technologies

Public-domain technology refers to technology that is not protected by IPR, i.e. not privately owned, classified, or proprietary. Such technology comprises 'knowledge spillovers' (byproducts of research that cannot be patented and are available to all who know of their existence), innovations in public research institutes, and innovations which are no longer protected. This technology can be used by anyone, irrespective of the existence of IPR legislation. Public-domain knowledge is often ignored and it has been argued that developing countries should emphasize efforts to screen this knowledge and use it to further their own development goals.

Public-domain developments in agriculture will continue to provide national scientists in developing countries with opportunities for the acquisition and use of new biotechnology. In the case of agricultural research, many developments have a long history of being generated in the public good, and hence, receiving no type of IPR. As regards biotechnological innovations, recipients may still need to ensure that no legal complications regarding the application of the technologies or materials in developing countries have arisen during their development.

Screening and using public-domain technology is a viable policy option for NARS. Many new and relevant biotechnological processes and techniques are in the public domain. Tissue culture techniques, for instance, were never patented and are used today in many countries to develop new products and technologies (Acharya 1991). The use of this kind of technology is entirely legal and is not contested internationally. Furthermore, many innovations will be in the public domain far earlier than is to be expected on the basis of the maximum protection term. For instance, whether a patented invention actually is protected for 20 years depends on the patent holder's ability and willingness to pay the annual fees in all countries that recognize the patent.

Assuming that a great deal of advanced biotechnology is in the public domain, it might be a useful strategy for NARS to monitor, select and acquire relevant processes or germplasm. National or regional patent offices could be helpful in obtaining information on local and foreign biotechnology on which the IPR protection has lapsed. However, obstacles to this strategy may appear, especially since most of the biotechnology or improved plant varieties are to be found in foreign (often OECD) countries. Moreover, products that are in the public domain are not necessarily easy to acquire. In many cases, it is likely that NARS will have to seek assistance from specialized organizations.

Collaboration with Advanced Public Research Institutes

Collaboration with advanced public research institutes may take place through international research programs in biotechnology. Many OECD countries provide funds to encourage such joint research projects between their national research institutes and counterparts in developing countries. The projects provide not only advanced technology, but also the essential hardware and know-how required by developing countries.

Many of these advanced institutes participate in international biotechnology programs which cover a wide range of research objectives, and can provide assistance or advice on IPR. In addition, a number of them seek to involve private-sector institutions, or have drawn

up agreements with the private sector to donate proprietary technology, to facilitate developing country access to and utilization of advanced proprietary technology and genetic materials.

However, there are limitations to this approach. For example, collaborative projects with foreign public biotechnology laboratories do not necessarily include public-domain technology only, and such collaboration may be used as a leverage in bilateral disputes over national IPR standards.

Foreign aid programs supporting joint international research and technology development may have specific IPR rules that could limit the public character of the research results (Commission of the EC 1992b). In other cases, biotechnology researchers may not be fully aware that they are working with protected technology. The confusion is often caused by the *research exemption* in patent statutes. This exemption allows researchers to use patented technology, but strictly for research purposes. It may happen that researchers, albeit in good faith, use patented technology in a manner unauthorized by the terms of the exemption. The patent holder may consider this to be an infringement of the patent, a situation which may terminate collaboration.

In addition, public research in OECD countries is increasingly being "privatized". Many public and private universities in the United States have set up intellectual property management offices or have engaged outside agencies, such as the *Research Corporation of America*, to manage and defend their interests. As universities have become sensitive to the value of their biological materials (e.g., biologically specific reagents, cell lines, or specific organisms), many routinely place restrictions on the availability of these materials. These restrictions amount to a form of intellectual property protection by dint of contract and trade secrecy (Barton and Siebeck 1992). Similar developments can be observed at universities in European countries.

Collaboration with the International Agricultural Research Centers

International agricultural research centers, including those sponsored by the *Consultative Group on International Agricultural Research* (CGIAR), are an important source of germplasm and technology for NARS. Their strategy for research is to apply biotechnology from advanced public and private laboratories to existing crop and animal improvement programs, rather than to undertake cutting-edge research themselves. Experience within the centers in seeking patents for biotechnology-based innovations is therefore limited.

The centers have easier access than many NARS to modern techniques and up-to-date information on biotechnology. In this respect, they can play an important facilitating role for the NARS.

Historically, the research programs of those IARCs sponsored by the Consultative Group on International Agricultural Research (CGIAR) had an entirely public character, which was reflected in their "open-door" policy with respect to the dissemination of genetic material and innovations. Under this policy, centers distributed germplasm to any researcher who demonstrated a legitimate interest. The centers made no attempt to exercise control over any subsequent commercial use of such germplasm (Barton and Siebeck 1992).

More recently, in response to the increasing importance of IPR, the CGIAR issued guidelines on IPR management for individual centers (CGIAR 1992). These guidelines reaffirm that the resources maintained in the gene banks at the centers should be freely available. They also recommend that the centers should not seek legal protection for their innovations, unless it is absolutely necessary to ensure that developing countries have access to new technologies and products. The guidelines also state that any intellectual prop-

erty right acquired by a center should be exercised without compromising in any manner whatsoever the fundamental position of the CGIAR regarding free access by developing countries to knowledge, technology, materials, and plant genetic resources.

Notwithstanding these guidelines, NARS should recognize that CGIAR center policies regarding protection of IPR may vary, as the centers are autonomous organizations and may have different views regarding the utility of IPR for their respective mandates.

6.1.2 Acquiring Proprietary Technology

The search for technology or germplasm which is in the public domain C and therefore, in principle, freely available — may not necessarily result in the acquisition of needed genetic material and may stimulate interest in acquiring proprietary technology. However, the acquisition of proprietary technologies requires special attention to exemptions relating to the type of IPR used and their implications for future research and production. Four means of acquiring proprietary technology need to be considered:

- searching for information on proprietary technologies;
- direct acquisition of technologies;
- collaboration with an intermediary organization or program; and,
- actions based on the biodiversity convention.

Searching for Information on Proprietary Technologies

Searching for *disclosed* information on proprietary biotechnology or germplasm is always a viable option from a legal point of view. There are, obviously, no legal objections to a NARS *searching* for patented or PBR-protected technology in any given situation. There may be practical obstacles, however, as we may assume that national patent offices will not have the expertise to carry out searches on biotechnology in international databanks if the patent laws do not consider living material as patentable subject matter. Similarly, it will be difficult to search for protected plant varieties when there is no national PBR authority. The prospects of searching for proprietary biotechnology or germplasm via national organizations in a country lacking protection for such technology will, therefore, be very limited.

If expertise is available, patent documents could be collected and studied, or they may be an important means of obtaining technological information. A survey among multinational companies revealed that published patent specifications are the most important source of technical information, surpassing technical conferences and meetings, academic and trade journals, fairs, exhibitions and the like (Bertin and Wyatt 1988).

Patent documents may also play an important role in the transfer of technology in all countries. The computerization of patent data bases makes these documents accessible to developing countries. In addition, companies specializing in retrieving patent information are able to secure copies of patent documents and make them available for sale in formats such as microfilm, or full-sized paper copies. WIPO and the European Patent Office have special programs designed to assist developing countries in this respect.

NARS seeking specific technology could seek assistance from a national or regional patent office if that office is linked to international data bases, such as the *International Patent Documentation Center* (INPADOC). INPADOC is a documentation center based in Vienna which stores the most important bibliographic data on patent documents. It can identify all the patent documents for any one of more than 55,000 groups of international patent classification and can provide copies of all patent documents which have been filed in various countries for the same invention (WIPO 1988b). The prospects of NARS obtaining

assistance from INPADOC depend largely on the effectiveness of their national patent office (see also Annex 2).

Direct Acquisition of Proprietary Technologies

Employing proprietary technology without authorization. As the scope of a patent is **territorial**, no legal provision prevents NARS from exploiting biotechnologies or their products that are patented or protected by PBR abroad but not in the NARS' own country. Innovations lacking national legal protection are considered to be in the public domain. The resulting products could be commercialized and even exported, provided that neither the technique nor the product are IPR-protected in the importing country. Indeed this may be considered a factor in favor of **not** adopting IPR policies in developing countries.

Employing proprietary technology under a license. NARS which are prepared to pay to import protected technology may choose to obtain a license from the foreign IPR holder. Such licenses generally provide for the transfer of the technology or germplasm requested as well as the know-how. The extent to which the lack of IPR in the importing country constitutes an obstacle to obtaining licenses varies, and will depend on several factors, such as the importance of the technology to the IPR holder and the probability of unauthorized use.

When there is no protection of IPR, the IPR holder is likely to try to protect technology by requiring confidentiality regarding the licensed matter. This may mean that the licensee is limited to disclosing confidential information only to specific employees who have signed individual confidentiality agreements with both the licensee and the licensor. In the case of biotechnology, which often deals with innovations that are embodied in self-replicating organisms, it will be difficult to protect trade secrets. If secrecy is a condition for obtaining a license, the contractor must ensure rigid control of confidentiality. For NARS, this may restrict opportunities to use and distribute the products of licensed technology or germplasm.

As developing countries liberalize their technology transfer regulations, NARS will increasingly have the opportunity to acquire proprietary technology through licenses. Negotiation of license agreements will require a careful institutional strategy. This may involve a change from the stance taken by developing countries over the past three decennia when they have objected to "restrictive business practices in licensing agreements", which they claim seriously hamper their use of advanced technologies (UN 1975). This is especially true for new technologies, such as biotechnology, which have a wide range of potential applications. Restrictions in the field of use, restrictions on exports, and the non-exclusivity of the license are all likely to be required by the licensor (Woodley 1989; Vickery 1988). Such restrictions, however, do not necessarily outweigh the benefits from licensing.

Applying for a compulsory license to employ proprietary technology. A compulsory license is one which government authorities or courts force the patentee to grant to a third party, if they consider it to be necessary in the national interest to terminate the monopoly of the patentee. NARS could apply for a compulsory license in a case where the holder of IPR in an important biotechnological innovation refused to license germplasm or technology. Although the compulsory license is an option for NARS, its importance should not be overstated, for two reasons.

Firstly, patent holders regard compulsory licensing as a serious weakening of patent protection. As a result, in all international negotiations on IPR, industrialized countries have insisted that the granting of such a license in other countries must be restricted. Secondly,

even if a compulsory license is granted, the effect of the license may be seriously limited as the compulsion does not extend to the know-how which may be needed to make the protected invention operational.

Collaboration with an Intermediary Organization

As mentioned in section 6.1.1, participation in international research programs in biotechnology can be a way to acquire advanced proprietary technology. Some international programs also involve research collaboration with private-sector institutions (Cohen 1993).

The Agricultural Biotechnology for Sustainable Productivity (ABSP) project, for instance, seeks to link public and private US institutions with partners in developing countries. Such collaborative projects have been launched in Costa Rica, Egypt, Kenya, and Indonesia. Research activities are complemented by analyzing relevant IPR-related issues for eventual production and assignment of property rights.

Other international programs negotiate agreement by the private sector to donate proprietary technology. The Plant Science Research Program (PSRP) has agreement from a UK company to waive IPR for four insect-resistance genes to be introduced into both sweet potato and potato (Witcombe 1992).

The potential for collaborative projects involving IPR waivers can be very large. The private sector may donate technologies, with which they would often find it difficult to make a profit in developing countries, thereby improving their public image and gaining experience in the application of the technology. A specialized organization in this area is the International Service for the Acquisition of Agri-Biotech Applications (ISAAA), which has initiated collaborative research projects in which companies, under certain conditions, donate proprietary technology to developing country NARS.

The Biodiversity Convention

The Convention on Biological Diversity, drawn up during the *United Nations Conference on Environment and Development* (UNCED) in Rio de Janeiro in June 1992, may represent an opportunity for acquiring technology. This Convention is an agreement between developing and industrialized countries by which the developing countries cooperate in the conservation of biological diversity in exchange for a share in the benefits arising from the exploitation of genetic resources which are collected in their countries. The benefits to developing countries may consist of financial support and access to relevant biotechnologies. The latter could be particularly useful for mitigating the restrictions ensuing from a biotechnology patent. Article 16(3) of the Convention stipulates that access to and transfer of (bio)technology to developing countries shall be facilitated under fair and most favorable terms, including concessional and preferential terms.

However, the potential opportunities to be derived from the Biodiversity Convention should not be overstated. Firstly, the wording of the convention is ambiguous and the interpretation of several articles is in dispute. The convention, for example, stipulates that access to and transfer of technology shall be provided on terms that recognize and are consistent with the adequate and effective protection of IPR. This means that transferred proprietary technology, relevant for biodiversity conservation, must be handled like every other protected technology. It is not yet clear how this relates to the above-mentioned provisions of Article 16. Secondly, although many industrialized countries have signed the convention, among them Japan, the EC member states and the USA, none of these countries have yet

ratified the convention. Thirdly, problems arise from the stipulation in the convention of a right to access the research activities that make use of indigenous resources.

In addition, serious doubts have been expressed as to the extent to which the biodiversity treaty may circumvent other international discussions on IPR. As noted earlier, the focus of many of these meetings, such as GATT, has been to strengthen IPR legislation and enforcement in developing countries.

6.2 Developing and Protecting National Biotechnology Innovations

In addition to acquiring agricultural biotechnologies, NARS may also want to protect biotechnology innovations which they have developed themselves. In such situations, one option is to develop national IPR policies, possibly following the guidelines issued by the CGIAR. As stated above, these guidelines suggest that the CGIAR-affiliated centers make their genetic material freely available to any researcher and do not seek IPR for purposes other than to ensure access to new technologies and products.

Most NARS have limited options for protecting their innovations, as very few developing countries explicitly provide for biotechnology patent or plant breeders' rights. In such a situation the best available options are: trade secrecy, material transfer agreements, access to know-how and IPR in foreign countries.

6.2.1 Protection through Secrecy

Trade secrets are a form of intellectual property protection provided by physical measures to ensure secrecy and by restrictive contracts controlling the limits of disclosure of the secret. Trade secrets need never be revealed and have no expiry date. Use of such a protection system for products in the commercial sector may be possible in developing countries, but do not seem a viable option for the need, where it exists, to protect public-sector innovations.

In theory, NARS could try to protect their innovations through secrecy. However, as is argued above, trade secrecy in biotechnology is difficult. Trade secrecy could be appropriate where NARS choose to shift their research emphasis from pure-line varieties to hybrid varieties with the objective of preventing unauthorized use of the parent material. Reproducing hybrid varieties is of little value for production purposes as long as the parental lines are kept secret.

6.2.2 Protecting Innovation in Foreign Countries

Lack of legal protection in its own country presents no legal obstacle to a NARS applying for protection in foreign countries. Innovations can be protected abroad provided that the innovation meets the requirements for protection in the foreign country. Thus, independent of the IPR situation in their own country, NARS can register biotechnology patents or apply for PBR in other countries. Depending on the scope of the patent or PBR, this could be beneficial for individual NARS wishing to safeguard exports, and, by protecting an innovation, prevent unauthorized release. However, there is an issue of reciprocity in that some nations refuse to grant a patent if their nationals do not receive similar patent protection.

6.2.3 Material Transfer Agreements

The use of material transfer agreements is a viable option for NARS and does not require a national IPR system. They are intended to provide the supplier of biological material with sufficient protection while facilitating the freedom necessary for research. Material transfer agreements, while requiring legal expertise in drawing them up, provide a safeguard for national investments in technology or biological resources by setting out the terms or conditions for using the material obtained under such an agreement. As a legal agreement, formalized between the partners involved, it is in effect a form of intellectual property protection. Standard formats for material transfer agreements have been developed which would simplify the exchange of biological materials between various institutions (AUTM 1992).

Where IPR protection does exist in a developing country it can use either PBR or patents, with the respective implications of these two systems as summarized in Chapter 3. If either system is employed, it can be linked to appropriate licensing arrangements.

6.3 Technology Transfer and IPR

Regardless of whether an innovation in biotechnology begins with public- or proprietary-domain technology, decisions still have to be taken regarding the best route for the technology transfer and final production. Various options are available, including public dissemination of goods for which no license is required following the registration and publication of results. For protected technologies, either exclusive or non-exclusive licenses may be granted.

Technology transfer mechanisms will need to be matched to the expectations for national technology objectives (Figure 1). If national policy is to encourage general distribution of public agricultural goods and services, including those of biotechnology, then technology transfer will occur without licenses or contracts. However, this can place a heavy burden on the NARS to deliver products. Alternatively, if expanded routes for technology transfer are desired, then the choice will relate directly to the primary options available for the protection of IPR.

If some form of IPR protection is envisioned, or already exists, for agricultural technology then the national agricultural research system has the option of using licensing or contracts, in either a non-exclusive or an exclusive manner. The question here is which option will result in the greatest general public benefit in the shortest time? In most cases a non-exclusive license will be preferable. However, a non-exclusive license may retard the pace of commercialization when a discovery requires exacting production conditions and quality standards. This may be the case for specialized products, especially those needed for animal health care. For such products, exclusivity may help stimulate private-sector investment in advertising and support of the extension activities needed to accompany distribution of the product.

Such decisions regarding licenses and technology transfer can be facilitated through an institutional Office of Intellectual Property. Such a service can help transfer and assign rights arising from innovations at public-sector institutions, such as universities and national agencies. To be effective, both the Office of Intellectual Property and other institutional professionals should gain a full appreciation of the complexities of licensing technologies for transfer, including the financial investment needed to bring biotechnology research products to the market, and the ability to value institutional inventions.

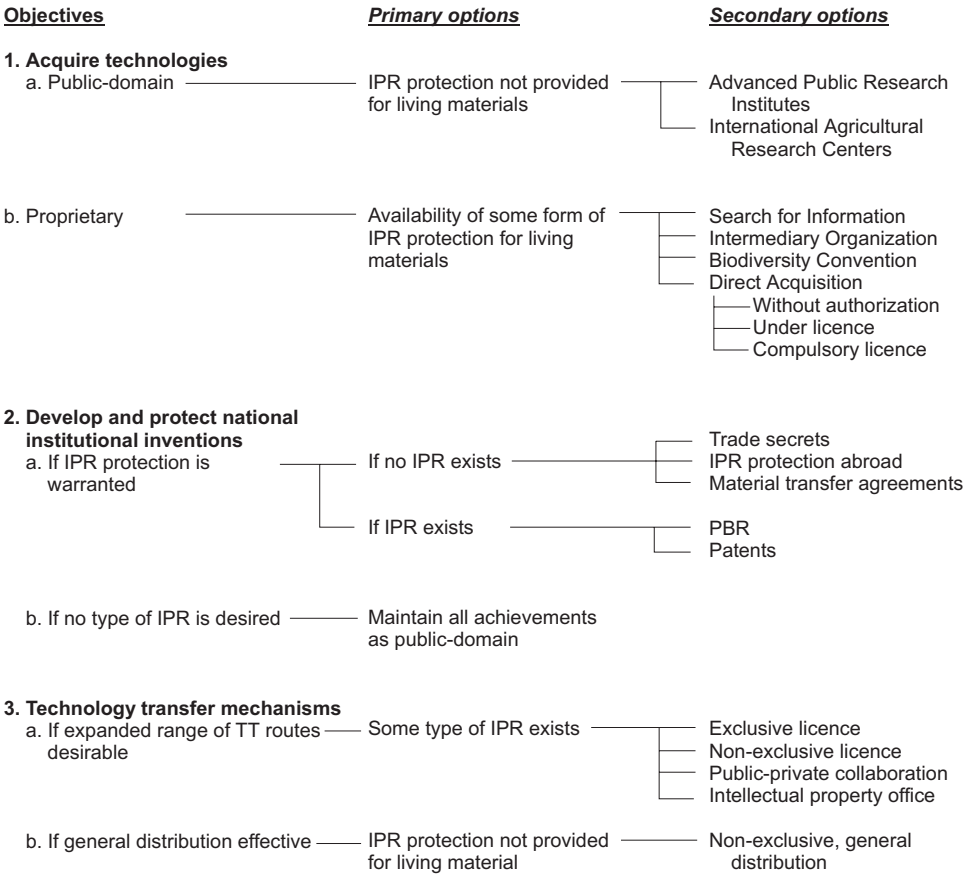

Figure 1. Decision tree illustrating technology objectives and options for IPR

NARS institutions will want to develop consistent policies for innovations in biotechnology which could be subject matter for licensing and special exemptions. The NARS will benefit from enacting such policies and providing a means to realistically assess potential funding arrangements. Researchers and administrators will have to decide which innovations are eligible for patenting or PBR, what are the consequences of these choices, and what can or cannot be done with the protected material (Baenziger et al. 1993).

Another technology transfer option open to NARS with respect to improved technology is that of research collaboration with commercial or private-sector firms. Opportunities for such collaboration, and complications in assessing value and potential commercial/proprietary interest, have been identified for crops of importance to subsistence farmers (Cohen and Chambers 1992). In general, it is recognized that private-sector involvement in the provision of agriservices increases the availability of technologies and inputs to farmers, consumers, and growers. This, in part, has led to widespread interest in increasing the opportunities available for involving the private seed industry (Barton and Siebeck 1992).

If **no** IPR system exists, as mentioned above in Section 6.2, there are other mechanisms which can begin to provide for future technology transfer agreements. These include material transfer agreements, trade secrets and access to know-how. Each of these mechanisms determines, in its own way, the conditions under which materials, know-how or technologies are exchanged and the conditions to be complied with for subsequent innovations. By invoking such mechanisms, national decision makers and directors of research are able to consider alternative technology transfer agreements.

7. CONCLUSION

Determining whether a stringent or permissive national policy on IPR is needed is just one factor among many which must be considered in building an effective national capability in biotechnology. Although empirical studies on the impact of the presence or absence of intellectual property protection in developing countries are still largely lacking, there is a growing consensus that adequate protection of IPR is necessary for increasing the flow of technology and know-how and for stimulating investment in biotechnology. While providing a stringent IPR system should not be regarded as mandatory for a national biotechnology initiative in developing countries, adequate IPR can be helpful in providing alternatives for technology acquisition, protecting institutional inventiveness and broadening technology transfer options.

National policymakers and directors of research can draw assistance from a number of alternative sources to help them determine IPR options for biotechnology. These sources include international biotechnology programs, the CGIAR centers, patent offices and public and private research organizations. Whichever route is chosen, and whether it is used to assist in direct acquisition of technology, technology transfer or developing national IPR legislation, it is important that biotechnological innovations are applied to local needs. This means that the right to use these inventions, which are generally protected through some form of IPR, must be extended under conditions agreeable to all parties concerned. Agreements may have to be negotiated one at a time until a precedent is set for agreement between those holding IPR and those seeking to use them to enhance productivity in the developing countries.

Decisions on biotechnology and IPR will also be guided by the extent to which national innovative capacity is an objective of general scientific and technology policy, and the ability of programs to use acquired material in various phases of biotechnology development. In nations where the local technology base is weak, stronger IPR are hardly likely to increase indigenous technological development. However, as national capabilities in biotechnology improve, and local innovative capacity is demonstrated, the opinions regarding the value of IPR may change.

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ANNEX I. Status of Intellectual Property Protection of Agricultural Innovations in Selected Developing Countries

Country	Plant Breeders' Rights (PBR)	Patents
	LATIN AMERICA	
Andean Pact countries*	In early 1993, the *Commission of the Cartagena Agreement* decided that plant varieties must be protected through PBR legislation.	A final decision on the patenting of life forms has not yet been taken in the Andean Pact countries. It is likely that life forms will be considered to be patentable, except for biological materials that exist in nature.
Argentina	Available since 1978. Effective only recently. Argentina is on the verge of acceding to UPOV.	The current patent law (from 1864) does not exclude living material. In mid-1991, President Menem submitted to Congress a modernized patent bill. Pursuant to this draft bill, modified microorganisms, subcellular parts, and transgenic plants would be patentable. The draft law is heavily disputed; eight other patent bills have been introduced by members of congress.
Brazil	Currently under consideration.	The current patent law excludes: plant and animal varieties as well as biological processes for producing them, microorganisms and substances obtained by microbial processes, and food products. The new patent law, under consideration since 1990, is heavily disputed. The present bill limits biotechnology patents to microorganisms with specific commercial applications. Plants and animals are not patentable.
Chile	Available since 1977. Effective only recently.	The new *Chilean Law on Industrial Property*, published in 1991, provides for patent protection for biotechnological inventions. Plant varieties and animal races are not patentable. Plant varieties are to be protected under PBR.
Mexico	Not available. Within the framework of the *North American Free Trade Agreement* (NAFTA), Mexico agreed to adopt PBR and accede to UPOV within 2 years after the entry into force of NAFTA.	The Law for the *Promotion and Protection of Industrial Property*, adopted in 1991, provides for patent protection for biotechnological processes for obtaining food and beverages, agricultural chemicals, plant varieties and inventions related to microorganisms. Not patentable are plant species, animal species and breeds, genetic material, and essentially biological processes for obtaining or reproducing plants, animals or their varieties, including genetic processes or processes related to material which is capable of self-replication.

Country	Plant Breeders' Rights (PBR)	Patemts
	AFRICA	
Kenya	Kenya's *Seed and Plant Varieties Act* was enacted in 1975, but is dormant.	Kenya's *Industrial Property Act* was adopted in 1989, but is not yet fully implemented. The act excludes plant varieties, but not parts thereof or products of biotechnological processes.
OAPI**	Not Available	Pursuant to the OAPI Agreement (1977) excluded are: plant varieties, animal species, and essentially biological processes for the breeding of plants or animals other than microbiological processes and the products of such processes.
South Africa	Available. South Africa is UPOV member	Patent law excludes plant and animal varieties as well as biological processes for producing plants and animals, other than microbiological processes and the products of such processes.
Uganda	Not available.	The 1991 *Patent Statute* excludes plant and animal varieties as well as biological processes for producing plants and animals.
	ASIA	
India	Not available.	The current *Indian Patent Act* (1970) excludes products in general, methods of agriculture or horticulture, and processes for the treatment of plants to render them free of disease or to increase their economic value or that of their products.
China	Not available.	The *Chinese Patent Law* (1984) has recently been revised under heavy American pressure. The revised law has been effective from 1993 onwards and excludes plant and animal varieties.
South Korea	Not available.	The *South Korean Patent Law* does not exclude specific subject matter in the realm of biotechnology. The patent office is currently considering the allowance of patent registrations on plant and animal inventions.
Thailand	Not available.	Thailand adopted *Patent Act No. 2* in 1992, which allows for the patenting of biotechnological inventions. Naturally existing microorganisms and their components, animals, plants or animal and plant extracts are not patentable.

Main sources: WIPO (1990), *Exclusions from patent protection.* HL/CM/INF/1, Geneva; *World Intellectual Property Report,* Volumes 1991-93.

* Member states of the *Andean Pact* are: Bolivia, Colombia, Ecuador, Peru and Venezuela.

** Member states of the *Organisation Africaine de la ProPriJtJ Intellectuelle* (OAPI) are: Benin, Burkina Faso, Cameroon, Central African Republic, Chad, Congo, C^te d'Ivoire, Gabon, Guinea, Mali, Mauritania, Niger, Senegal and Togo.

ANNEX II. The Patent Literature

In the light of the growth of commercial biotechnology, the patent literature is becoming an important source of information for the biological researcher. This brief note outlines the information available and provides an introduction to the search task.

No one should approach the literature without a prior understanding of what they are seeking — there are patent searches and there are patent searches. For example, one can use the patents in a particular area as a source of scientific information, one can search to see if a discovery has been previously patented, or one can do a search and conduct careful analysis to see if a particular course of action is likely to infringe any prior patent. The task will be increasingly expensive as exhaustiveness becomes more important or as searching must be supplemented by detailed legal analysis of the precise scope and vulnerabilities of the specific patents.

A patent itself contains a variety of indexing data, a specification, and a series of claims. The indexing data usually includes the names of the patent holder and his or her employer, an abstract, and a set of category numbers, as well as the patent number itself. The specification is a scientific essay describing the invention and telling how to practice it. By law, it must enable a skilled person to practice the invention and will often include examples of ways to use the invention, worked out in detail. The claims are the precise legal definitions exactly describing the monopoly conferred by the patent.

Because the effective scope of a patent (save for certain export and import issues) is limited to the nation for which it is granted, most applicants seek patents for the same invention in all markets of importance to them. For global research purposes, the most important patents are those issues by the European Patent Office (in Munich), the Japanese Patent Office (Tokyo), and the United States Patent and Trademark Office (Washington).

Although there are technical differences in the laws of the different patent offices, one can usually find counterpart patents reflecting the different applications covering the same invention. One difference of great importance to the researcher is that Europe and Japan make applications public 18 months after the application has been filed, while the United States does not make the application public until the patent is granted (which usually takes several years). Although this pattern may change as a result of current international negotiations, the implication for now is that the published US patent data reflects technology several years behind that described elsewhere.

Each of the offices publishes its patents in printed form, and many are now offering their patents on CD-ROMs as well. Moreover, the World Intellectual Property Organization is producing a CD-ROM series of applications under the Patent Cooperation Treaty, a treaty that streamlines the international filing process. In addition, there are a number of on-line services. Among the leading on-line systems are World Patents Index, which provides a single entry for each invention including all the references necessary to find the counterpart patents in different nations, LEXPAT available on LEXIS/NEXIS, which includes the full texts of U.S. patents, and INPADOC, assembled by the International Patent Documentation Center in Vienna. In addition, there are more specialized sources that include patents along with other data sources such as BIOTECHNOLOGY ABSTRACTS, which is available in hardcopy, CD-ROM, and on-line. Except for LEXPAT, which is available only on LEXIS/NEXIS, these services are available on-line on Dialog, STN, or Orbit.

National patent offices and the World Intellectual Property Office in Geneva are also assisting developing nations by making available many of the materials — typically in

CD-ROM form — to national patent offices. There are also a number of depositories in the United States which have complete US patent libraries, on a combination of paper, microfilm, and CD-ROM, and with a number of good searching indices and tools.

The easy way to obtain access to these materials is through a firm which will do a patent search. For a basic review, this will normally cost in the low thousands of dollars. The least expensive, but difficult, way is to work at one of the patent office libraries scattered around the world. The on-line services will pose an intermediate cost; there are substantial access charges for some of the services.

ANNEX III. Experts Consulted

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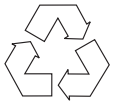

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