Issues in Genetic Resources No. 6 June 1997

Intellectual Property Rights and Plant Genetic Resources: Options for a *Sui Generis* System

Dan Leskien and Michael Flitner

Abstract

This study aims at the development and evaluation of elements for inclusion in an intellectual property rights system *sui generis* for the protection of plant varieties. Pursuant to the TRIPS Agreement, members shall provide patent protection for any inventions, whether products or processes, in all fields of technology. Members are allowed to exclude from patentability *inter alia* plants and animals other than microorganisms. However, the TRIPS Agreement explicitly requires members to provide for the protection of plant varieties either "by patents or by an effective *sui generis* system or by any combination thereof."

The report studies the legal obligations posed by the TRIPS agreement in relation to plant genetic resources. It further analyzes the status of plant genetic resources under the existing international regulatory framework, in particular the Convention on Biological Diversity. The study gives an overview of and discusses possible elements, for example recognition of Farmers' Rights, which, if included in a protection system for plant varieties, may contribute to reconciliation of the interests of formal breeders with the rights and interests of informal breeders. The study also examines the options for regulating the interface between a *sui generis* legislation and other intellectual property rights, such as patents. There is a broad range of possible TRIPS-compatible *sui generis* systems. Those systems should be explored and discussed before ready-made protection systems currently being used in many industrialized countries are adopted.

Volume editor: Jan Engels

Issues in Genetic Resources is an occasional series of papers published by IPGRI on important topics of interest to the genetic resources community.

The **International Plant Genetic Resources Institute** (IPGRI) is an autonomous international scientific organization operating under the aegis of the Consultative Group on International Agricultural Research (CGIAR). The international status of IPGRI is conferred under an Establishment Agreement which, by March 1997, had been signed by the Governments of Algeria, Australia, Belgium, Benin, Bolivia, Brazil, Burkina Faso, Cameroon, Chile, China, Congo, Costa Rica, Côte d'Ivoire, Cyprus, Czech Republic, Denmark, Ecuador, Egypt, Greece, Guinea, Hungary, India, Indonesia, Iran, Israel, Italy, Jordan, Kenya, Malaysia, Mauritania, Morocco, Pakistan, Panama, Peru, Poland, Portugal, Romania, Russia, Senegal, Slovak Republic, Sudan, Switzerland, Syria, Tunisia, Turkey, Uganda and Ukraine. IPGRI's mandate is to advance the conservation and use of plant genetic resources for the benefit of present and future generations. IPGRI works in partnership with other organizations, undertaking research, training and the provision of scientific and technical advice and information, and has a particularly strong programme link with the Food and Agriculture Organization of the United Nations. Financial support for the research agenda of IPGRI is provided by the Governments of Australia, Austria, Belgium, Canada, China, Denmark, Finland, France, Germany, India, Italy, Japan, the Republic of Korea, Luxembourg, Mexico, the Netherlands, Norway, the Philippines, Spain, Sweden, Switzerland, the UK and the USA, and by the Asian Development Bank, CTA, European Union, IDRC, IFAD, Interamerican Development Bank, UNDP and the World Bank.

Citation:
Leskien, Dan and Michael Flitner. 1997. Intellectual Property Rights and Plant Genetic Resources: Options for a *Sui Generis* System. Issues in Genetic Resources No. 6, June 1997. International Plant Genetic Resources Institute, Rome, Italy.

ISBN 92-9043-329-9

IPGRI
Via delle Sette Chiese 142
00145 Rome
Italy

Contents

Preface

As per the Agreement on Trade Related aspects of Intellectual Property Rights of the World Trade Organization (WTO), member countries shall provide patent protection for any invention. However, according to Article 27 (3) b of the Agreement, member countries are allowed to exclude from patentability *inter alia* plants and animals other than microorganisms as well as essentially biological processes, other than non-biological and microbiological processes, for the production of plants or animals. Should countries choose not to recognize patent protection on plants, they are required to provide for the protection of plant varieties by an "effective *sui generis* system". The TRIPS Agreement foresees a review of this provision four years after the date of entry into force of the WTO-TRIPS Agreement, i.e. in 1999.

In view of the importance of the decision of countries to opt for patents, an effective *sui generis* system, or a combination thereof, to protect plant varieties, the International Plant Genetic Resources Institute (IPGRI) has commissioned a study of these options with the aim of also developing elements which might be incorporated within *sui generis* legislation. Such a study, it was hoped, would facilitate the establishment of "tailor-made" protection systems which are well adapted to the national needs and requirements of individual countries.

The study and production of the subsequent report have been carried out by Dan Leskien, an academic lawyer based in Hamburg, and Michael Flitner, an economic geographer currently with the University of Freiburg, Germany. Throughout the study and report-writing, wide consultation with experts was carried out. A first draft was sent to selected organizations and individuals with the request to provide a written critique and to point to any factual errors in the report. While many comments came in, few critiques were received. Therefore, it was decided to incorporate all the inputs directly into the report and these contributions and comments are hereby duly acknowledged and individuals thanked for their time and efforts. The financial contribution from the Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ), Eschborn, Germany is also gratefully acknowledged.

Rome, June 1997
Geoffrey Hawtin
Director General

Acknowledgements

This study would never have materialized but for the opportunity provided to us by the International Plant Genetic Resources Institute (IPGRI), in particular Geoffrey Hawtin, Director General and Jan Engels, Director of the Genetic Resources Science and Technology Group.

We are particularly indebted to Lyle Glowka (IUCN Environmental Law Centre, Bonn) and Carlos M. Correa (University of Buenos Aires) for their numerous suggestions for editorial and substantive improvements. Chapter 3 of this study was produced in collaboration with Ms Gudrun Henne (Free University of Berlin). Special thanks go to Remke den Bremer (Dutch Ministry of Agriculture, The Hague), Bees Butler (University of California, Davis), José Esquinas-Alcazar (FAO, Rome), Mary E. Footer (International Development Law Institute, Rome), Bart Kiewiet (European Plant Variety Office, Brussels), Bernard Le Buanec (FIS/ASSINSEL, Nyon), R.S. Paroda (Ministry of Agriculture, New Delhi), Wolfgang Ritter (ATSAF, Bonn), Tim Roberts (Lawyer, UK), Stephen Smith (Pioneer HI-Bred, Iowa), Peter-Tobias Stoll (Max-Planck-Institut für ausländisches öffentliches Recht und Völkerrecht, Heidelberg), M.S. Swaminathan (M.S. Swaminathan Research Foundation, Madras), Carl-Gustaf Thornström (Sida-SAREC) and M. Yeater (UNEP, Nairobi) for their helpful comments on the first draft.

Our thanks are also due to Nelson Alvarez, Miges Baumann and Henk Hobbelink, (GRAIN, Barcelona), Frank Begemann (Centre for Agricultural Documentation and Information, Bonn), Barry Greengrass and André Heitz (UPOV, Geneva), Huib Ghijsen (CPRO-DLO, Wageningen), Reiner Hron (Variety Protection Office, Vienna), Pat Mooney (RAFI, Ottawa), Adrian Otten (WTO, Geneva), Gurdial Singh Nijar (Third World Network, Penang), Klaus Supp (Federal Ministry for Food, Agriculture and Forestry, Bonn) and Karl-Heinz Wolpers (GTZ, Eschborn), who made time to discuss different ideas with the authors.

We would also like to express our warm appreciation for the efforts of the editors Richard Boyce, Erica Rolfe and Linda Sears, to Gill Lacroix for producing successive versions of the text and to the Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) for their contribution to the production of this paper.

The findings, interpretations, and conclusions expressed in this paper are those of the authors only.

Dan Leskien, Hamburg
Michael Flitner, Freiburg

Introduction

The aim of this study is the development and evaluation of elements for inclusion in an Intellectual Property Rights (IPR) system *sui generis* for plant varieties. The obligation to provide for the protection of plant varieties either by patents or by an "effective *sui generis* system or by combination thereof" is enshrined in the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

In the debate over plant genetic resources, the term '*sui generis* system' has no uniform meaning. It is sometimes used to denote alternative rights regimes for the protection of community innovations not protectable under conventional intellectual property laws, or to mean a system embodying farmers' and indigenous peoples' rights. Since this study aims to explore TRIPS-compatible elements for the protection of plant varieties, we use the term '*sui generis* system' not in this wider sense, but strictly in accordance with its meaning within the TRIPS Agreement.

Yet, the *sui generis* system for plant varieties could contain elements serving as a tool or 'trigger' for benefit-sharing mechanisms between providers and users of germplasm and related knowledge. Some of these elements which could at least facilitate the sharing of benefits will be discussed in this study. However, it seems that the *sui generis* system is not the most suitable and most effective instrument for addressing this issue, as the coverage of any *sui generis* system in the sense understood in the TRIPS Agreement will inevitably be less broad than that by access legislation or product authorization laws. Similarly, 'traditional resource rights' cannot be realized solely by a *sui generis* system in the sense understood in the TRIPS Agreement. Property issues relating to biological resources are only one among many concerns of farming communities and indigenous peoples. Consequently, the establishment of a reward system *sui generis* for plant varieties may require that complimentary legislation be implemented simultaneously, providing for fair and equitable benefit-sharing and recognizing traditional resource rights including Farmers' Rights.

The study consists of five main chapters. Chapter 1 elaborates on the obligations and options with regard to the patenting of plant genetic material under the TRIPS Agreement. Chapter 2 summarizes the minimum requirements a TRIPS-compatible *sui generis* system for the protection of plant varieties has to comply with. Chapter 3 outlines the international framework on plant genetic resources as it has developed over the last decade. There are several international legal texts dealing specifically with biological resources and with the rights and obligations of their caretakers and users. Any future legislative intervention in this area should certainly take account not only of the existing binding agreements but also of the emerging non-binding principles in international law. Chapter 4 discusses a range of different possible elements for inclusion in a *sui generis* right for the protection of plant varieties. The elements of existing plant variety protection laws of several countries are analyzed and several new elements that may be helpful in tailoring national laws to the specific needs of different countries, in line with the obligations of the TRIPS Agreement, are proposed. Chapter 5 summarizes the considerations that should be taken into account when designing a *sui generis* system and furnishes an example of one of the many possible ways to bring the different elements of a *sui generis* system together.

1. Plant Genetic Resources and the TRIPS Agreement

Summary

Members of the World Trade Organization (WTO) shall provide patent protection for any inventions, whether products or processes, in all fields of technology, provided the inventions are new, involve an inventive step and are capable of industrial application. They are allowed, however, to exclude from patentability *inter alia* plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. Yet members are required to provide for the protection of plant varieties either by patents or by an "effective *sui generis* system or by any combination thereof".

If member states do not opt for this general exclusion, however, plants and parts thereof would still have to comply with the general requirements of patent law, which may pose serious impediments to the granting of patents which claim or relate to plants or parts thereof.

Member states remain free to refuse patents for living material which has merely been discovered or whose use is already known. It does not follow from the TRIPS Agreement that by their first isolation or by purification, naturally occurring gene sequences and other parts of plants must become eligible for patent protection.

The TRIPS Agreement does not oblige member states to recognize the deposit of self-replicable material as equivalent to the written, sufficiently clear and complete disclosure of an invention. This non-recognition of the deposit of plants and parts thereof for patent purposes may *de facto* exclude many plant genetic innovations from patentability.

Furthermore, plant genetic innovations may fall under the optional exclusion from patentability of inventions, the prevention of the commercial exploitation of which within their territory is necessary to protect *ordre public* or morality. This includes protecting human, animal or plant life or health and avoiding serious prejudice to the environment. While such exclusions must not be made merely because the exploitation of the invention is prohibited by a member state's law, approval of the exploitation does not *per se* suffice to establish compliance of an invention with *ordre public* and morality.

The TRIPS Agreement enumerates the patent protection requirements (novelty, non-obviousness, industrial applicability/usefulness) but does not define them in detail. In particular, the requirement of non-obviousness (inventive step) may constitute a serious obstacle for plant genetic innovations.

Finally, the TRIPS Agreement does not define in detail the scope of protection of patents on biological material and biotechnological processes. Although it is not clear from the TRIPS Agreement whether members providing patent protection for plants would have to ensure that the protection conferred by such patents also extends to plants which have been produced without using the invention, but by propagation or multiplication instead, it is certainly not impossible that a panel would take this view. In order to be on the "safe side" members which are not interested in providing any patent protection in relation to plants should therefore exclude plants and essentially biological processes from patentability.

On 1 January 1995 the Marrakech Agreement establishing the World Trade Organization entered into force. So far 131 countries have accepted the Agreement and a further 29 countries are in the process of negotiating their accession to it. Membership of the WTO is thus almost universal.

Pursuant to the WTO Agreement's Annex 1C, which is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), members shall provide patent protection for any invention, whether product or process, in all fields of technology, provided the invention is new, involves an inventive step, is capable of industrial application, and is disclosed in a manner sufficiently clear and complete to be carried out by a person skilled in the art.[1] Member states are allowed, however, to exclude from patentability *inter alia* plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, members are required to provide for the protection of plant varieties either by patents or by an "effective *sui generis* system or by any combination thereof".

In relation to plants there are at least four alternative approaches (see Table 1) from among which WTO member states may choose:

- They may exclude plants (including plant varieties) from patentability. Consequently they would have to establish a *sui generis* system for the protection of plant varieties. Technically such a *sui generis* system could form part of other IPR laws such as the patent law. Alternatively it could be included in a separate law.
- Member states may also choose not to exclude plants (including plant varieties) from patentability and, consequently, apply the normal patent requirements to plant varieties. In this case they would not have to set up a *sui generis* system for the protection of plant varieties.
- Member states could also decide not to exclude plants from patentability and to provide for the protection of plants / plant varieties by two forms of protection, a *sui generis* system and patent law. This approach would reflect the legal situation as it exists in principle in the United States.
- Finally, member states could choose to exclude only plant varieties from patentability. In this case the question would arise as to whether 'plant varieties' as such would then be patentable. In any case member states choosing this alternative, which is reflected in the European Patent Convention (EPC), would have to provide for the protection of plant varieties by a *sui generis* system. (The reverse option – exclusion of plants other than plant varieties – is a non-option since a plant variety is always physically represented by plants while, vice versa, not all plants necessarily belong to a variety.)

While this study focuses on the development of a *sui generis* system for the protection of plant varieties, the alternatives have not been ignored. First, because even if plants are excluded from patentability there may be overlaps between a *sui generis* system and patent legislation, which need careful consideration. Second, the option not to exclude

[1] The terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively; cf. Article 27 (1) TRIPS Agreement.

Table 1. Article 27 (3) b TRIPS Agreement and the options relating to plants

	No exclusion of plants	Exclusion of plant varieties only	Exclusion of plants (including plant varieties)
Patentability of:	• plants (including plant varieties)	• plants other than plant varieties	
Establishment of a *sui generis* system for plant varieties	• optional ("combination thereof")	• required	• required

plants (including plant varieties) from patentability needs to be considered since it could turn out to be an easier and more cost-effective way to follow the obligations posed by the TRIPS Agreement without prejudicing the actual granting of patents for plants.

Thus, after considering briefly the time frame for implementing the TRIPS Agreement (1.1) and the principles which are relevant for its interpretation (1.2) this chapter discusses the patentability of plant genetic materials in case plants are not excluded from patentability (1.3). The subsequent sections discuss the option to exclude inventions from patentability on grounds of *ordre public*, morality and protection of the environment (1.4) and the option to exclude plants (1.5) and essentially biological processes from patentability (1.6). Subsequently the rights conferred by patents on biological material (1.7) as well as the scope of such patents (1.8) are discussed. Finally possible exceptions to the rights conferred by such patents (1.9) as well as the instrument of compulsory licensing (1.10) are discussed.

1.1 The time frame for implementing the TRIPS Agreement

1.1.1 Developed and developing countries

The Agreement establishing the World Trade Organisation came into effect on 1 January 1995. Member states are obliged to apply all the provisions of the TRIPS Agreement from 1 January 1996 (Art. 65 (1) TRIPS). Developing country members and, under certain conditions, also members in the process of transformation from a centrally planned to a market, free-enterprise economy may delay the date of application of the TRIPS Agreement to 1 January 2000 (Art. 65 (2) and (3) TRIPS).

A further transition period is available for developing countries. Developing countries which are obliged under the TRIPS Agreement to extend product patent protection to areas of technology which have not been protectable before 1 January 2000, may delay the granting of such product patents for a further period of five years. This transition period is likely to be of relevance primarily for pharmaceuticals and chemicals as well as microorganisms. However, only if these products have not been patentable before 1 January 1995, may a developing country make use of this transition period (Art. 65 (4) TRIPS). Given that the TRIPS Agreement does not oblige member states to extend product patent protection to plants, the second transition period is not relevant for plants. And since Art. 65 (4) TRIPS is applicable to patents only, neither is this second transition period available for the *sui generis* system for the protection of plant varieties, even if a *sui generis* system would provide for patent-like protection.

1.1.2 Least-developed countries

Least-developed countries are not required to apply the provisions of the TRIPS Agreement before 1 January 2005. However, insofar as they provide for intellectual property protection, least-developed countries have to treat nationals of other WTO members no less favourably than their own nationals. They also have to accord any advantage, privilege or immunity granted to the nationals of any other country to the nationals of all other WTO members (Art. 66 (1) TRIPS).

Upon a duly grounded request by a least-developed country, the ten-year transition period may be extended.

1.1.3 Exclusive marketing rights

Irrespective of whether a member is a developed or least-developed country, the TRIPS Agreement requires members which do not make available, as of 1 January 1995, patent protection for pharmaceutical and agricultural chemical products, to provide some means by which patent applications concerning such products can be filed. The rationale behind this obligation is two-fold. Firstly, it ensures that as soon as pharmaceutical and agricultural chemical products finally become patentable (by 2005 at the latest in developing countries) countries will have to grant product patents not only for new applications, but also for all those submitted since the beginning of 1995.

Secondly, and more importantly, least-developed as well as developing country members that avail themselves of the full ten-year transition period for product patents are required to grant exclusive marketing rights for pharmaceutical and agricultural chemical products. These exclusive marketing rights shall be granted for a period of five years after obtaining marketing approval in that country, or until a product patent is granted or rejected, whichever period is shorter. Exclusive marketing rights must be granted if a patent application has been filed after 1994 and a patent for that product, as well as marketing approval, has been granted in another member state. Thus, to be eligible for an exclusive marketing right, an applicant will have to:

- file a patent application in the developing or least-developed country,
- file an application and obtain a patent for the same product in another WTO member state, and
- obtain marketing approval in that WTO member and in the developing/least-developed country.

In practice, the differences between exclusive marketing rights and product patents might well be of minor relevance. It has been argued that the obligation to grant such rights from 1995 onward has made the transition period for developing countries an empty promise (Dubey 1996).

1.1.4 Review of Art. 27 (3) b TRIPS

It is important to bear in mind that, in 1999, just one year before developing countries will have to implement the TRIPS Agreement into their respective national laws, Article 27 (3) b – the provision of the Agreement which requires the protection of plant varieties – is to be reviewed. The outcome of this review is certainly not predictable. Whatever the outcome, however, the elaboration of possible elements of a rights regime '*sui generis*' for plant varieties is not premature. If this provision passes the review in 1999 unchanged, it leaves less than a year for the development and thorough discussion of a '*sui generis* system'. Moreover, several states are already in the process of developing plant variety legislation, without any international obligation to do so. Thus, no matter whether the requirement to

provide for the protection of plant varieties will be strengthened, weakened or completely abandoned in the 1999 review, considerations related to the legal status of plant genetic resources and related knowledge will continue to be of great importance.

1.2 Interpretation of the TRIPS Agreement

As will be shown, the TRIPS Agreement leaves unanswered quite a number of questions that may arise when it comes to the protection, in particular the patenting, of plant genetic material. Although the legal competence to interpret the TRIPS Agreement lies with the WTO Dispute Settlement Body (Art. 64 (1) TRIPS Agreement), for the purposes of this study some interpretation of those provisions crucial for assessing the scope of obligations under TRIPS is unavoidable. The basic rules on interpreting the TRIPS Agreement are therefore summarized here.

There are three main schools of thought on the subject of treaty interpretation in international law. The first, textual, approach focuses on the ordinary meaning of the words of the treaty. The second concentrates on the intention of the parties to the treaty. Finally, the third approach looks at the treaty's aims and objectives. The Vienna Convention on the Law of Treaties (1969) takes a cumulative approach giving credit to all three: according to Art. 31 (1) a treaty shall be interpreted in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose. Where the interpretation according to Art. 31 leaves the meaning ambiguous or obscure or leads to a result which is manifestly absurd or unreasonable, recourse may be had to supplementary means of interpretation, such as the preparatory work of the treaty and the circumstances of its conclusion (Art. 32 Vienna Convention).

1.2.1 Dispute Settlement Understanding (DSU)

Since the rules of interpretation as codified by the Vienna Convention are considered an expression of customary international law (Bernhardt 1995), they are of paramount importance in interpreting the provisions of the TRIPS Agreement. Art. 3 (2) of the WTO Understanding of Rules and Procedures Governing the Settlement of Disputes (Dispute Settlement Understanding, DSU) explicitly states that "customary rules of interpretation of public international law" shall be applied to disputes brought under this Understanding.

However, the Dispute Settlement Understanding also states that "recommendations and rulings of the Dispute Settlement Body cannot add to or diminish the rights and obligations provided in the covered agreements" (Art. 3 (2) DSU). The purpose of this qualification is not very clear, given the fact that the dispute settlement system only serves to preserve the rights and obligations of the member states under the covered agreements and to "clarify the existing provisions of those agreements". What is clear, at least, is that panels, or the Appellate Body on appeal, should not make law. Some commentators, however, have interpreted this specific prohibition to add to or diminish the rights and obligations as a rejection of the rather pragmatic and dynamic approach taken, from their point of view, by the former GATT panels (Kohona 1994; Stoll 1994).

The legal status of plant genetic resources under the TRIPS Agreement may depend in some cases on technical and scientific aspects. A panel may, for example, wish to draw a dividing line between plants which may be excluded from patentability and microorganisms which member states are not allowed to exclude (Art. 27 (3) b TRIPS). In such a case panels have the right to seek information and technical advice from any individual or body which they deem appropriate (Art. 13 DSU).

1.2.2 TRIPS as minimum standard

The TRIPS Agreement only sets minimum standards; members may, but shall not be obliged to, incorporate into their law more extensive protection than that required by the TRIPS Agreement. The mere fact that certain innovations have been granted patent protection in some member states does not imply an obligation for other member states to do the same if the TRIPS Agreement does not require them to do so. It should be noted, however, that as a consequence of the national-treatment principle, members providing their own nationals with patent protection for certain categories of inventions have to make this same protection available to the nationals of all other members.

1.3 The patentability of plant genetic innovations under Article 27 (1) TRIPS

This section examines the extent to which and under which conditions WTO member states have to grant patent protection for inventions whose subject is composed of, uses or is applied to plant genetic material, if they decide not to make use of Art. 27 (2) and (3). For the purpose of this examination, plant genetic material is to be understood as any plant material containing genetic information which is capable of self-reproduction or of being reproduced in a biological system. Plant genetic material embraces genetic resources of actual or potential value, containing functional units of heredity which may be utilized for practical applications.

1.3.1 Plant genetic innovations as inventions

Whether plant genetic material may constitute the subject of an invention has been and is still controversial among the WTO member states (Verma 1994; Pacon 1995; WTO 1995). The TRIPS Agreement is clearly based on the assumption that there may at least be inventions relating to plants; otherwise the negotiating parties would not have included the possibility of excluding plants from patentability.

The first and basic requirement an innovation has to comply with, for the purposes of patent law, is that there be an invention. Neither the TRIPS Agreement nor the Paris Convention give any definition of what an invention should be. The EPC does not define the term 'invention', while US patent law only gives a definition of what may be invented, i.e. any new and useful process, machine, manufacture or composition of matter, or any useful improvement thereof (35 USCS 101). There is, however, general agreement that, for the purposes of patent law, innovations need to be practical and technical (European Commission 1995).

These requirements, practicality and technicality, should not be confused with the specific patent requirements (novelty, non-obviousness/inventive step, usefulness/industrial applicability, sufficient disclosure) that inventions also have to fulfil. Thus, as a first step, innovations must be of a practical and technical nature in order to constitute an invention in the meaning of patent law. Thereafter, to be eligible for patent protection, these

inventions have to fulfil the patent requirements of novelty, non-obviousness and usefulness. And finally, their disclosure has to be sufficiently clear and complete.

However, this first step concerning the required practical and technical character of inventions may present serious impediments to the patenting of innovations which are composed of, use or are applied to plant genetic material.

1.3.1.1 Practicality

The requirement of practicality essentially means that there must be something more than a mere discovery of an abstract idea, something more than a natural phenomenon.

In the field of biotechnology, defining the precise line between unpatentable discoveries and patentable inventions may lead to specific problems that have yet to be solved. This is because most products of biotechnology are or are based on genes or cells that have been taken from nature or isolated from pre-existing living microorganisms, plants, animals or humans. Secondly, biotechnological innovations make use of or are applied to living material, which may be described as a natural phenomenon. Although patent applications concerning such innovations do not claim the invention of life as such, their very cause and effect are inextricably linked with the self-replicability of biological material.

Naturally occurring substances

Although the patent laws of some countries use the words 'invention' and 'discovery' synonymously, it is a universally accepted principle that discoveries in the strict sense of the word are not patentable (Straus 1987). The EPC, like the laws of many other countries, goes so far as to explicitly exclude discoveries from patentability. The Guidelines for Examination in the European Patent Office (EPO) highlight the difference between inventions and mere discoveries by way of example: "If a man finds out a new property of a known material or article, that is mere discovery and unpatentable. If, however, a man puts that property to practical use he has made an invention which may be patentable" (Part C, chapter IV, 2.3).

In most industrialized countries, the fact that the subject matter of an innovation is composed of pre-existing material is no longer considered as an impediment to its patentability. However, according to the above Guidelines a substance found in nature is patentable only if the substance has first to be isolated from its surroundings, can be properly characterized either by the process by which it is obtained ('product-by-process'), by its structure or by other parameters, and finally, is 'new' in the sense of having no previously recognized existence. Thus, as soon as some human intervention has been required to isolate a naturally occurring substance, and the inventor has undertaken to properly characterize it, the 'discovered' substance is held to be a patentable invention.

As with the EPC, under Section 101a. of the US Patent Law, naturally occurring substances as such would not be considered a "manufacture" or "composition of matter" eligible for patent protection. In *Funk Bros. Seed Co. vs. Kale Inoculant Co*., a patent for a mixture of nitrogen-fixing *Rhizobium* bacteria was denied on the grounds that it was a discovery of a phenomenon of nature. The US Supreme Court held that "the qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none" (333 US 127 [1948]). The so-called product-of-nature doctrine was reaffirmed by the landmark case of *Diamond vs. Chakrabarty*, in which the Supreme Court emphasized that the genetically modified oil-consuming bacteria in that case were a "manufacture" rather than an unpatentable product of nature (206 USPQ 193).

However, since then, as is the case under the EPC, naturally occurring substances, like cells or genes, have also become patentable under US law if they have been purified or isolated from pre-existing material. It is in fact a very thin line that separates invention from discovery under both US law and the EPC (Correa 1994b).

Nonetheless, there is reason to assume that even in some member states of the European Union the discovery objection could still be successfully raised in the case of patent applications claiming biological material. This assumption is confirmed by a Proposal for a European Directive on the Legal Protection of Biotechnological Inventions which was published in the end of 1995 (European Commission 1995). By explicitly stipulating that the subject of an invention concerning a biological material should not be considered a discovery "merely on the grounds that it already formed part of the natural world", the proposal indicates that there is still a risk that without such additional legislation no common practice in relation to the patentability of pre-existing biological material would develop in the European Union (Leskien 1996).

Although in most industrialized countries there is a clear, though not uniform, trend towards recognizing isolated or purified products of nature as patentable subject matter if their existence was previously unknown, the TRIPS Agreement does not oblige WTO member states to follow this trend. TRIPS gives no indication that by their first isolation, naturally occurring gene sequences and other parts of plants have to be regarded as patentable inventions. Nor does it include any provisions on where the line between inventions and discoveries is to be drawn. Clearly, member states remain free to refuse a patent for plant genetic material which has merely been discovered or where its use was already known (Correa 1994b; WTO 1995). We would argue that they are also free to treat products of nature whose existence was previously unknown as unpatentable discoveries.

However, in the case of modified or even artificial gene sequences the argument that they are products of nature and, consequently, unpatentable discoveries may turn out to be less successful. A panel established under the dispute settlement system would probably seek expert advice on this question. One would expect that the product-of-nature rejection would be accepted only in cases where the subject matter claimed actually shows no significant difference from the substance existing in nature. If, however, genetic material has been modified so that it shows effects distinct from the naturally occurring original material, or the material is used in a manner that does not occur in nature, it is less clear whether the product-of-nature argument would succeed.

Living matter

While the distinction between products of nature and patentable inventions is still and may remain controversial in many industrialized countries, the courts in a number of countries have taken a clear position on whether living material may be patentable. The US Supreme Court declared in its 1980 decision of *Diamond vs. Chakrabarty* that "everything under the sun made by man" was patentable. In this it followed a tradition founded by the German Federal Supreme Court which, back in 1969, took the position that there was nothing in patent law to exclude in principle the repeatable application of the natural powers of living organisms (BGHZ 52, 74 - *Rote Taube*) from patentability. In *Propagating Material / CIBA GEIGY* (T 49 / 83 - OJ EPO 1984, 112) the Technical Board of the European Patent Office stated that "no general exclusion of inventions in the sphere of animate nature can be inferred from the EPC".

Though not explicitly dealing with the issue of patentability of living material, the position of the TRIPS Agreement is nonetheless clear. The mere fact that the subject matter of a patent application is or makes use of living beings or genetic material must not render the innovation unpatentable. If the negotiators of the TRIPS Agreement had intended to allow the exclusion of innovations on these grounds, they would not have included a provision which specifically allows the exclusion of certain categories of living organisms (plants and animals), while explicitly exempting microorganisms from this option.

1.3.1.2 Technicality

In order to fulfil the technicality requirement, an invention must be of a technical nature. It must also be such that a person skilled in the art can reproduce it on the basis of the information provided in the patent application.

Technical nature

The requirement that inventions must be of a technical nature is also reflected in the TRIPS Agreement, according to which patents shall be available for any inventions "in all fields of technology". In many countries living beings used not to be considered to be of a technical nature. However, this has changed over time, as can be seen in the TRIPS Agreement. Thus it follows from the explicit prohibition to exclude microorganisms and microbiological processes from patentability, that it shall not be permissible to exclude from patentability inventions which are composed of, use or are applied to biological material on the mere grounds that they are not of a technical nature. Otherwise the prohibition against excluding microorganisms and microbiological processes from patentability would be without effect.

Reproducibility

The requirement of reproducibility[2] may be problematic, especially in the case of biotechnological innovations and genetic material. It is often difficult to disclose, for example, a genetically engineered organism in such a way that the written patent application enables persons skilled in the art to reproduce the modification process so that the resulting organism is genetically identical to that claimed by the patent. The same applies to genetic sequences. A complete disclosure may be even more difficult if applicants have to indicate the best mode for carrying out the invention known to the inventor (Art. 29 (1) TRIPS).

The problem of disclosing inventions which relate to or rely on biological material that is not publicly available and cannot be described in writing alone led to the development of the instrument of deposit. In 1949 the US Patent and Trade Mark Office began recommending to inventors that patent applications for an invention involving a microorganism should include the deposit of the pertinent microorganism with a culture collection. (cf. OTA 1989). Now in the United States all material that is capable of self-replication either directly or indirectly may be deposited for patent purposes. Other industrialized countries followed the United States in accepting the deposit of microorganisms to complete the written patent application. However, even in countries like Germany, which has been a pioneer in recognizing the patentability of

[2] While the requirement of reproducibility is universally applied in patent law, some countries regard reproducibility as a question of whether the claimed product or process constitutes an invention; others treat it as a problem of sufficient disclosure (see Chapter 1.3.2 - disclosure).

biotechnological innovations (Bent *et al.* 1987), it was not until 1987 that the Federal Supreme Court overruled former decisions and accepted for the first time the deposit of a microorganism, a rabies virus, as a sufficient description of a product patent claiming that microorganism as such (BGH GRUR Int. 1987, 357- *Tollwutvirus*). Prior to this the court had accepted the deposit of samples only for the purpose of describing processes using microorganisms.

One of the main reasons for this turnaround was the European Patent Office's recognition in 1982 of the deposit of microorganisms for patents claiming microorganisms as such (cf. Rule 28 of the Implementing Rules, Part C, chapter IV, 3.5 and 3.6 of the Guidelines for Examination in the European Patent Office).

It is not yet clear whether the courts in Europe will finally also accept the deposit of biological material other than microorganisms for the purpose of sufficiently disclosing an invention. In a recent case concerning a patent on tetraploid camomile plants, the German Federal Supreme Court explicitly left unanswered the question of whether the deposit of plant seeds discloses an invention sufficiently (BGH GRUR 1993, 651 - *Tetraploide Kamille*). Even among those countries which in principle recognize the deposit of microorganisms for patent purposes, there are considerable differences as to when deposit must be made, the date from which samples of deposited material have to be made available to experts and the public, and the period of storage (Moufang and Straus 1992). Bent *et al.* state that a review of the varied national practices regarding the deposit of biological material for patent purposes reveals a "striking lack of agreement over basic principles, even among countries having any manner of established policy on the subject" (Bent *et al.* 1987). These differences also exist among those countries that are bound by the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, which entered into force on 19 August 1980.

It has been argued that the TRIPS Agreement includes an implicit obligation for member states to recognize the deposit of self-replicable material as a way of disclosing such inventions (Straus 1996). However, the fact that the TRIPS Agreement does not allow the exclusion of microorganisms and microbiological processes from patentability does not mean that member states are under an obligation to accept the deposit of microorganisms or even other self-replicable materials, for patent purposes. Such an interpretation of the TRIPS Agreement would be compelling only if the deposit of microorganisms were an absolute precondition for disclosing microorganisms sufficiently. This, however, is not the case. Usually a microorganism deposit is necessary only if the microorganism is not available to the public and cannot be described in such a way that a person skilled in the art could carry out the invention. The German Federal Patent Court, for example, held in 1978 that a microorganism may also be disclosed by a description of the process to prepare it (BPatG GRUR 1978, 586 - *Lactobacillus bavaricus*). In such a case the microorganism need not be deposited. Even if it is assumed that the depositing of biological material is essential for a complete disclosure of most innovations in the field of microbiology and biotechnology, it is certainly not correct to state that the non-recognition of the deposit for patent purposes would amount to an exclusion of microorganisms and/or microbiological processes from patentability. The argument that the TRIPS Agreement includes an implicit obligation for member states to recognize the deposit of self-replicable microorganisms for patent purposes is therefore ill-founded.

This interpretation of the TRIPS Agreement is supported by a further argument. Although the TRIPS Agreement made extensive references to existing international treaties in the field of intellectual property, there is no reference to the Budapest Treaty which

provides an international framework for the mutual recognition of deposits of microorganism strains. This clearly indicates that the negotiators did not intend the TRIPS Agreement to address the issue of depositing biological material for patent purposes.

The fact that the TRIPS Agreement does not include the Budapest Treaty's principle of recognition of deposits of microorganisms in another country means that the date of deposit of the microorganism in one country would not have to be recognized by other states. This would, however, have serious implications for the right of priority which WTO member states shall accord to nationals of other member states according to Art. 2 (2) of the TRIPS Agreement.[3] In practice the deposit of a microorganism in one state could lead to a lack-of-novelty[4] rejection in states where the application for the patent is subsequently filed, if these states are not bound by the Budapest Treaty. Thus, if member states had intended to require the recognition of the deposit of biological material for patent purposes, they would certainly have included the Budapest Treaty's principle of mutual recognition of deposits.

1.3.2 Plant genetic innovations and the patent requirements

The TRIPS Agreement does not specify what exactly is to be understood under the protection requirements of novelty, inventiveness and industrial applicability which an invention has to fulfil in order to be eligible for patent protection. Even among industrialized countries there are considerable differences in interpreting these requirements. The protection requirements may present serious impediments to the patenting of plant genetic material. Still, it is perhaps unrealistic to assume that they pose an insurmountable hurdle for all plant genetic innovations.

1.3.2.1 Novelty

Under the EPC, 'novelty' refers to a state of the art comprising everything made available anywhere to the public by means of written or oral description, by use, or in any other way, before the date of filing the patent application. Under US patent law an invention is still novel if it was not published or described in a printed publication more than one year prior to the date of the application. In contrast to the EPC, applications which claim a foreign union priority are still novel as long as they have not been filed in the United States (Straus 1996).

In relation to inventions that make use of or relate to genetic material, the patent requirement of novelty may pose specific difficulties. From the TRIPS Agreement it follows, however, that inventions relating to biological material must not be considered as lacking novelty solely on the grounds that they relate to biological material. On the other hand, members are certainly free to refuse, on the grounds of lack of novelty, a patent for biological material that has merely been discovered, or where the particular use of material, claimed to be new, was already known.

---

[3] The right of priority means that patent applicants have the right first to file a patent application in any member state and thereafter to file a patent application in any other member state within 12 months of said first filing, with the effect that these subsequently filed applications will enjoy the right of priority, i.e. they will be treated as if they were filed on said first filing date. The right of priority is of utmost importance if "novelty" is defined as absolute novelty on a global scale, since without the right of priority the first application would lead to lack of novelty rejections of all subsequent applications in other states.

1.3.2.2 Inventive step/non-obviousness

Under the EPC an invention must include an inventive step. An invention is considered to include an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. Given the enormous speed of technological progress in the field of biotechnology, the requirement of inventiveness may turn out to be a serious hurdle to the patenting of many biotechnological innovations. WTO countries may decide, for example, that if an isolated gene sequence only expresses proteins that the organism from which it was isolated is also known to produce, the invention may not be considered to include an inventive step. They may also decide that routine methods of genetic cloning may be cited against claims to DNA sequences for specific proteins (Seide and Smith 1995).

> According to US law, patents may only be granted if differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would not have been obvious to someone skilled in the art at the time when the invention was made. This non-obviousness requirement under US law until recently presented a serious impediment to the patenting of biotechnological processes, which are often state of the art and are only being applied to new starting materials or for the production of new products. In *In re Durden* (226 USPQ 359) the Court of Appeal for the Federal Circuit had denied the patentability of these so-called 'analogous process' claims by arguing that the mere use of a new and patentable starting material in a known process, or the production of a new and patentable product by using a known process, did not necessarily make the process itself new and patentable. By amendment of Section 103 of the Patent Statute (35 USC 103) the United States overturned this decision in 1995. In future a biotechnological process will be deemed non-obvious if it uses or results from a composition of matter that is itself novel and non-obvious and therefore patentable.

1.3.2.3 Industrial applicability/usefulness

While in industrialized countries the concept of industrial applicability/usefulness denotes 'practical utility', WTO member states may interpret this requirement differently. It has been suggested, for example, that the concept of usefulness and industrial applicability be revitalized and applied to the problematic effects of protecting an invention (Winter 1992).

1.3.2.4 Disclosure

An applicant for a patent shall disclose the invention in a manner "sufficiently clear and complete for the invention to be carried out by a person skilled in the art" (Art. 29(1) TRIPS). Members may require applicants to indicate the best mode for carrying out the invention known to the inventor. The best mode requirement also exists in US patent law (Sec. 112 (1)). It is often still difficult to disclose, for example, a genetically engineered organism in such way that the written patent application enables persons skilled in the art to reproduce the modification process so that the resulting organism is genetically identical. But as discussed above (see 1.3.1.2 - Reproducibility) the TRIPS Agreement includes no obligation to recognize the deposit of biological material for the purpose of disclosing an invention in a sufficiently clear and complete way.

---

[4] For a further discussion of the novelty requirement, see Chapter 1.3.2 - novelty.

It has been suggested that, as part of the patent law's disclosure requirement, regulations should be introduced requiring that all applicants filing for a patent identify the provider of the genetic material from which a patent or a *sui generis* right has been derived. Insofar as patent applications are directed to plants, such regulations would certainly comply with the TRIPS Agreement which even allows plants to be excluded in general from patentability and therefore also allows the granting of patent protection for plants under more restrictive conditions than the usual patent requirements. However, where patent applications are directed to subject matter which must not be excluded from patentability, it is quite clear that the disclosure of the country of origin of the material used by a patent applicant must not be made an additional patent requirement. This is because Art. 29 TRIPS only requires that the disclosure is sufficiently clear and complete for the invention to be carried out by a person skilled in the art. The country of origin of the material used might appear to be irrelevant for that purpose.

1.4 The option to exclude inventions on grounds of *ordre public*, morality and protection of the environment (Article 27 (2) TRIPS)

This section examines to what extent and under which conditions inventions relating to or using plant genetic material may fall under one of the exceptions allowable under Art. 27 (2) TRIPS Agreement.

Apart from Art. 27 (2) and (3) TRIPS, the TRIPS Agreement provides for general exceptions which are applicable to all IPR covered by the Agreement. These exceptions focus on the prevention of IPR-related anticompetitive practices. Article 8 allows measures "necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development". Such appropriate measures may be needed to prevent right-holders abusing IPR or resorting to practices which unreasonably restrain trade or adversely affect the international transfer of technology. However, the measures mentioned in Art. 8 are allowable only if they are consistent with the provisions of the TRIPS Agreement as a whole. Furthermore, Art. 40 of the TRIPS Agreement allows measures to prevent or control licensing practices, which may in particular cases constitute an abuse of IPR, having an adverse effect on competition in the relevant market (e.g. exclusive grant-back conditions, conditions preventing challenges to validity and coercive package licensing). Again, such measures have to be consistent with the provisions of the TRIPS Agreement.

1.4.1 The necessity to prevent commercial exploitation

Article 27 (2) of the TRIPS Agreement allows member states to exclude from patentability those inventions, the prevention of whose commercial exploitation within the territory of the member state is 'necessary' in order to protect *ordre public* or morality (including to protect human health, animal or plant life or health or to avoid serious prejudice to the environment). However, such exclusions must not be made merely because the exploitation is prohibited by the law of the member state.

By stating that inventions may be excluded from patentability only if the prevention of their commercial exploitation is 'necessary', the TRIPS Agreement limits the scope of the application of this provision. The necessity requirement is also included in some of the general exceptions of the GATT 1994 (Art. XX (a), (b) and (d)) and has been the subject of several GATT panel decisions. Reference was also made to it in the first decision handed down under the new Dispute Settlement Understanding (*United States - Standards for Reformulated And Conventional Gasoline - WT/DS2/9*). In the *Section 337* case, the term 'necessary' has been interpreted in the context of Art. XX (d) by a GATT panel which stated that "a measure is not 'necessary' if an alternative measure which a state could reasonably be expected to employ and which is not inconsistent with other GATT provisions is available" *(United States - Section 337 of the Tariff Act of 1930, BISD 36S/345).* The same reasoning was adopted by the 1990 *Thai Cigarette* panel in examining a measure under Art. XX (b).

Given the aforementioned interpretation by the GATT Panels, it seems difficult to justify exclusions on grounds of *ordre public* or morality. Some authors even argue that Art. 27 (2) TRIPS prohibits member states from refusing a patent for an invention whose application, or at least commercial exploitation, is not prohibited by their national laws (Correa 1994a; Otten 1996; Straus 1996). However, this opinion finds no support in the TRIPS Agreement since Art. 27 (2) TRIPS does not require an actual **ban** of the commercialization as a condition for exclusions; only the **necessity** of such a ban is required. In order to justify an exclusion under Art. 27 (2) TRIPS, a member state would therefore have to demonstrate that it is necessary to prevent – by whatever means – the commercial exploitation of the invention. Yet, the member state would not have to prove that under its national laws the commercialization of the invention was or is actually prohibited.[5]

In fact, approval or disapproval of the exploitation by national laws or regulations does not constitute *per se* a sufficient criterion for examining whether an invention may be excluded from patentability on the grounds of Art. 27 (2) TRIPS. This means that a legal ban of the exploitation of an invention is neither a condition for excluding it, nor is it necessarily sufficient for justifying such exclusion. This is underlined by the qualification contained in Art. 27 (2) TRIPS, "that such exclusion is not made merely because the exploitation is prohibited by their laws". This qualification makes clear that the assessment of whether or not the commercialization of a particular invention is necessary in order to protect *ordre public* or morality does not depend on any national laws. Conversely and by

[5] In fact, the inevitable time lag between technological developments and the legal regulation of their application requires that member states be free to consider the prevention of the commercial exploitation of an invention as being necessary to protect *ordre public* or morality, even where the exploitation of the invention has not (yet) been banned by any law. If inventions could be excluded from patentability only when their exploitation is banned under the member state's national law, certain inventions, especially milestone inventions nobody had thought of before and which, therefore, are unregulated, would pass the morality test, whether their exploitation ought to be prevented or not.

the same token, a particular invention may be excluded from patentability although its commercialization is (still) permitted under a member state's national laws.

1.4.2 Scope of the exceptions

The possibility of excluding inventions from patentability on grounds of *ordre public* or morality met with the approval of the negotiating parties at a relatively early stage of the negotiations. The negotiations on Art. 27 (2) concerned the fine tuning of the language and the conditions to be attached (WTO 1995). While a few further treaties in the field of IPR, especially the EPC and the Convention after which it was modelled[6], provide for similar exceptions, these exceptions have only rarely been used in the past and only in extreme cases. It seems nonetheless useful to recapitulate those precedents handed down by the European Patent Office in recent years, especially since the terms "*ordre public*" and "morality" have been included in the Chairman's text at the suggestion of the European Communities (European Communities 1990).

1.4.2.1 Ordre public

While the term 'public order/law' which was orginally used in the Chairman's text (GATT 1990) is primarily known from general clauses included in those domestic laws by which public order is to be maintained, the concept of *ordre public* has a more precise and narrower meaning, especially in international private law. This is underlined by the qualification that under Art. 27 (2) exclusions must not be made merely because the exploitation is prohibited by a member state's national law, which means that the laws of a member state do not necessarily form part of *ordre public.* Echoing Art. XX (b) of the GATT 1994, Art. 27 (2) TRIPS indicates, however, that at least the protection of life and health of humans, animals and plants as well as protection of the environment may be regarded as essential elements of *ordre public.*

> The Guidelines for Examination in the European Patent Office describe as the purpose of the exclusion of inventions contrary to *ordre public*, "to exclude from protection inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour" (Part C, chapter IV, 3.1). As an obvious example of subject matter which should be excluded as being contrary to *ordre public* the Guidelines mention the letter-bomb. In *Plant Cells/PLANT GENETIC SYSTEMS* (T 356/93 - OJ EPO 1995, 545) the Technical Board of Appeal of the European Patent Office interpreted the term *ordre public* as covering "the protection of public security and the physical integrity of individuals as part of society". According to the Board's judgement, the concept of *ordre public* also encompasses the protection of the environment. Accordingly, the Board went on to say, "inventions the exploitation of which is likely to breach public peace or social order (for example, through acts of terrorism) or to seriously prejudice the environment are to be excluded from patentability as being contrary to '*ordre public*'".

[6] Article 2 of the Strasbourg Convention on the Unification of certain Points of Substantive Law on Patents for Invention (1963) reads: "The contracting States shall not be bound to provide for the grant of patents in respect of (a) inventions the publication or exploitation of which would be contrary to '*ordre public*' or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by a law or regulation; (...)".

In *Onco-mouse/HARVARD* (T 19/90 - OJ EPO 1990, 476) the Technical Board of Appeal of the European Patent Office held that whether or not *ordre public*/morality were a bar to the patenting of an experimental transgenic mouse depended "mainly on a careful weighing up of the suffering of the animals and possible risks to the environment on the one hand, and the invention's usefulness to mankind on the other". While the examining division to which the case was referred back finally granted the patent on the onco-mouse[7], the weighing-up as required by the Technical Board of Appeal led to the rejection of a another patent application concerning a mouse destined to be used not for cancer research experiments, as in the Harvard case, but for the testing of cosmetics.

1.4.2.2 Morality

The concept of morality is even more vague than that of *ordre public*. While morality as a legal term is used by several human rights instruments like the International Covenant on Civil and Political Rights (ICCPR) as well as by the regional patent conventions like the EPC, it has to date played a negligible role in patent law.

Recently the European Patent Office had to deal with the question of whether an invention relating to genetically modified herbicide-resistant plants conformed with the morality clause. In *Plant Cells/PLANT GENETIC SYSTEMS* the Technical Board of Appeal held that the concept of morality is related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the "totality of the accepted norms which are deeply rooted in a particular culture". The concept of morality might thus find different interpretations in the different cultures. This is also reflected in Art. 27 (2) TRIPS which by referring to the member states' territory does not aim at a uniform and universal substantive definition of '*ordre public'* and 'morality'.

1.4.3 Biodiversity-related considerations

It has been suggested that Art. 27 (2) TRIPS may enable member states to avoid or limit patent protection on plants to the extent that patents could adversely affect genetic diversity by accelerating genetic erosion (Crucible Group 1994; Cameron and Makuch 1995). However, it is inconceivable that such exclusion or limitation should be based upon Art. 27 (2) TRIPS, given the fact that Art. 27 (3) TRIPS explicitly allows the exclusion of plants in general. Furthermore, Art. 27 (2) only allows the exclusion of inventions whose "commercial exploitation" is necessary to be prevented; it does not seem to allow exclusions where the mere patent itself could have adverse effects.[8]

[7] The case is still pending, since several oppositions to the granted patent have been raised (see Jaenichen and Schrell 1993).

[8] Some authors argue, however, that the patenting of an invention is always an integral part of its commercial exploitation (Moufang 1988) and that, consequently, an exclusion should also be allowable where patenting (and not the use) of the invention is contrary to *ordre public* or morality. However, it is questionable whether a panel would accept such an interpretation. And

It has further been suggested that WTO member states could, by relying on Art. 27 (2), refuse patents on inventions which make use of or are composed of genetic material if the provider of this material is not disclosed or the material has been taken by the patent applicant without the consent of the country of origin or the local community. This proposal raises the question of whether the violation of laws governing access to genetic resources and/or implementing aspects of the concepts of Farmers' Rights or traditional resource rights could be invoked under Art. 27 (2) of the TRIPS Agreement.

However, as far as plants and animals are concerned, such regulations requiring applicants to identify the provider of the material from which a patent was derived do not need to be based on Art. 27 (2). The option to exclude plants and animals from patentability (Art. 27 (3) TRIPS) embraces the option to grant patents (or *sui generis* rights) on plants and animals under more restrictive requirements than the usual patent requirements.

The situation is different, however, for patent applications directed to genetic material which must not be excluded from patentability, such as microorganisms. For those inventions the TRIPS Agreement does not allow further protection requirements to be introduced, since the patent requirements are exhaustively regulated in Art. 27 (1) and 29 TRIPS. Here the question may actually arise whether the principles of PIC and benefit-sharing as laid down in the Convention on Biological Diversity (CBD) may be invoked under Art. 27 (2) TRIPS. A member state could argue, for example, that it would be against the totality of the accepted norms deeply rooted in that member state's culture to commercialize inventions without the disclosure of the country of origin of the material to which the invention is directed. However, a panel might be reluctant to accept this sort of argument since, even if the country of origin is not disclosed for patent purposes, this does not mean that the invention could not be commercialized in accordance with that member state's norms. A patent applicant may wish, for example, to disclose the country of origin not for patent purposes but as soon as the invention is actually being marketed.

1.5 The option to exclude plants (Article 27 (3) b TRIPS)

Art. 27 (3) b TRIPS allows member states to exclude *inter alia "*plants and animals other than microorganisms" from patentability.

There is general agreement that whereas Art. 53 (b) of the EPC excludes plant and animal varieties only, the TRIPS Agreement is broader in that it allows member states to exclude plants and animals in general (Otten 1996; Straus 1996). It is also clear that under Art. 27 (3) b TRIPS, member states are free to exclude plant varieties only since the option to exclude plants implies the option to only exclude the narrower category of plant varieties.[9]

---

even if this argument were accepted in principle, it would still be necessary to demonstrate that there is a direct link between a specific patent and, for example, genetic erosion.

[9] However, the European Patent Office's jurisdiction on the exclusion of plant varieties demonstrates that as far as genetically modified plants are concerned a distinction between plant varieties and plants is rather sophistic. The EPO's original practice was to allow in spite of the exclusion of plant varieties claims directed to groups of plants larger than plant varieties if the invention related and was applicable to such larger groups. It did not matter that those broader claims clearly embraced within their scope plant varieties (Greenpeace UK vs. Plant Genetic Systems, IIC 1993, 618). That practice, however, did not accommodate the well-established principle that a claim is not allowable if the invention claimed therein is (also) necessarily defining something which is excluded from patentability. Accordingly, the EPO's practice changed in 1995

The question may arise, however, whether the TRIPS option to exclude plants also implies an option to exclude **parts** of plants from patentability. It may be argued that parts of plants may be excluded from patentability unless they fall under the category of microorganisms. If member states could not exclude parts of plants from patentability, patent applicants could circumvent the exclusion of plants from patentability by claiming all cells of a plant instead, which would completely undermine the exclusion of plants. Moreover, the rationale behind Article 27 (3) b TRIPS seems to back up an interpretation of 'plants' as to include parts of plants. The option to exclude plants from patentability and instead to establish a *sui generis* system for the protection of plant varieties is obviously based on the consideration that member states should be free to decide whether patents or a different system of protection should be available in the sphere of plant breeding. Members which choose the *sui generis* option should therefore also be free to provide nothing more than *sui generis* protection in the field of plants.

Others may argue that a general exclusion of 'parts of plants' would also encompass agricultural and pharmaceutical chemical products gained from plants and that it would therefore contravene Art. 70 (8) TRIPS according to which agricultural and pharmaceutical chemical products may only be excluded for an interim period and only by certain member states. It is questionable, however, whether the obligation to grant patent protection for agricultural and pharmaceutical chemical products further means that those products must not be excluded in case they consist of plants or parts thereof. Art. 70 (8) TRIPS was certainly not intended as an exemption to the optional exclusions foreseen in Art. 27 TRIPS.

However, even if the right to exclude parts of plants is conceded in principle, member states may only exclude parts of plants "other than microorganisms". In some member states, certain parts of plants, like cells, are generally deemed to be microorganisms and thus patentable (Correa 1994a). The EPO Guidelines for Examination interpret the term 'microorganism' broadly so as to include plasmids and viruses. Similarly, phages, bacteria, fungi, yeasts and cell cultures are regarded as microorganisms (Jaenichen 1993). In *Plant Cells/PLANT GENETIC SYSTEMS* (T 356/93 - OJ EPO 1995, 545) the Technical Board of the EPO even defined 'microorganism' to include "all generally unicellular organisms with dimensions beneath the limits of vision which can be propagated and manipulated in a

---

when the Technical Board of Appeal held in *Plant Cells/PLANT GENETIC SYSTEMS* that a claim defining genetically modified plants having a distinct, stable genetic characteristic was not allowable under Art. 53 (b) EPC if the claimed modification itself made the modified or transformed plant a 'plant variety'. 'Plant variety' was defined as 'plant grouping within a single botanical taxon of the lowest rank which, irrespective of whether it would be eligible for protection under the UPOV Convention, is characterized by at least one single transmissible characteristic distinguishing it from other plant groupings and which is sufficiently homogeneous and stable in its relevant characteristics'.

After the decision in *Plant Cells/PLANT GENETIC SYSTEMS* which did not conflict with previous decisions of the Technical Boards (see G 03/95, 1996 EPOR 505) transgenic plants and the seeds thereof are no longer patentable under the EPC. Owing to the technologies used and the aims pursued by modern plant biotechnology, i.e. the production of new plant varieties, transgenic plants fall under Art. 53 (b) EPC and are, therefore, excluded from patentability (Roberts 1995; Schrell 1995; Lange 1996; Straus 1996). Given the EPO's interpretation, an exclusion of plant varieties amounts de facto to an exclusion of (genetically modified) plants. In order to avoid legalistic battles over the defintion of patent exclusions, the approach suggested by the TRIPS Agreement, either to exclude or not exclude plants from patentability, therefore seems much more appropriate than the approach taken by the EPC.

laboratory". The Board also held that plant cells as such, since modern technology allows them to be cultured like bacteria and yeasts, could not be considered to fall under the definition of a plant. Given this interpretation members would not be allowed to exclude from patentability those parts of plants that are unicellular organisms and can be propagated and manipulated in a laboratory.

It is not possible to predict which definition of 'plants' and 'microorganisms' a WTO panel would finally accept. It should be noted, however, that the TRIPS Agreement does not include any explicit obligation to apply as broad an interpretation of microorganisms as has become common in most industrialized countries. It should also be noted that with new technology, whole plants can be regenerated from single plant cells (Lange 1996). In the light of these technological developments, it seems therefore reasonable to define at least those plant cells from which plants can be regenerated as included within 'plants'. It is less clear whether those parts of plants which cannot be regenerated to whole plants can also be excluded from patentability under Art. 27 (3) b TRIPS. But even if a panel interpreted the term 'microorganism' as covering certain parts of plants, plants which then include patented material would not necessarily have to be affected by such patents (see 1.8).

1.6 The option to exclude essentially biological processes (Article 27 (3) b TRIPS)

Since under Art. 28 (1) b process patents shall confer to their owners' exclusive rights not only in relation to the process but also in relation to the products obtained directly by a patented process, the option to exclude essentially biological processes (Art. 27 (3) b TRIPS) is of crucial importance. Whether plants or parts of plants may fall under the category of products directly obtained by a patented process depends to a large extent on the definition of "essentially biological processes". While member states have to grant patent protection for processes in all fields of technology, they may still exclude from patentability "essentially biological processes for the production of plants other than non-biological and microbiological processes". Straus distinguishes four different processes: microbiological processes, non-biological processes, essentially biological processes and biological processes (Straus 1996). While the first two processes must not be excluded, essentially biological and biological processes may be excluded from patentability. One may assume that the latter category of biological processes was not mentioned in the TRIPS Agreement since it would not be eligible for patent protection anyway.

The definition of the three remaining categories poses significant difficulties and may also lead to controversy among WTO member states. Since Art. 53 (b) of the EPC includes a similar wording, the decisions handed down by the EPO so far may again be instructive.

1.6.1 Essentially biological processes

Whether a process for the production of plants is 'essentially biological' depends on which part of the process one is looking at. In the field of plant biotechnology, claims usually relate to multistep processes comprising the modification of plant cells, the subseqeuent regeneration of plants from those cells, and, finally, the propagation or planting of the regenerated plants.

Neither the TRIPS Agreement, nor the EPC define the term "essentially biological process for the production of plants and animals". In *Plant Cells/PLANT GENETIC SYSTEMS*, the Technical Board of the EPO gave a negative definition of what does not constitute an essentially biological process, i.e. "a process for the production of plants

comprising at least one essential technical step, which cannot be carried out without human intervention and which has a decisive impact on the final result". Similarly, the European Commission's Proposal for a directive on the legal protection of biotechnological inventions (European Commission 1995) defines essentially biological processes as "any process which, taken as a whole, exists in nature or is not more than a natural ... breeding process".

However, there is nothing in the TRIPS Agreement following this line of definitions. It would therefore seem to comply with Art. 27 (3) b TRIPS if multistep processes consisting of the genetic modification of plant cells, the subsequent regeneration of plants and, finally, the propagation of these plants, are treated as 'essentially biological' and, consequently, refused patent protection. It also seems to be allowable under the TRIPS Agreement to treat processes that include as an essential element a biological step, such as the propagation of plants, as 'essentially biological'.

1.6.2 Microbiological processes

Article 27 (3) b TRIPS exempts microbiological processes from the option to exclude essentially biological processes. This exemption thus restores for microbiological processes the general principle of patentability laid down in Art. 27 (1) TRIPS. Again, neither the TRIPS nor the EPC define "microbiological process".

> In *Plant Cells/PLANT GENETIC SYSTEMS* the Technical Board of the EPO held that the concept of 'microbiological processes' refers only to processes in which microorganisms, or their parts, are used to make or modify products or in which new microorganisms are developed for specific purposes. Even more importantly, the Technical Board explicitly refused to interpret 'microbiological process' to include any process which is 'essentially microbiological' or includes at least one essential microbiological step.
>
> The claim underlying the decision was directed at a multistep process which, in addition to the initial microbiological process of transforming plant cells comprised the step of regenerating plants from the transformed plant cells and that of propagating the plant material. Since under the EPC not only microbiological processes but also the "products thereof" are patentable, the Board had to decide whether the multistep process as a whole could be regarded as microbiological and, consequently, the resulting plants as "products thereof". In the Board's judgement the initial microbiological step undeniably had a decisive impact on the final result because by virtue of this step the plant acquired its characterizing feature that is transmitted throughout generations. However, the Board stated that the subsequent steps of regenerating and reproducing the plants have an important added value and contribute, although in a different manner, to the final result as well. In the Board's judgment, these two process steps involve complex phenomena and events such as cell differentiation, morphogenesis and reproduction and may, therefore, "not be equated to the much simpler process step of multiplying and propagating transformed plant cells or tissue in culture, which is a typical microbiological process".

According to the EPO's interpretation, a process consisting of an initial transformation of a plant cell, and the subsequent regeneration and propagation of plants, would not have to be treated as a microbiological process as a whole. Only the initial step of transforming the plant cell would have to be treated as microbiological.

1.6.3 Non-biological processes

Lastly, member states must not exclude from patentability 'non-biological processes'. There are several examples in patent history which may be regarded as non-biological processes for the production of plants. There are, for instance, cultivation methods which have been patentable for many years in most industrialized countries. Another example is the chemical treatment of propagating material in order to protect it against pests or chemicals. Such a process, and even the propagating material that was treated with the chemical, have been held by the Technical Board of the EPO not to contravene Art. 53 (b) EPC, since "the innovation claimed here does not lie within the sphere of plant breeding, which is concerned with the genetic modification of plants" (*Propagating Material/CIBA GEIGY*).

1.7 Rights conferred by a patent

According to Art. 28 (1) of the TRIPS Agreement a patent shall confer on its owner the following exclusive rights:

- where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling or importing for these purposes that product;
- where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

Consequently, members which provide for the protection of plants (including plant varieties) by patents only and which which do not exclude essentially biological processes from patentability would have to grant:

- firstly, product protection under Art. 28 (1) a TRIPS for all inventions the subject of which are plants or parts of plants, and
- secondly, process protection under Art. 28 (1) b TRIPS for inventions the subject of which are (essentially biological) processes for the production of plants. In addition those member states would have to grant the right to prevent third parties from using, offering for sale, selling or importing for one of these purposes at least the "product obtained directly" by that process which could include plants and parts of plants.

On the other hand, member states which exclude plants and essentially biological processes from patentability would neither have to grant any exclusive rights in relation to plants (and, in our opinion, parts of plants) nor would they necessarily have to patent processes which include as an essential element a biological step (see 1.VI.1).

However, while plants and – in our opinion – also parts thereof may be excluded from patentability, they may by virtue of Art. 28 (1) b of the TRIPS Agreement, be classed as products directly obtained by a patented process. The question may arise whether the option to exclude plants from patentability embraces the option to also refuse any protection for plants that have been directly obtained by a patented process. The TRIPS Agreement does not address this question explicitly. However, it is quite clear that Art. 28

(1) b TRIPS is not meant to prohibit or limit something which Art. 27 (3) b TRIPS explicitly allows. Apart from this, the option to exclude plants from patentability would actually be an empty promise if member states making use of this option would nonetheless have to extend the protection conferred by a process patent to plants directly obtained by that process.

1.8 Scope of protection and exhaustion of patents

By virtue of Art. 28 TRIPS patented biological material as such and processes making use of biological material fall under the exclusive rights conferred on the patent owner. It is a completely different question whether these exclusive rights also need to extend to material which has not been produced by using the patented invention but has been obtained by multiplication or propagation of patented material or material produced with a patented process. The question which needs to be addressed first is:

- Does the protection conferred by a patent on genetic material (e.g. from a microorganism) have to extend to all material (e.g. plants), in which the product is incorporated and in which the patented material is contained and expressed?

Even for member states which exclude plants and essentially biological processes from patentability this question is not irrelevant given that genetic material must not be excluded in general from patentability. The question may therefore arise whether the protection conferred by a patent on such material would also have to extend to plants in which the patented material is contained and expressed. The TRIPS Agreement does not offer a ready-made answer to this question. However, in member states that make use of the option to exclude plants from patentability, one may assume the protection conferred by patents on genetic material does not need to extend to plants which contain this material. Otherwise the option to provide for the protection of plant varieties by a *sui generis* system only would be severely undermined.

However, in member states that provide for the protection of plants (including plant varieties) by patents only and which do not exclude essentially biological processes from patentability, one may assume that the protection conferred by a patent on genetic material would also have to extend to those plants in which the patented material is contained and expressed. These member states would be confronted by two further questions:

- Does the protection conferred by a patent on a plant have to extend to any biological material derived from that plant through multiplication or propagation?
- Does the protection conferred by a patent on a process not only have to extend to all plants and parts of plants directly obtained through that process, but also to all material derived from these plants / parts of plants through multiplication or propagation?

The TRIPS Agreement is again silent on these very specific though crucial questions and it is difficult to predict how a panel would decide. On the one hand it is true that once a patented product (or a product which has been directly obtained by a patented process) has been released on the market with the consent of the patent holder, the **use** of this product no longer requires the patent holder's consent. It is said that the patent is 'exhausted'. However, in the case of biological material the **use** might often include the propagation or multiplication of the material which may be seen as an act of 'making' the material, which is, of course, the patent holder's non-exhaustable and exclusive right.

A panel could take the view that only under certain conditions the protection does not have to extend to plants obtained from the multiplication or propagation of patented plants (or plants directly obtained by a patented process). These conditions might include that the plants have been marketed (nationally or internationally[10]) with the patent holder's consent. A further condition might be that the propagation or multiplication necessarily results from the application for which the plants are marketed. Another could be that the obtained harvest is not subsequently used for further multiplication or propagation.

One may conclude that, to be certain, member states not interested in providing any patent protection in relation to plants should exclude plants and essentially biological processes from patentability. Although it is not clear from the TRIPS Agreement whether members providing patent protection for plants would have to ensure that the protection conferred by such patents also extends to plants which have been produced without using the invention, but instead by propagation or multiplication, it is certainly not impossible that a panel would take this view.

1.9 Exceptions to rights conferred

According to Article 30 of the TRIPS Agreement, WTO member states may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

It is clear from the drafting history that an act performed for experimental purposes was intended to be one of the exceptions allowable under Art. 30 (WTO 1995). The TRIPS Agreement, however, does not define the scope of the experimental use exception. While in most industrialized countries this exception is interpreted in such an extremely narrow manner, that, as Bruzzone stated, "it is fair to say that a private defendant whose only defence is the research exemption would do well to settle the case out of court" (Bruzzone 1993), WTO member states are free to choose a broader interpretation.

[10] According to Art. 6 TRIPS nothing in this Agreement, subject to the provisions of Articles 3 (national treatment) and 4 (most-favoured nation treatment) shall be used for the purposes of dispute settlement to address the issue of exhaustion of intellectual property rights.

1.10 Compulsory licensing

According to Art. 31 of the TRIPS Agreement, members may allow for use of the subject matter of a patent without the authorization of the right-holder. It should be noted, however, that owing to Art. 2 (1) TRIPS, such measures have to be consistent with Art. 5 A (2) of the Paris Convention according to which compulsory licences may be granted only "to prevent the abuses which might result from the exercise of the exclusive rights". Even if compulsory licences are being justified as a measure necessary to protect public health or nutrition or to promote the public interest in sectors of vital importance to their socioeconomic or technological development (Art. 8 TRIPS), they have to comply with Art. 5 A (2) of the Paris Convention, since measures under Art. 8 TRIPS have to be consistent with the TRIPS Agreement, and therefore with Art. 5 A of the Paris Convention as well.

Article 31 sets out the further conditions under which compulsory licences may be granted: each case shall be considered on its individual merits. Prior to the granting of a compulsory licence, negotiations with the holder of the right on the granting of a voluntary licence shall take place. The licence shall be limited as to its scope and duration and it shall be of a non-exclusive nature. The compulsory licence shall not be transferable and shall be granted for the supply of the domestic market of the member country only. Compulsory licences shall be terminated if and when the circumstances which have led to it cease to exist and are unlikely to recur. The holder of the right shall be compensated adequately. The legal validity of compulsory licences as well as any decision relating to the compensation shall be subject to judicial review.

Where compulsory licences are granted in order to permit the exploitation of a second, "dependent" patent which cannot be exploited without infringing the first patent, three additional criteria apply: (i) the invention claimed in the dependent patent shall involve an "important technical advance of considerable economic significance in relation to the invention claimed in the first patent; (ii) the owner of the first patent shall be entitled to a so-called cross licence, i.e. a licence to use the invention claimed in the dependent patent, and (iii) , the use authorized in respect of the first patent shall be non-assignable except with the assignment of the dependent patent.

Developing countries in particular may in some cases have an interest to grant compulsory licences where patented products are not locally produced but imported only. According to Art. 5 A (2) of the Paris Convention compulsory licences may actually be granted "to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work". However, under Art. 5 A (4) of the Paris Convention a compulsory licence may not be applied for on the ground of failure to work or insufficient working before the expiration of certain minimum periods and it shall be refused if the patentee justifies his inaction by legitimate reasons. It is even more important that the TRIPS Agreement indicates that import of products may consitute sufficient exploitation of an invention: according to Art. 27 (1) "patent rights shall be enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced". One may, therefore, conclude that compulsory licensing as it is allowable under the TRIPS Agreement does not seem to be an adequate instrument for addressing general issues such as the question of the patenting of plants or parts thereof.

2. The Minimum Requirements of a *Sui Generis* System for the Protection of Plant Varieties

Summary

WTO member states which exclude plant varieties or even plants in general from patentability have to provide for the protection of plant varieties by an "effective *sui generis* system". Although the TRIPS Agreement does not give any details on what elements this effective *sui generis* system would have to include, certain minimum requirements that such a system would have to fulfil may be drawn from the context of Art. 27 (3) b, the context of the Agreement as an integral part of the WTO Agreement and, finally, from the objectives of the TRIPS Agreement itself.

Since the TRIPS Agreement elaborates no further upon the term 'plant variety', member states have to provide for the protection of plant varieties of all species and botanical genera, by providing protection either through patents or a *sui generis* system or a combination thereof.

The *sui generis* system has to be an Intellectual Property Right (IPR), i.e. a legally enforceable right either to exclude others from certain acts in relation to the protected plant variety, or to obtain a remuneration in respect of at least certain uses of the plant variety by third parties.

The *sui generis* system needs to comply with the basic principle of national treatment. Thus, member states have to accord to the nationals of other members treatment no less favourable than that which they accord to their own nationals with regard to the protection of plant varieties.

Any advantage, favour, privilege or immunity granted by a member to the nationals of any other country has to be accorded immediately and unconditionally to the nationals of all the other member states (most-favoured-nation treatment).

Finally, in order to be effective, a *sui generis* system requires an enforcement procedure so as to permit action against any act of infringement of the *sui generis* right.

Member states which do not provide for the protection of plant varieties by patents have to provide for their protection by an "effective *sui generis* system" or by a combination of patents and a *sui generis* system. There is general agreement that countries have considerable room to develop their own systems, even "in a way that may have – paradoxically – a deharmonizing effect" (Correa 1994a; see also Reichman 1993; Bronckers 1994; Pacon 1995; Singh Nijar 1995; Verma 1995; Straus 1996).

The TRIPS Agreement goes no further towards defining the words "effective *sui generis* system" and there is no drafting history which can be invoked to explain these terms (Otten 1996). While the main *sui generis* systems existing at the time of the conclusion of the TRIPS negotiations were embodied in the various UPOV Acts and reflected in the national laws of UPOV member states, the TRIPS Agreement does not refer to UPOV. Thus Art. 27 (3) b TRIPS neither includes an obligation to become a member of UPOV, nor does it oblige member states to adopt legislation identical to, or consistent with, any of the UPOV Acts.

On the other hand, WTO member states that exclude plants from patentability do not necessarily satisfy the requirement of Art. 27 (3) b TRIPS by having implemented one of the UPOV Acts.

It is true, the former Director General of GATT, Peter Sutherland, explained in 1993, that "while the TRIPS provisions on plant variety protection do not refer to any international convention, it is clear that, if the standards of protection of UPOV 1978 were to be followed, it would be reasonable to claim that an effective *sui generis* protection had been provided" *(The Times of India, New Delhi, 12 March 1993)*. However, this statement is misunderstood to mean that if a country's legislation conforms to the UPOV Act of 1978, it would be unlikely to be successfully challenged. Sutherland limited his statement to the "standards of protection" as foreseen by the UPOV Act of 1978 and did not address the required coverage or scope of a *sui generis* system. Nor did he address the question of whether member states are required to apply the basic principles of the TRIPS Agreement to the *sui generis* system.

In the following sections we argue that although the TRIPS Agreement does not define what is meant by the term "effective *sui generis* system", certain minimum requirements such a system would have to fulfil may nonetheless be drawn from the context of Art. 27 (3) b, the context of TRIPS as an integral part of the WTO Agreement and, finally, from the objectives of the TRIPS Agreement itself. We conclude that the *sui generis* system has to provide for the protection of plant varieties of all species and genera (2.1) by an IPR (2.2) to which the obligations under Art. 3 (national treatment, 2.3) and Art. 4 TRIPS (most-favoured nation treatment, see 2.4) fully apply. To be effective, the *sui generis* system needs to permit effective action against any act of infringement of the right available under the *sui generis* system (2.5).

2.1 Plant varieties

Member states which do not provide for the protection of plant varieties by patents have to provide for their protection by an "effective *sui generis* system".

The statement quoted at the beginning of this chapter by the former Director General of GATT, Peter Sutherland, is sometimes understood to mean that under the UPOV Act of 1978[11] member states do not have to provide for the protection of plant varieties of all

[11] The 1978 UPOV Act only requires contracting parties to apply the UPOV Convention to a minimum of five genera when first acceding to the Convention and then within three years

botanical genera and species under the TRIPS Agreement. However, as has been stated, Sutherland limited his statement to the "standards of protection" as foreseen by the UPOV Act of 1978 and did not address the required coverage or scope of a *sui generis* system. Since the TRIPS Agreement neither defines the term 'plant variety' nor specifies any species or genera the varieties of which have to be protected, it seems clear that member states have to provide for the protection of plant varieties of all species and botanical genera. Any other interpretation of Art. 27 (3) b TRIPS would have to indicate for how many species or for which type of species member states have to grant *sui generis* protection and there is no such provision in the TRIPS Agreement.

2.2 Intellectual Property Right

According to Art. 1 (2) of the TRIPS Agreement the term 'intellectual property' refers for the purposes of this Agreement "to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II". These sections deal with copyrights and related rights, trademarks, geographical indications, industrial designs, layout designs of integrated circuits, patents and the protection of undisclosed information (trade secret). The requirement to provide for the protection of plant varieties by patents or by an effective *sui generis* system or by any combination thereof is the subject of Section 5 of the TRIPS Agreement. It follows that, like patents and all the other rights mentioned in sections 1 through 7, the *sui generis* system also has to be an IPR.

It has been suggested that the TRIPS Agreement considers the protection of plant varieties only casually as an exception to patentability, defining neither the requirements nor the scope of protection a *sui generis* system would have to foresee, and that therefore the *sui generis* system does not fall under the category of "intellectual property rights" within the meaning of Art. 1 (2) TRIPS. However, the purpose of TRIPS as a whole does not seem to allow such interpretation. Since the national treatment principle and the principle of most-favoured nation treatment only have to be applied to IPR (cf. Art. 3 (1) and Art. 4 TRIPS), neither principle would apply, if the *sui generis* system were not to be considered as an IPR within the meaning of Art. 1 (2) TRIPS. This would, however, mean that member states would be allowed to refuse nationals of other member states any plant variety protection. The TRIPS requirement to provide for the protection of plant varieties by establishing a *sui generis* system would therefore be of no use to (the nationals of) other member states. However, the very purpose of the TRIPS Agreement is without doubt to make the property rights covered by it available to the nationals of all the member states. It is inconceivable that the mutual obligation to establish a protection system for plant varieties should not result in any mutual rights.

Furthermore, Art. 68 TRIPS indicates that the *sui generis* system is a form of IPR. According to Art. 68 TRIPS, the TRIPS Council has to monitor the operation of this agreement and, in particular, Members' compliance with their obligations under TRIPS. If the *sui generis* system was not an IPR within the meaning of TRIPS, members would not have to notify their *sui generis* laws since Art. 63 (2) TRIPS only requires them to notify those laws and regulations, final judicial decisions and administrative rulings which are of relevance for IPR. Thus, if the *sui generis* system were not a form of IPR the TRIPS Council would be obliged to monitor the member states' *sui generis* provisions but would not have

apply it to at least ten genera or species, within six years to at least eighteen, and within eight years to at least twenty-four genera or species in all (Art. 4).

the right to be informed by the member states about these provisions. It should be noted that, by asking member states to notify their *sui generis* laws for the protection of plant varieties under Art. 63 (2) TRIPS, the TRIPS Council itself has actually indicated that it regards the *sui generis* system as an IPR.

Thus, from the wording and context of Art. 27 (3) b and the aim of the TRIPS Agreement as a whole, it seems obvious that the *sui generis* system for the protection of plant varieties has to be an IPR within the meaning of Art. 1 (2) TRIPS.

2.2.1 Intellectual Property Rights covered by the TRIPS Agreement

The TRIPS Agreement does not define in detail the term "intellectual property right". 'Intellectual property rights' are usually defined as rights granted by a state authority for certain products of intellectual effort and ingenuity (OECD 1996b). Most often the term IPR is used as a collective name for rights such as those dealt with by the TRIPS Agreement. Most IPR must be applied for to the relevant national authority. However, neither copyright nor trade secret protection require any application or formalities. From an analysis of the IPR covered by TRIPS one can further draw the conclusion that IPR are legally enforceable rights either to exclude others from certain acts in relation to the described subject matter and / or to obtain a remuneration in respect of certain uses of the described subject matter.

Most IPR covered by the TRIPS Agreement give a right to exclude others from certain acts in relation to the protected subject matter. This right implies, of course, a right to obtain remuneration where the right-holders allow third parties to perform acts which the right confers exclusively to the holders. However, in relation to certain acts covered by an IPR, the TRIPS Agreement requires no exclusive right to be conferred on the right-holder except the right to equitable remuneration. If, for example, a WTO member had a system of 'equitable remuneration' in place on 15 April 1994 in respect of the rental of phonograms, members do not have to provide producers of phonograms with the right to authorize or prohibit the commercial rental of their phonograms (Art. 14 (4) TRIPS).

2.2.2 The *sui generis* system as an additional IPR

In many cases a product of intellectual effort or ingenuity may be protected by several IPR. The inventor of a new can-opener may, for example, apply for a patent and at the same time register a certain name for this opener as a trademark. The question may therefore arise whether a member state would fulfil the requirement to provide for the protection of plant varieties by referring, for example, to the possibility of registering the name of a plant variety as a trademark.

The *sui generis* system certainly needs to confer on the holders an additional right which WTO members do not have to make available in relation to plant varieties according to other obligations posed by the TRIPS Agreement. A WTO member could not satisfy Art. 27 (3) b TRIPS by allowing variety denominations to be registered as trademarks since, under Art. 15 TRIPS, member states already have to register variety names as trademarks. If the negotiators of the TRIPS Agreement had felt that such trademark protection was sufficient, they would certainly not have included the requirement to establish an additional system for the protection of plant varieties. For the same reason, Art. 27 (3) b cannot be satisfied by giving interested parties the right to prevent others from using misleading or false geographical indications for their plant varieties. According to Art. 22 TRIPS, member states already have to provide the legal means to prevent the false use of geographical indications, provided that the material originates in a country, region or locality where a

given quality, reputation or other characteristic of the material is essentially attributable to its origin. Finally, and again for the same reason, Art. 27 (3) b requires more than just ensuring trade secret protection since under Art. 39 (1) TRIPS members are already obliged to ensure effective protection against unfair competition.

Thus, the *sui generis* system has to be an additional IPR conferring on the right-holders a legally enforceable right either to exclude others from certain acts in relation to the protected plant variety, or to obtain a remuneration in respect of at least certain uses of the plant variety.

2.2.3 *Sui generis* legislation and Farmers' Rights

It has been suggested that the *sui generis* system provided for in Art. 27 (3) b TRIPS could be implemented through the concept of Farmers' Rights. Given that the *sui generis* system has to provide for an IPR, this approach might not conform with the TRIPS Agreement.

This does not, however, prevent the inclusion of provisions that implement Farmers' Rights and/or Traditional Resource Rights. Such an incorporation of Farmers' Rights based, for example, on the Indian proposals for Community Intellectual Property Rights and the Plant Variety Recognition and Rights Model Act (Crucible Group 1994; Swaminathan 1995, 1996), could complement the *sui generis* system by compensating those who have been conserving plant genetic resources for the past centuries and thereby have contributed until now to the development of plant varieties protectable under the *sui generis* system foreseen in the TRIPS Agreement.

2.3 National treatment

As an IPR any *sui generis* system needs to comply with the basic principle of national treatment.

The national treatment principle as laid down in the Paris Convention only relates to specific rights.[12] But as defined in Art. 3 (1) TRIPS the principle applies to "all categories of intellectual property that are the subject of Sections 1 through 7 of Part II" of the TRIPS Agreement and this includes the *sui generis* system for the protection of plant varieties. Thus, as an IPR any *sui generis* system needs to comply with the basic principle of national treatment. This means that members have to accord to the nationals of other members treatment no less favourable than they accord to their own nationals with regard to the protection of plant varieties.

A rather astonishing consequence of the applicability of the principle of national treatment to the *sui generis* system is, that by implementing the minimum standards of the UPOV Acts of 1978 and 1991, WTO member states would not fully comply with their obligation laid down by the TRIPS Agreement. According to the UPOV Acts, UPOV member states only have to afford the nationals and residents of all the other UPOV member states and legal persons having their headquarters there the same treatment as their laws provide for their own nationals. Under the UPOV Act of 1978 member states may even limit the right to apply for protection of a variety to nationals or residents of those member states which also apply that Act to the genus or species to which the variety belongs. This

[12] Art. 1 (2) of the Paris Convention for the Protection of Industrial Property reads: "The protection of industrial property has as its object patents, utility models, industrial designs, trademarks, service marks, trade names, indications of source or appellations of origin, and the repression of unfair competition."

reciprocity rule, as well as the limitation of national treatment to nationals and residents of other UPOV member states, would clearly fall foul of the national treatment requirement as laid down in Art. 3 of the TRIPS Agreement. With regard to the protection of plant varieties UPOV member states have to accord treatment no less favourable than they accord to their own nationals to the nationals of all WTO member states, whether these are UPOV members or not.

It is clear that the applicability of the national treatment principle to the *sui generis* system makes it far less attractive for WTO members to join UPOV. Since UPOV members have to apply their plant variety protection laws in compliance with the TRIPS national treatment principle, there is no need for WTO member states to join UPOV just because they want to benefit from the legal protection available for plant varieties in UPOV member states. This may be why some UPOV member states argue that the TRIPS national treatment principle is not applicable to the *sui generis* system (UPOV 1996).[13]

2.4 Most-favoured-nation treatment

Any advantage, favour, privilege or immunity granted by a member to the nationals of any other country with regard to the protection of plant varieties has to be accorded immediately and unconditionally to the nationals of all other member states. It should be noted, however, that in the field of intellectual property the most-favoured-nation principle is of rather minor practical relevance, since only in exceptional cases would countries be likely to grant more protection to foreigners than to their own nationals (Pacon 1995). This type of discrimination has occasionally arisen when unilateral actions by a particular country have led to concessions favouring that country's own nationals only (Correa 1994a).

[13] Although, as mentioned above, this position is barely compatible with the TRIPS Agreement, it raises the question of whether not to implement any sui generis system would be a political option. If for their own interest UPOV members themselves do not regard the sui generis system as an IPR they might not be interested in challenging a country on the grounds of a lack of sui *generis* protection for plant varieties. However, it should be noted that some UPOV members do regard the *sui generis* system as an IPR, as do other WTO members. WTO members should therefore not rely on those members which currently argue that the *sui generis* system is not an IPR and, consequently, does not have to comply with the national treatment principle. Rather, they should start to develop and implement a TRIPS-compatible *sui generis* system that meets their needs. The existence of such a system might be particularly helpful for the review of Art. 27 (3) b TRIPS in 1999 (see 1.1.4).

2.5 Effective enforcement

Article 27 (3) b requires explicitly that the *sui generis* system be 'effective'. However, the TRIPS Agreement does not specify any criteria for effectiveness. It has been suggested that effectiveness relates to the level of protection of the *sui generis* system and therefore requires certain substantial minimum rights to be conferred by the *sui generis* right. Such interpretation, however, causes enormous difficulties as soon as one attempts to define those minimum rights. The UPOV Acts do not qualify as a yardstick since, while there are many references to relevant international IPR treaties in the TRIPS Agreement, references to the UPOV Acts are conspicuous by their absence. Furthermore, and more important, it might be impossible to define effectiveness on a global scale. The same protection system may be of different effectiveness in different countries whatever specific criteria are being used for evaluating the effectiveness.

It is, finally, the TRIPS Agreement itself which points at a different interpretation of the term 'effective'. The TRIPS Agreement employs the term 'effective' in particular in the context of the national enforcement of rights and the procedures for the multilateral prevention and settlement of disputes between governments (cf. Preamble, Art. 41 (1) TRIPS), while the rights to be conferred by an IPR are either defined in detail or as 'equitable remuneration' (Art. 14 (4); Art. 70 (4) TRIPS). Against this background an 'effective' *sui generis* system needs to allow effective action against any act of infringement as required by Arts. 42-49 TRIPS. Its effectiveness does not, however, depend on its requirements for or on the level of protection.

It should be noted that the civil and administrative procedures as required by Arts. 42-49 TRIPS are based on the presumption, also emphasized in the preamble to the TRIPS Agreement, that IPR are private rights for the enforcement of which members only have to provide the judicial procedures. The right-holders are responsible for uncovering infringements of their rights and, subsequently, taking the appropriate action in court, if they so wish. A *sui generis* system which provides for a form of distribution of revenues obtained from a seed tax levied by the government would not seem to fit the concept of the civil and administrative procedures and remedies as required by the TRIPS Agreement. Such a system would require the state to control compliance with the *sui generis* system, which means the state would have to ensure that consumers actually pay tax when they buy or plant back seed of a protected variety. The right-holder, however, would certainly not be in a position to take action against any act of infringement, i.e. tax evasion, which would mean that the civil and administrative procedures and remedies as foreseen by the TRIPS Agreement could not be made use of. A remuneration system based on a seed tax system does not therefore seem to comply with the TRIPS Agreement.

3. Leading Principles of the International Framework on Plant Genetic Resources

Summary

Apart from the minimum requirements laid down by the TRIPS Agreement, any *sui generis* system should also take into account the objectives of other international treaties and/or emerging principles of the international community, especially those dealing with plant genetic resources and Traditional Resource Rights (TRR). Relevant multilateral treaties include the Convention on Biological Diversity (CBD) and the ILO Convention 169. Soft law is contained in a wide range of instruments, such as the Rio Declaration, Agenda 21, the International Undertaking on Plant Genetic Resources (IUPGR), the UNESCO/WIPO Model Provisions for National Laws on the Protection of Expression of Folklore, and the Draft Declaration on Indigenous Rights (DDIR).

A set of obligations and widely accepted principles emerges from these instruments that is certainly relevant in the shaping of a *sui generis* system:

- States have the sovereign right over their own natural resources, including genetic resources.
- Farmers' Rights arising from the past, present and future contributions of farmers in conserving, improving and making available plant genetic resources are recognized in order to allow farmers, their communities and countries in all regions of the world to participate fully in the benefits derived at present and in the future, from the improved use of plant genetic resources, through plant breeding or other scientific methods.
- Biological diversity, including genetic diversity, shall be conserved, enhanced and sustainably used. Patents and other IPR shall be supportive of and not run counter to this objective.
- Access to genetic resources shall be subject to Prior Informed Consent (PIC). Where granted, access shall be on mutually agreed terms.
- Benefits arising from the commercial and other utilization of genetic resources shall be shared in a fair and equitable way upon mutually agreed terms, multilaterally or on a bilateral basis.
- The results of research and development arising from the utilization of genetic resources, as well as the technology using such resources, shall be shared in a fair and equitable way on terms mutually agreed upon. Transfer of technologies relevant to the conservation of biological diversity, and access to the sustainable use of its components, and to technologies that make use of genetic resources shall be provided and/or facilitated under fair and most favourable terms.
- Indigenous and farming communities' knowledge, innovation and practices related to plants and plant genetic resources shall be protected and encouraged. Special measures shall be taken to ensure this, including mechanisms of free and informed consent.

The *sui generis* system as required by the TRIPS Agreement is not an adequate instrument to realize all aspects of the above obligations and rights. Neither can it address all the problems related to the sharing of benefits between users and providers of genetic resources as well as related knowledge. Nevertheless, in the process of developing *sui generis* systems for the protection of plant varieties, these principles should be taken into account and it should be ensured that neither the overall *sui generis* system nor any other IPR run counter to them.

The *sui generis* system as required by the TRIPS Agreement neither aims at the sustainable conservation and use of biodiversity, nor is its purpose to protect and promote local knowledge systems, stressing the collective and non-proprietary nature of those systems. Yet there are other legally binding as well as non-binding instruments which were designed to deal specifically with questions concerning plant genetic resources and so-called traditional resource rights. There is also a growing body of internationally accepted principles dealing with the socioeconomic rights of local communities and especially of indigenous peoples. These rights and principles often cover the natural resources forming the basis of local communities' and indigenous peoples' livelihood, in most cases including biological resources, implicitly or explicitly. They also cover certain types of uses of natural resources, i.e. acts that might be affected by IPR legislation dealing with plant varieties. The principles and obligations enshrined in these texts certainly merit attention in the development of a *sui generis* system for the protection of plant varieties.

Thus, the purpose of this chapter is briefly to outline these internationally accepted principles and to explore what demands they pose to IPR in the field of plant genetic resources and to the *sui generis* system for the protection of plant varieties, in particular. It should be noted, however, that the *sui generis* system as required by the TRIPS Agreement is only one and not necessarily the most adequate instrument to realize all those principles. Nevertheless, in the process of developing *sui generis* systems for the protection of plant varieties, member states may consider introducing provisions implementing, for example, Farmers' Rights in order to balance the privilege being granted to plant breeders by the *sui generis* right. In the development of a *sui generis* system it should also be ensured that neither the overall system itself nor any other IPR run counter to the principles and rights enshrined in those agreements and international treaties dealing specifically with the use and conservation of biodiversity.

3.1 The principle of national sovereignty over genetic resources

3.1.1 The basic international instruments

In 1983 the first document of global relevance dealing with the exploration, preservation, evaluation and the making available of plant genetic resources was adopted by the 22nd session of the FAO Conference. At the time of its adoption, the (legally non-binding) International Undertaking on Plant Genetic Resources (IUPGR) which, at the latest count in 1995, was adhered to by 110 countries, was primarily based on the "universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction".

However, the claimed principle of free exchange incurred the displeasure of some countries providing breeders' rights for plant varieties, since the Undertaking not only applied to plant genetic resources *sensu strictu* but also to "special genetic stocks" as well as "current breeders' lines". Countries providing Plant Breeders' Rights (PBR) felt there was a danger that such rights might be in conflict with the principle of free exchange as enshrined in the Undertaking. In an attempt to reconcile PBR with the principle of free exchange, FAO therefore qualified the free-exchange principle in 1989 by adopting an "agreed interpretation" of the Undertaking (Resolution 4/89). The agreed interpretation states on the one hand that PBR as provided for under UPOV are "not incompatible" with the International Undertaking". On the other hand it emphasizes that plant genetic

resources should nevertheless be freely available as a "heritage of mankind", while at the same time making sure that "free access" does not mean free of charge.

The approval of Plant Breeders' Rights was balanced with the simultaneous recognition of the Farmers' Rights concept (Resolution 5/89) which can partly be understood as a direct response to the PBR regimes.

Finally, in 1991, the Undertaking's free-exchange principle was further qualified by an FAO resolution explicitly endorsing that nations have sovereign rights over their plant genetic resources. Additionally, Resolution 3/91 states that breeders' lines and farmers' breeding material should only be available at the discretion of their developers during the period of development. The introduction of the sovereignty principle was accompanied by a decision in favour of setting up the International Fund for Plant Genetic Resources, through which the concept of Farmers' Rights should be implemented. Based on strictly voluntary contributions, this fund has up to now failed to reach its objectives.

The difficulties in achieving any substantial and operational concept of Farmers' Rights in FAO may have been one reason why, in 1992, plant genetic resources, among others, were made the subject of another agreement, the Convention on Biological Diversity (CBD). The CBD, which has been ratified (as at 23 April 1997) by 168 countries, is the only instrument of international law dealing with biodiversity and genetic diversity as such (Glowka *et al.* 1994). While reaffirming and building upon the principle that states have sovereign rights over their own biological resources, the Convention aims at the conservation of biological diversity, at the sustainable use of its components, and at the fair and equitable sharing of the benefits arising from the use of genetic, including plant genetic, resources.

The interface between the IUPGR and the CBD

The CBD has not replaced the IUPGR. First of all, both instruments are different in scope. While the IUPGR covers (and is confined to) all plant genetic resources, the CBD, which in principle covers all biological resources, does not address access to collections of genetic resources that were acquired before its entry into force. Secondly, the CBD is silent on the issue of Farmers' Rights, while this is one of the important building blocks of the IUPGR. Consequently, Resolution 3 of the Nairobi Final Act has recognized the need to seek solutions for both issues, i.e. access to pre-existing collections and Farmers' Rights, within the FAO Global System for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Agriculture.

Although such solutions have not been reached yet, FAO has made some progress in contributing to the implementation of the IUPGR and the CBD. The International Code of Conduct for Plant Germplasm Collecting and Transfer, adopted by the FAO Conference in 1993, offers a model framework for national legislation on plant germplasm, whether collected in accordance with the Convention or not, which would allow countries to exercise sovereignty over, and to benefit from, their plant genetic resources. Furthermore, in 1994, FAO negotiated a model agreement with the Consultative Group on International Agricultural Research (CGIAR) placing the international collections of plant germplasm maintained at the CGIAR Centres under the auspices of FAO. The agreements, which in the meanwhile have been concluded between FAO and all the CGIAR Centres holding plant genetic resources, identically state that the Centres shall hold designated material in trust for the benefit of the international community and shall not claim legal ownership over the germplasm or apply any form of IPR to the material itself or related information.

However, the agreements neither provide for any regulations on the sharing of benefits arising out of the use of the germplasm, nor address the issue of Farmers' Rights.

Moreover, as a follow-up to Resolution 3 of the Nairobi Final Act, the FAO Conference took the decision to start negotiations on the issue of the realization of Farmers' Rights, on the issue of access on mutually agreed terms to plant genetic resources including *ex situ* collections not covered by the CBD (cf. IPGRI 1996), and on the harmonization of the IUPGR with the CBD. Important contributions to these questions are expected from the ongoing negotiations in the FAO Commission on Genetic Resources for Food and Agriculture (CGRFA).

3.1.2 The meaning of national sovereignty over plant genetic resources

The sovereign right of a state over its territory, including its natural resources, is a well-established principle in international law (Correa 1994b). The CBD as well as the IUPGR (through Resolution 3/91) are premised on the concept of the sovereign rights of states to exploit their own resources according to their own policies. The Convention explicitly infers from this right the authority of states to determine and regulate access to their genetic resources. Although this principle of sovereignty over genetic resources had already been stated by the UN Conference on the Human Environment in Stockholm in 1972, it is to the Convention's credit that it has enshrined this principle for the first time in a provision of a binding international treaty.

While the sovereign right of states over their genetic resources is no longer questioned, it should be noted that it may be very difficult to exercise this right in practice. Difficulties in exercising a right do not limit the right as such; they may, however, render this right less significant.

3.1.2.1 Exclusiveness of the sovereign right

The significance of a country's right to determine access to its genetic resources greatly depends on whether this right is exclusive.

The fact that genetic resources are replicable and that many genes occur in more than one country has considerable implications for the realization of a country's sovereign right over its genetic resources. While in such cases one may argue that each of the two or more countries of origin have sovereign rights separately, it is also clear that these rights do not extend to each other's resources. Thus, sovereign rights over genetic resources can be of an exclusive nature only if the resources occur in not more than one country, or if all countries of origin have agreed to exercise their rights jointly.

3.1.2.2 Controllability of access to genetic resources

A further difficulty for countries to exercise their sovereign right over genetic resources is due to the enormous problems of controlling access to genetic resources. There is evidence that in the follow-up to the entry into force of the CBD, a growing number of countries have started to regulate access to their genetic resources (Barber and La Vina 1995; Ruiz 1995; Zakri 1995). In fact, many developed as well as developing countries had such legislation in place long before the CBD explicitly reaffirmed their competence to regulate access (Ajai 1995). However, as is the case with laws in general, access laws are only as good as the possibilities to control compliance with them.

Controlling compliance with access legislation is especially difficult because seeds are small and their removal is almost impossible to control physically. A small number of seeds having illegally left the country may suffice to deprive that country of its actual control over the resource. Losing control over the resource does not of course mean that the country is also deprived of its sovereign right. It means, however, that the tool for exercising this right, which is exclusive control over the resource, is no longer available.

3.1.2.3 Legal limitations to the sovereign right

Apart from the rather technical limitations mentioned above, the sovereign right over genetic resources is also limited by legal duties. The CBD, as well the IUPGR, clearly aim at an exchange system for plant germplasm which should be as free as possible. Thus, the CBD requires contracting parties to endeavour to facilitate access by other contracting parties and not to impose restrictions that run counter to the objectives of the Convention. Similarly, the above-mentioned FAO Code of Conduct on Germplasm emphasizes that access to plant genetic resources should not be unduly restricted.

In order to ensure a smoothly working system for germplasm exchange, both the CBD and the IUPGR require that access to genetic resources be granted on "mutually agreed terms". The CBD, as well as the FAO Code, require as an additional instrument the Prior Informed Consent (PIC) of the country providing resources. The PIC procedure is to ensure compliance with access legislation (see IPGRI 1996).

Finally, the sovereign right over plant genetic resources is limited by two further important factors which are explicitly mentioned in the CBD. Firstly, the sovereign right must be exercised in accordance with the Charter of the United Nations and the principles of international law. Secondly, the right of states to exploit their own resources does not affect their responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other states or of areas beyond the limits of their national jurisdiction.

3.2 Access to plant genetic resources on mutually agreed terms

The sovereign right of states over their plant genetic resources implies the right to grant or refuse access to plant genetic resources.

The IUPGR does not use the expression 'free access' in its main text. Instead, it specifies the conditions under which states are required to allow access to samples of their genetic resources and to permit their export, where the resources have been requested for the purposes of scientific research, plant breeding or genetic resource conservation. It has been argued that the Undertaking clearly excludes access with the aim of reproducing the materials for commercial purposes, such as for propagating seeds (Correa 1994b). While this is formally correct, the line between commercial and breeding purposes may sometimes be difficult to draw.

According to the Undertaking, samples are to be made available "free of charge, on the basis of mutual exchange or on mutually agreed terms". From this it is not clear at all – though it seems to be a common understanding – that the Undertaking in its 1983 version subscribes to the concept of free exchange. Instead, one could interpret the Undertaking as allowing three alternative ways by which plant genetic resources may be made available: free of charge, on the basis of mutual exchange, or finally, on mutually agreed terms. In 1983, states adhering to the IUPGR obviously focused on the first and second alternatives.

All three ways to make plant genetic resources available are also allowable under the CBD which, however, only explicitly mentions the last option: Art. 15 (4) makes mutual agreement on terms a condition for access to genetic resources. Additionally, Art. 15 (5) CBD offers contracting parties the option to make access to genetic resources subject to their PIC. As a means of ensuring compliance with bilateral or multilateral access agreements or with a state's national legislation, the PIC procedure may be an appropriate though not the only conceivable instrument.[14]

The CBD, the IUPGR and the Code of Conduct make access to plant genetic resources conditional on reaching mutually agreed terms, and, thus, imply negotiations between the party granting access and another entity desiring access (Glowka *et al.* 1994).

The negotiators of the CBD left it up to the Convention Parties to decide on how the provisions on access to genetic resources and on PIC are to be implemented. In particular, the Convention does not include any provisions on the actual contents of possible access agreements nor does it give any hint on how the PIC procedure should be implemented.

3.2.1 Mutually agreed terms

While the Undertaking makes access to genetic resources conditional on negotiations between the resource providers and governments as well as 'institutions' active in the field of plant genetic resources, the CBD only provides for negotiations between the contracting parties granting access and other entities. However, by setting up the necessary legislation, contracting parties make their access conditions binding on private resource providers as well.

Although the Convention leaves considerable discretion to the negotiators (Glowka *et al.* 1994, cf. UNEP 1995), the terms to be agreed have to be consistent with the obligations and general aims of the CBD.

3.2.2 Prior Informed Consent

The principle of prior informed consent (PIC) is inextricably connected with the requirement of mutually agreed terms as set out above. Depending on the terms for access and use, PIC will be given or not. So far the PIC procedure has only been used for dangerous substances. The best-known convention requiring PIC of the importing country is the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal [28 I.L.M. 649 (1989)]. Two further non-binding instruments using the PIC principle, the FAO International Code of Conduct on the Distribution and Use of Pesticides and the UNEP London Guidelines for the Exchange of Information on Chemicals in Trade, also focus on dangerous substances exclusively. While these instruments use the PIC requirement in order to give countries the choice of whether importation of certain dangerous substances shall be allowed, the PIC requirement as provided for by the CBD will mainly have to serve as an instrument to control export and as a tool for negotiations on the conditions under which access is granted and export permitted.

[14] The agreement between FAO and the CGIAR Centres holding genetic resources makes the granting of access to designated germplasm conditional on a further requirement, i.e. that any entity receiving samples shall not claim legal ownership over the samples received and shall further ensure that this condition is respected in transfers to third parties (cf. Barton and Siebeck 1994).

3.2.3 Approval and involvement of the holders of knowledge

According to Art. 8 (j) CBD, contracting parties shall as far as possible and appropriate promote the wider application of traditional knowledge, innovations and practices and encourage the equitable sharing of the benefits from the utilization of such knowledge, innovations and practices "with the approval and involvement" of their holders. Thus, the CBD makes access to plant genetic resources conditional not only on reaching mutually agreed terms between the party granting access and another entity desiring access. In addition the CBD requires approval of and benefit-sharing with the holders of knowledge, innovations and practices. However, this requirement is subject to the parties' national legislation which implies that all national legislation will take precedence (Glowka *et al.* 1994).

The Convention gives no hint as to how this sort of domestic PIC procedure and benefit-sharing should be organized. To implement the domestic PIC procedure as part of the international PIC procedure suggested in Art. 15 (5) CBD, one could, however, consider making the international PIC dependent on the prior informed consent of the local communities involved (Hendricks *et al.* 1994).

3.3 Benefit-sharing

The sustainable use, conservation of biological diversity and the equitable sharing of benefits arising out of the utilization of genetic resources are the aims which the CBD pursues by recognizing the right of states to determine and regulate access to their genetic resources and by requiring that access to genetic resources shall be subject to PIC and shall, where granted, be on mutually agreed terms. The principle of benefit-sharing is a generally accepted principle of international law. Beyond the different language of the legal instruments and the different actors addressed by the instruments, a principle has emerged in recent years that those who have been caring for and who provide (plant) genetic resources should participate in the benefits arising from the use of these resources and related knowledge.

> The principle of benefit-sharing with communities or individuals providing resources is also endorsed by Agenda 21. Chapter 14 (57) calls for measures for "the fair and equitable sharing of benefits and results of research and development in plant breeding between the sources and users of plant genetic resources". Chapter 15 (4g) reiterates this objective by requiring users to "ensure the opportunity for the participation of [indigenous people and their communities, emphasizing the particular role of women] in the economic and commercial benefits derived from the use of such traditional methods and knowledge". Furthermore, the principle of benefit-sharing is reflected by the Farmers' Rights Resolution 5/89 to the IUPGR which requires that farmers, especially those in developing countries, should benefit from the use of the natural resources they have conserved. According to the FAO Code of Conduct on Germplasm, the sharing of benefits between donors and users of plant genetic resources, and the facilitating of compensation of local communities and farmers for their contribution to the conservation and development of plant genetic resources, shall be promoted. Users of genetic resources shall, in particular, provide compensation to the local communities and farmers for the benefits derived from the use of germplasm (Art. 14). The compensation may, for example, consist of technology transfer, training or support of research.

The rationale behind the idea of the sharing of benefits is that those conserving and developing genetic resources through their sustainable utilization shall be compensated and shall obtain incentives to carry on doing so (e.g. Gollin 1993; Cooper *et al.* 1994).

According to Art. 15 (7) CBD contracting parties shall take legislative, administrative or policy measures with the aim of fairly and equitably sharing the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the contracting party providing such resources.

Moreover, contracting parties shall encourage, also at national level, the equitable sharing of benefits arising from the use of traditional knowledge, innovations and practices (see 2.2.3). For this purpose, it is certainly not enough simply to ensure that benefits return to the parties providing resources. Compensation should also flow back to the particular people who conserve biodiversity (WRI *et al.* 1992; Downes 1993).

The benefits may be shared in cash or other forms, such as monetary benefits, royalties or access to (bio)technologies developed with the genetic resources in question (Glowka *et al.* 1994; UNEP 1995). The Convention leaves considerable discretion to the contracting parties as to the form of multilateral or bilateral, individual or general benefit-sharing agreements. However, benefit-sharing agreements need to comply with the general aims of the Convention. In particular, any benefit-sharing regime should ensure the involvement of the holders of the resources and related knowledge (cf. ICCBD 1994; IPGRI 1996).

Both the CBD and the FAO Code of Conduct on Germplasm suggest building up the scientific research capacity of those countries which provide genetic resources. The FAO Code proposes, as one form of compensation for the benefits derived from the use of germplasm, various measures in training, support for research, support for programmes to evaluate and enhance local 'landraces', and supply of scientific and technical information obtained from the germplasm. The Convention requires contracting parties to endeavour to develop and carry out scientific research based on genetic resources provided by other contracting parties with the full participation of such contracting parties, where possible within their territory (Arts. 15 (6), 19 (1) CBD).

3.4 Traditional Resource Rights

The term 'Traditional Resource Rights' (TRR) has been introduced to encompass many different types of rights relating to the traditional or customary use of resources by indigenous people and local farming communities. The term reflects an attempt to build upon the concept of IPR protection without restricting it to the concept of property, while recognizing that traditional resources – tangible and intangible – are also covered under several other international agreements (Posey and Dutfield 1996).

TRR as a package of rights primarily aim at the protection of the traditional or customary use of tangible and intangible resources by indigenous people and local farming communities. Some of these rights have as yet barely materialized in binding regulations, even though the necessity to strengthen them is widely recognized, not least with respect to the possible benefits on the conservation and sustainable use of biological resources.

It is, however, difficult to define the holders of TRR. This is why the IUPGR provides for an international fund, by which Farmers' Rights shall be implemented. A further problem with TRR is that some of the common legal terms and concepts – like 'property' and 'tenure' – cannot always be easily applied to social situations, institutions and relations existing among indigenous peoples or traditional farming communities. For indigenous people,

'property' frequently has intangible, spiritual manifestations and any attempts at individual control, privatization or creation of a commodity of these is incomprehensible or at least highly problematic.

3.4.1 Indigenous peoples' rights

There is no internationally accepted definition of the term 'indigenous' or the term 'tribal' which is sometimes used synonymously (CHR 1979; ILO No. 169; Axt *et al.* 1993; Hitchcock 1994; Greaves 1996). Furthermore, there is a long-standing debate whether indigenous groups are to be called 'communities', 'people', 'peoples' or 'populations'. The term 'peoples' is associated with the right of complete self-determination, which governments often have no intention of according to indigenous groups residing within their national territory. However, the terms now seem to be used interchangeably (Axt *et al.* 1993). According to the Independent Commission on International Humanitarian Issues (1987) the term 'indigenous' includes the four elements of pre-existence, non-dominance, cultural difference and self-identification.

3.4.1.1 The right to self-determination

The basic right of indigenous peoples urged for in many international declarations is the right to self-determination. Many general international norms relevant to self-determination are contained in texts which do not specifically address indigenous people(s) but focus on human rights in general, such as the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights, and the International Covenant on Economic, Social and Cultural Rights. These instruments of international law contain *inter alia* the right to own property individually or collectively, the right to maintain and enjoy one's own culture, the right to equal protection of the law and minority rights (Shelton 1995). The only international human rights treaty specifically concerned with indigenous peoples is ILO Convention No. 169 Concerning Indigenous and Tribal Peoples in Independent Countries which was adopted in 1992 and is at present legally binding on eight parties only.

In accordance with many other instruments and declarations, ILO Convention No. 169 calls for measures to realize the social, economic and cultural rights of indigenous and tribal peoples with respect to their social and cultural identity, their customs and traditions and to safeguard their property, labour and culture, in accordance with their own "freely-expressed wishes". By aiming at protecting against arbitrary discrimination, deprivation or other prejudicial actions, most of these rights are of a rather defensive nature, whereas the positive rights to material and immaterial aspects of indigenous peoples' livelihood are generally secured more vaguely. While it is recognized unequivocally in international environmental law that indigenous people possess knowledge and use traditional practices that are essential for the conservation and sustainable use of the environment, this has had little effect in the past on the rights granted to indigenous people regarding the protection of their knowledge, their land rights or their rights to control over their natural wealth and resources (Shelton 1995).

3.4.1.2 The right to land

However, there is a clear trend towards the establishment of such rights, as they are embodied, for example, in the 1993 agreed Draft Declaration on the Rights of Indigenous Populations (CHR 1993). The rights to land and territory are also addressed in the Universal Declaration on Human Rights, ILO Convention No 169 and the International

Covenant on Economic, Social and Cultural Rights. Art. 26 of the Draft Declaration on the Rights of Indigenous Populations attributes to indigenous communities the right to their land, including "fauna and flora and other resources which they have traditionally owned or otherwise occupied or used". Such a right would clearly enable indigenous communities to regulate access to the genetic resources, including plant varieties, situated on their land and territories. While their property right to the land where the resources are based is still controversial, the right of indigenous communities to participate in those decision processes which affect them and their local livelihood systems is clearly established in international law.

However, even if such rights were recognized, the ability in practice to prevent others from using the resources would be a more likely basis for an agreement to use these resources under which a system of returns to the community could be established (ICCBD 1994).

3.4.1.3 The right to indigenous intellectual and cultural property

A trend similar to that which concerns tangible resources exists in relation to the knowledge and culture of indigenous people. Because of the nature of most knowledge of indigenous and local communities – held collectively, evolved over time – existing intellectual property regimes are largely inadequate for protecting or rewarding this knowledge (Axt *et al.* 1993; Lesser 1994). Intellectual property legislation, like patent or copyright law, is basically designed to protect readily identifiable, differentiated contributions to existing, general knowledge, while due to its very nature indigenous knowledge is gradually built over decades or centuries (CHR 1992; Shelton 1995) and is often **traditional** knowledge which due to its lack of novelty is, in particular, not protectable under patent law.

ILO Convention 169 states that governments shall "respect the special importance of the cultures and the spiritual values of the peoples concerned, of their relationship with the lands and territories ... and in particular the collective aspects of this relationship" (Art. 13 (1)). In general terms, the protection of the intellectual property and traditional knowledge of indigenous people is also recognized by Agenda 21 (Chapter 26, 4b) which explicitly calls for action to "adopt or strengthen ... legal instruments that will protect indigenous intellectual and cultural property". Also, the Draft Declaration on Indigenous Rights clearly recognizes the ownership, control and protection of cultural and intellectual property of indigenous peoples (Art. 29). They are accorded the "right to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seeds, medicines, knowledge of properties of fauna and flora".

Suggestions that the "intellectual integrity" of indigenous communities be recognized also resulted from the debate about the protection of "expressions of folklore" (UNESCO/WIPO 1985; UNESCO 1989). The Model Provisions for National Laws on the Protection of Expressions of Folklore, set up jointly by UNESCO and WIPO in 1985, are directed against any "illicit exploitation and other prejudicial actions" and aim at the control of cultural 'folklore' expression through people still using these expressions in their customary context. The Model Provisions define folklore as "the totality of tradition-based creations of a cultural community ... recognized as reflecting the expectations of a community insofar as they reflect its cultural and social identity" (UNESCO 1989). In indigenous societies, plant varieties sometimes referred to as 'folk varieties' (Keystone 1990) may well fall under that definition. Finally, as set out above, Art. 8 (j) of CBD requires

contracting parties to respect the achievements of indigenous and local communities, including their knowledge, innovations and practices.

3.4.1.4 The right to benefit from the use of indigenous knowledge

The right to indigenous intellectual property requires not only that the value of such knowledge is recognized, but also that the holders of such property shall benefit from the use of their knowledge or material. While the UNESCO/WIPO Model Provisions suggest that the authorization to use folklore be made dependent on payments, Art. 8 (j) of the CBD urges for the "equitable sharing of the benefits arising from traditional knowledge innovation and practices". The Draft Declaration on Human Rights requires "just and fair compensation" where resources of indigenous communities are being affected. Finally, Art. 15 of ILO Convention 169 states that indigenous people shall participate in the benefits arising from any activities relating to resources pertaining to land of indigenous and tribal peoples.

3.4.1.5 Participatory rights

Indigenous peoples' rights also include the right of indigenous or local communities to participate in any decision relating to their resources and knowledge, particularly when commercial acts are envisaged. This principle is directly reflected in the CBD's Art. 8 (j) requiring the approval and involvement of the holders of knowledge (see 2.2.3).

Pointing in the same direction, the WIPO/UNESCO Model Law makes any expressions of folklore with gainful intent subject to authorization by the traditional users. Art. 15 of ILO Convention 169 urges that wherever a state "retains the rights to ... resources pertaining to lands, governments shall establish or maintain procedures through which they shall consult these peoples" to assess their interests before undertaking or permitting any programmes for the exploration or exploitation of such resources. Similarly, Principle 22 of the Rio Declaration supports the recognition of interests of indigenous peoples and calls for their "effective participation in the achievement of sustainable development".

The strongest mechanism to realize the requirement of authorizing the use of resources is the instrument of PIC as discussed above. Usually applied at the international level, the PIC mechanism may also be applied to acts at the national level.

To sum up, participation in decision-making, including PIC, and the sharing of benefits based on the use of indigenous knowledge or resources, are principles which are increasingly recognized or at least reflected by international law as a means for the realization of indigenous peoples' rights.

3.4.2 Farmers' Rights

There are important differences between indigenous communities who may also often be farmers, and farming communities that are not indigenous (GRAIN 1995). Indigenous communities have distinctive and often unique social characteristics and there are many situations where their interests may conflict with the interests of farming communities belonging to a dominant culture. However, both groups are faced with similar problems in relation to their traditional resources. Both tend, for example, to be marginalized, they are often directly dependent on the functioning of local ecosystems and they may have common demands for self-management and control over their resources (Singh Nijar 1994). They often have very similar interests in relation to the protection of their knowledge, innovation and practices relating to plant genetic resources.

Since Farmers' Rights serve the purpose of attaining the IUPGR's overall purposes, it should be noted that any actions contrary to the goals of the Undertaking must also be termed as incompatible with the concept of Farmers' Rights. Implementing the Farmers' Rights concept does not just mean implementing the International Fund on Plant Genetic Resources. The Farmers' Rights concept poses demands on the international resource policy and it certainly requires that farmers in developing countries participate in the advantages and benefits derived from plant genetic resources. Furthermore, in line with the CBD, Farmers' Rights demand that national and international agricultural research fully respond to the needs and demands of farming communities. The Farmers' Rights concept also calls for the full participation of farmers in the results of and the benefits resulting from the use of plant genetic resources and related knowledge (Leskien and Flitner 1996).

3.4.2.1 Farmers' Rights as IPR?

As with other Traditional Resource Rights, however, it would be a misconception to consider Farmers' Rights as a type of IPR, similar to PBR or patents. Rather, they are a concept which can be realized only with a package of measures to support farmers in their ongoing contributions to plant varietal diversity.

The fact that Farmers' Rights in the context of the IUPGR cannot be claimed by individual farmers and are not directed to anything specific, such as plant varieties, is represented very clearly in FAO Resolution 5/89. This defines Farmers' Rights as "rights arising from the past, present and future contributions of farmers in conserving, improving and making available plant genetic resources, particularly those in the centres of origin/diversity. These rights are vested in the International Community as trustee for present and future generations of farmers in order to ensure full benefits for farmers, and supporting the continuation of their contributions as well as the attainment of the overall purposes of the International Undertaking".

3.4.2.2 Farmers' Rights as a demand on IPR

Most relevantly, the concept of Farmers' Rights imposes clear demands on the existing system of IPR. As already mentioned, in 1989, Farmers' Rights were declared "not incompatible" with PBR "as provided for under UPOV" (see 3.1.1).

This statement, however, obviously related to the UPOV Act of 1978 and not to the (then non-existent) Act of 1991.

By leaving the so-called farmers' exemption to the discretion of the member states, the UPOV Act of 1991 directly concerns the Farmers' Rights concept. A prohibition on planting back saved seed would virtually take away a central input resource for the large majority of all farmers in the world (cf. Jaffee and Srivastava 1994). It would thus be in striking contradiction to the concept of Farmers' Rights which was developed to balance the preferential treatment of plant breeders.

However, it should be noted that even countries that are party to the 1991 UPOV Act will be allowed to retain the farmers' exemption (see below, 4.3.2.2). Hence, the 1991 Act does to a certain extent allow Plant Breeders Rights to be regulated in cohesion with Farmers' Rights. In the light of the Farmers' Rights concept, countries having PBR laws in place may exploit this possibility by guaranteeing the farmers' exemption for all plant varieties eligible for protection.

While PBR as provided for by the UPOV Act of 1978 (and under certain conditions also as provided for by the UPOV Act of 1991) are "not incompatible" with Farmers' Rights, patents on components of plants or even entire plants do not seem to comply with the

International Undertaking. Patents on plant material would directly restrict practices that are common to the large majority of all small-scale farmers in the world. Being absolutely exclusive, patents on plant genetic resources thus do not seem to be in line with the general goals of the Undertaking. This view is supported by the Agreed Interpretation adopted by FAO in 1989. Although at that time the granting of plant patents in some industrialized countries was already common knowledge, the Agreed Interpretation only declares plant breeders' rights as being "not incompatible" with the International Undertaking. The Agreed Interpretation does not mention patents. However, against the background that access to protected materials would be more restricted by patents than by PBR, it can hardly be assumed that the patenting of plants would be compatible with the International Undertaking.

3.5 The leading principles of the international framework on plant genetic resources as demands on IPR

3.5.1 The relationship between the CBD and TRIPS

The relationship between the TRIPS Agreement and obligations resulting from other instruments of international law, in particular the CBD, has been and is still under debate (cf. Straus 1993; Cameron and Makuch 1995; Downes 1995).

While the TRIPS Agreement neither explicitly addresses the issue of plant genetic resources nor mentions the issue of conservation of resources, the CBD states that patents and IPR may have an influence on the implementation of the Convention. Art. 16 (5) explicitly requires contracting parties to ensure that patents and IPR are supportive of and do not run counter to the objectives of the Convention. On the other hand, according to Art. 16 (2) CBD, in the case of a transfer of technology which is subject to patents and other IPR, access to and transfer of the technology shall only be provided on terms "which recognize and are consistent with the adequate and effective protection of Intellectual Property Rights". However, the application of this requirement to recognize IPR shall be consistent with the former statement, that IPR shall be supportive of and not run counter to the objectives of the Convention.

The real question is whether WTO member states may invoke the objectives of the Convention in order to justify any measures which are contrary to the WTO TRIPS Agreement. This is a question of conflict of laws for which neither the TRIPS nor the CBD provides any special rules. Art. 22 of the CBD only relates to pre-existing agreements and is therefore not applicable to the TRIPS Agreement which was signed after the entry into force of the CBD. Although it has been argued that in a case of conflict (between two countries being members of both treaties) the CBD would as the more specific treaty take priority over the more general TRIPS Agreement (Cameron and Makuch 1995), it is rather doubtful that a WTO Panel would agree. A panel could certainly also take the view that the TRIPS Agreement as the later of the two treaties takes priority over the CBD.

It should be noted, however, that the TRIPS Agreement allows measures (see 1.4-1.10), such as prevention of the abuse of IPR (Art. 8 TRIPS), the exclusion from patentability (Art. 27 (2) and (3) TRIPS), exceptions to the rights conferred (Art. 30 TRIPS), and certain uses of inventions without authorization of the patent holder, including compulsory licensing (Art. 31 TRIPS), which may possibly help to limit potentially detrimental effects of the patent system on the objectives of the Convention, such as technology transfer, the sustainable use of biodiversity or the equitable sharing of benefits (WTO 1995).

3.5.2 Specific demands on IPR

Any legal measure to be taken in the field of plant genetic resources should avoid restricting practices that are typical 'traditional' or 'customary' uses of the resources for livelihood in the widest sense, especially if such practices are sustainable and form part of the culture of indigenous people or marginalized farming communities. It is important to clearly limit the scope of IPR when it comes to all kind of acts performed by indigenous people and farming communities as part of their traditional cultural heritage. In this context, the concept of tradition or cultural heritage cannot be understood solely in a conservative, static sense but has to allow for the dynamic development of such practices as well. It could be argued that such an approach should include the right of farmers to freely choose their seeds and planting material and to use freely all harvested products for further production and, where it is common, also to sell these products as propagating material (cf. Swaminathan 1996).

In particular, IPR legislation (including *sui generis* legislation) should avoid interfering with established or emerging principles of traditional resource rights. One may argue, for example, that the *sui generis* system and other IPR should not hinder any acts, such as the planting-back of plant varieties, which form part of traditional agriculture.

Another option to be considered is to include in the *sui generis* system elements that can serve as a tool or 'trigger' to facilitate the sharing of benefits with the informal innovators who created material or knowledge used in the creation of varieties to be protected under that *sui generis* system. More generally, the *sui generis* system could become a trigger point for negotiations on benefit-sharing (see 1.3.2 and 1.4.3). It should be noted, however, that the principle of benefit-sharing certainly requires more than just being integrated into IPR legislation, simply because not all applications of plant genetic resources end up being protected by an IPR. Since in many countries plant varieties and other products need to undergo an authorization or certification procedure before they are allowed to be released, the application for such marketing authorization could also be used as a trigger for benefit-sharing.

Furthermore, in order to implement indigenous people's rights one may also consider designing a *sui generis* system in such a way that would facilitate the protection of 'traditional resources', i.e. 'landraces', and thus to provide for a direct reward for the (historical and present) cultural efforts necessary for their creation.

4. Possible Elements of an Intellectual Property Right *Sui Generis* for Plant Varieties

Summary

Various elements can be included in a TRIPS-compatible *sui generis* system for the protection of plant varieties:

- Firstly, the protectable subject matter must be defined. There are several ways to define the term plant variety. Furthermore, the TRIPS Agreement leaves the option to protect additional subject matter.
- Secondly, the requirements for protection must be set up. The 'traditional' requirements for the protection of plant varieties – that they be novel, distinct, uniform and stable – can be altered substantially. But the plant grouping to be protected still has to be distinct from other plant groupings and it must be possible to clearly identify it with reasonable effort. Moreover, additional requirements for protection may be set up, such as Value for Cultivation and Use (VCU) or declaration of origin. While the former may allow member states to provide for incentives to fit their specific priorities in plant breeding, the latter may, for example, be helpful in verifying whether the Prior Informed Consent (PIC) of the providers of breeding material has been obtained.
- Thirdly, the scope of protection must be defined. The physical elements (representing a plant variety) which are to be covered by the right may include vegetative or reproductive propagating material, and they may also include the harvested material. Also in modelling the scope of the *sui generis* right, the legal acts will have to be defined which shall require the authorization of the right-holder. Member states could follow the models provided by current patent law or by the different UPOV Acts. They may also define a different scope of protection subject to the general requirements as set out in Chapter 2. This includes, for example, the option to grant the exclusive right to use a PVP seal for material of a specified, registered variety in combination with its registered denomination. Such a seal would not relate to the material as such.
- Fourthly, the definition of the duration of the *sui generis* right – which is not specified under TRIPS – is an important factor to deal with.
- Fifthly, the interface with other IPR should be clearly regulated to avoid the problem of overlapping claims, as they have been set out in Chapter 1.
- Finally, there is a package of elements that can be introduced to balance the privilege conferred to the right-holder, such as community gene funds, registers to facilitate benefit-sharing mechanisms and the institute of a public defender. Each single element must be carefully designed, but the main focus should be directed at balancing the different interests in the overall package of elements establishing the *sui generis* system.

In this chapter a selection of different TRIPS-compatible options are discussed which member states have in relation to the subject matter to be protected under a *sui generis* system (4.1), the requirements for protection (4.2) and the scope of protection (4.3) of a *sui generis* system. Further decisions which need to be made by the member states concern the duration of the *sui generis* right (4.4) and its interface with other IPR (4.5). Member states may also consider introducing provisions balancing the privileges made available by a *sui generis* system (4.6).

4.1 Protectable subject matter

The TRIPS Agreement itself does not provide any definition of the term plant variety, nor is there any unambiguous and agreed botanical definition.

It seems useful to make a clear distinction between a variety as the protectable subject matter which must be defined as an immaterial concept, and the material of a variety as its physical embodiment (UPOV 1992). The delimitation of the physical elements representing the legal (immaterial) concept 'variety' is of particular relevance when it comes to the definition of the scope of protection, i.e. the question of what kind of acts in relation to what kind of material of the variety require the authorization of the holder of a plant variety right (see 4.3 below).

Still, there are also quite different definitions of the immaterial concept of 'plant variety'; the extensive discussions within the framework of UPOV (UPOV 1974, 1992) make it perfectly clear that the definitory problems cannot be settled by simply referring to the protection requirements of Distinctness, Uniformity and Stability (DUS).

4.1.1 Plant varieties

As has been mentioned previously (see 2.1) member states have to provide under the TRIPS Agreement for the protection of plant varieties of all botanical genera and species (Table 2). While the UPOV Act of 1978 did not provide any definition of a plant variety other than the protection requirements, the UPOV Act of 1991 has followed a different approach. Lengthy discussions during the 1991 diplomatic conference included proposals to completely drop or replace the term, but finally led to a new UPOV definition of 'variety' as a:

plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeders' right are fully met, can be

- defined by the expression of the characteristics resulting from a given genotype or combination of genotypes,
- distinguished from any other plant grouping by the expression of at least one of the said characteristics, and
- considered as a unit with regard to its suitability for being propagated unchanged.

By this definition the UPOV Convention explicitly acknowledges the existence of plant groupings which are less uniform than required to fullfill the uniformity requirement and can still be called plant varieties. This may be the case for many 'traditional' or 'local' varieties, sometimes also referred to simply as 'germplasm' (obscuring in the latter case the cultural effort involved in their origin).

Neither the term 'variety' itself, nor the words used to explain the term, abide by the proposals of the International Code of Nomenclature of Cultivated Plants which proposes the term 'cultivar', and plant 'assemblage' instead of plant 'grouping'. Also, the expression 'botanical taxon of the lowest known rank' may raise some questions, as the term 'variety'

(as used in this definition) is obviously not identical with the botanical *varietas* and thus does not seem to refer to any scientifically agreed ranking system at all.

In contrast to the definitions in the UPOV Acts, Decision 345 of the Junta del Acuerdo de Cartagena (JUNAC) specifically excludes non-cultivated plant groupings, i.e. wild (sub)species or botanical *varietates*, in its definition of protectable subject matter. A 'variety' in the sense of Decision 345 is a "set of cultivated botanical individuals that are distinguished by specific morphological, physiological, cytological and chemical characteristics and can be perpetuated by reproduction, multiplication or propagation". Although the TRIPS Agreement does not allow certain varieties to be excluded from the protection under the *sui generis* system, it certainly allows member states to require that plant varieties must be the result of a breeding or at least a cultivation process (see 4.2.3.5 below).

In a first attempt to define the subject matter for a *sui generis* right according to the TRIPS Agreement it should be enough here to refer simply to two characteristics upon which all the different definitions agree: firstly, plant variety inevitably means more than one plant, i.e. a group or 'assemblage' of plants. Secondly, plants of such a plant assemblage need to have some degree of similarity with each other, so that they can be distinguished from other groups of plants.

4.1.2 Coverage of more than just plant varieties?

The TRIPS Agreement does not restrict members to the definition of plant varieties as developed by UPOV. Neither is there anything in the Agreement to preclude members from additionally granting protection under their *sui generis* system to subject matter other than plant varieties. As the TRIPS Agreement sets only minimum standards for protection (see 1.2.2), members would be free under their *sui generis* system to protect not only plant varieties, but also for example traditional or indigenous knowledge, 'Farmers' Rights', communal rights or TRR.

Certainly, the recognition of such rights, whether by separate legislation or by inclusion into a *sui generis* law, is not legally required under the TRIPS Agreement, nor does it satisfy the obligations of the Agreement. However, it would seem perfectly in line with the Agreement and, furthermore, it might be an adequate way to implement commitments resulting from other recognized principles of the international framework on plant genetic resources (see Chapter 3).

Table 2. Protectable subject matter

	TRIPS option *sui generis*	UPOV Act of 1978	UPOV Act of 1991	JUNAC Decision 345
All plant varieties	required	optional	required 1	required 3
Discovered or uncultivated plants	optional 2	required	required	not foreseen 3
Additional subject matter	optional	not foreseen	not foreseen	not foreseen

[1] After a five-year transition period; additional period for new members of the Union.

[2] Depending on the definition of the term 'variety'.

[3] Definition of 'variety' excludes uncultivated plants.

4.2 Requirements for protection

All four versions of the UPOV Acts of 1961, 1972, 1978 and 1991 require implicitly or explicitly that a plant variety be new, distinct, homogeneous (uniform) and stable in order to be eligible for protection. These requirements have been subject to criticism for many years. It is the criterion of homogeneity (uniformity) that was and still is heavily criticized for reinforcing trends towards genetic uniformity, thus leading to a higher degree of genetic vulnerability in farmers' fields (Fowler and Mooney 1990; Crucible Group 1994).

4.2.1 Novelty

Even if not explicitly, the 'novelty' requirement can be found in all existing PBR laws. A variety commonly known and already placed on the market for more than a limited (grace) period cannot be eligible for protection; otherwise, it could be protected over and over again. There are only minor differences in how novelty is defined in different laws. Usually, the respective provisions specify the maximum period for which the variety may have been sold (or otherwise disposed of) to others at the date of application. UPOV requires absolute novelty. Propagated or harvested material of the variety must not have been sold (or otherwise disposed of, under the 1991 UPOV Act) to others in the territory of the state in which the application has been filed for more than one year and in the territory of other states for more than four years (six years for trees and vines) before the date of application.

The requirement of novelty is certainly an impediment to the protection of truly 'traditional' varieties, i.e. varieties that have already existed for a long time and are commonly known. Still, many of the so-called traditional varieties undergo important changes thanks to the continued selecting and breeding efforts of rural communities, and so they may qualify as 'new / novel' under certain circumstances.

4.2.2 The DUS requirements

The three criteria distinctness, uniformity and stability, often referred to as DUS criteria, are closely interrelated. Their purpose is, first of all, to define the subject matter to be protected. Obviously, it is a necessary condition for any system of property rights for plant varieties that it be possible to define a plant grouping with sufficient specificity to allow the unambiguous assignment of property rights and the enforcement of those rights (Sedjo 1988). The TRIPS Agreement, however, does not make the DUS criteria obligatory protection requirements of a *sui generis* system. It may therefore be useful to reflect upon the DUS criteria and on possible modifications of these criteria in order to adapt them to the specific needs and circumstances of the particular country.

4.2.2.1 Distinctness

The UPOV Act of 1978 specifies that a variety must be "clearly distinguishable in one or more important characteristics from any other variety". In the 1991 UPOV Act, the specification "in one or more important characteristics" has been dropped. It is argued that this change was due to the fact that the epithet "important" has in practice related to the actual distinguishing of varieties, and not to any economic or practical interest or relevance that the characteristic serving to distinguish varieties might have (Elena Rosselló 1994).

The General Introduction to the Guidelines for the Conduct of Tests for Distinctness, Homogeneity and Stability (UPOV Guidelines) specifies that two varieties have to be considered distinct if the difference determined at least in one testing place is clear and consistent. Both qualitative and quantitative characteristics are taken into account. The

Test Guidelines for individual species (e.g. wheat, rice, etc.) illustrate that most of these characteristics are external and visible (leaf shape, stem length, colour of decorticated grain, etc.). Thus, in the criterion of distinctness there is some inherent tendency towards what is called 'cosmetic breeding': minor changes in character without any practical relevance which are, however, of decisive importance in qualifying a variety for protection.

Today, the different characteristics are mainly assessed on single plants and small groups of plants with the underlying assumption that there is only minimal variation among these plants, i.e. that the plant grouping is uniform. Usually, there is no assessment of characteristics made on plant groupings (assemblages) as a whole to compare them with other such groupings.

Some national laws show, however, that quite diverse wording is possible while still comforming to the UPOV framework. The Czech(oslovakian) *Law on the Legal Protection of New Varieties of Plants and Breeds of Animals* (1989), for example, requires that protectable varieties be distinguishable by "at least one major trait or property from any other variety that is commonly known". The wording "major trait or property" seems to allow, if not to urge, for more than merely cosmetic changes. Similarly, the French *Law on the Protection of New Plant Varieties* (1970) demands that a protectable variety be "different from similar already known varieties by one characteristic that is important, precise and subject to little fluctuation or by several characteristics the combination of which is such as to give it the status of a new variety". Whatever the practice of granting PBR in these two countries, it seems perfectly in line with UPOV (1978) standards to require truly 'important' characteristics, i.e. characteristics of agronomic or other practical relevance, to distinguish varieties.

4.2.2.2 Homogeneity/uniformity

Under the UPOV Acts a variety has to be "sufficiently homogeneous" (UPOV 1978) or "sufficiently uniform in its relevant characteristics" (UPOV 1991), subject to the variation that may be expected from the particular features of its propagation.

To be considered homogeneous, according to the existing UPOV Guidelines, the variation shown by a variety, depending on the breeding system of that variety, must generally "be as limited as necessary to permit accurate description and assessment of distinctness and to ensure stability" (UPOV 1979). No doubt this definition implies a certain tolerance depending on the different reproductive systems of varieties – a cross-pollinated variety has to be judged in a different way than a vegetatively propagated one. Whereas the maximum acceptable number of off-types is defined exactly for vegetatively propagated varieties and self-pollinated varieties, tolerance limits in cross-pollinated varieties are set up only "through comparison with comparable varieties already known" (UPOV 1979).

These specific test parameters allow at least for some flexibility concerning, for example, the number of off-types or the degree of genetic identity in a given plant grouping. Still, the current interpretation of the uniformity / homogeneity requirement can be justified neither by agronomic nor by practical reasons. It is widely acknowledged today that in many situations, especially in risk-prone areas, it is an advantage to have a higher degree of variability in the fields (Berg 1996). The current interpretation does not allow for the protection of plant groupings with a high degree of diversity as is typical of many 'landraces', thus depriving their breeders of potential benefits.

Some of the national laws set up by UPOV members contain elements of moderation with respect to uniformity. The Irish *Plant Varieties Act* (1980), for example, explicitly

acknowledges possible changes in time: a variety must "be sufficiently uniform or homogeneous as to satisfy standards and criteria for the time being specified" by the competent authority. A wording with comparable flexibility is contained in the US *Plant Variety Protection Act* (PVPA 1970/80) which requires "uniformity in the sense that any variations are describable, predictable and commercially acceptable" (Section 41a). All three specifications – describable, predictable and commercially acceptable – may be interpreted more or less strictly and thus allow for adaptation to the specific situation in a country or region.

An interesting definition is also found in the Austrian *Federal Law on the Protection of Plant Varieties* (1993). It allows varieties to be regarded as entities and not merely as assemblages of largely identical plants. Thus, a variety shall be deemed to be homogeneous "if its individuals, as a whole or with respect to a given distribution, are sufficiently uniform in the expression of each relevant characteristic, notwithstanding a small number of variations ...". This definition explicitly allows for the protection of quite heterogeneous groupings of plants as long as the groupings as a whole express certain given characteristics in a predictable manner (R. Hron, Vienna, pers. comm.). The requirement of homogeneity/uniformity may then be interpreted simply to mean that a certain plant grouping as a whole should have certain well-defined (useful) characteristics, even if only a limited number of plants actually has these characteristics.

The requirement of homogeneity/uniformity is highly controversial and has been the subject of severe criticism, in particular by those concerned about the erosion of agricultural genetic diversity. In rewarding only the breeding of uniform varieties, today's plant breeders' rights create what mainstream economists have called "perverse incentives" (OECD 1996a). Alternative protection requirements which member states could introduce in their *sui generis* legislation instead are, therefore, discussed below (see 4.2.3).

4.2.2.3 Stability

The definition of stability is directly linked to the requirement of homogeneity/ uniformity. The uniformity of a plant grouping is seen to guarantee its stability. In practice, what has been shown to be homogeneous is usually considered to be stable as well (UPOV 1979). Stability means continued uniformity, i.e. uniformity in time. Like the requirement of distinctness, stability is usually understood as the stability of single plants or a group of identical plants and their offspring. Just like uniformity, however, stability could theoretically be judged on a 'population' level using, for example, economically important traits like yield or pest resistance in a plant grouping and testing their stability through several generations.

The Japanese *Seeds and Seedlings Law* (1982) does not include stability as a requirement for protection at all, regulating this problem simply under the section "nullity": The registration of a variety shall be cancelled, "where it has been found that the characteristics of the plant of the registered variety have become different from the characteristics of the plant at the time of its registration".

The stability requirement poses the same sort of problem as the uniformity requirement when it comes to the protection of 'landraces'. The genetic plasticity or potential for 'genetic drift' may be characteristic for some traditional varieties and even sought for by farmers and local breeders (Brush 1994). This problem can only be solved through changing or replacing both criteria.

4.2.3 Alternative and additional protection requirements and their

implications

The most controversial requirement for protection common to all PBR laws is that of homogeneity / uniformity. As set out above (4.1.1) the definition of plant varieties included in the 1991 UPOV Act makes it perfectly clear that there are plant groupings which can be defined by their characteristics, are distinct and more or less stable, but do not comply with the requirement of uniformity as required by the UPOV Convention. This might be the case, for example, for the vast majority of 'landraces', 'local' or 'traditional' varieties. In trying to include these kinds of plant groupings in a property rights system *sui generis*, it is thus the lack of uniformity / homogeneity that poses the main problem. As pointed out before, a certain level of uniformity may be advantageous in agricultural production and for the quality of final products. However, the limits posed by many existing PBR regimes cannot be and are not justified by practical needs (cf. Flitner 1995). On the other hand, the broadening of the limits of acceptable heterogeneity leads directly to broader property claims. In accepting more (genetic) diversity in the definition of the potentially protectable subject matter, the IPR granted on this subject matter may turn out to be more problematic. If, nonetheless, broader claims shall be accepted in order to make 'local' or 'traditional' varieties protectable, the rights conferred by the *sui generis* IPR need to be of a rather limited nature. Otherwise agricultural development and progress in plant breeding would be severely restricted.

4.2.3.1 Identifiability: from DUS to DI

On the one hand, it is clear that the broadening of the acceptable limits of heterogeneity within a plant grouping to be protected inevitably leads to broader property claims. On the other, the levels of uniformity currently required by national authorities and international guidelines seem to be far higher than justified by the needs of agricultural production or processing industries.

The widely applied DUS requirements may seem justified to clearly define the protectable subject matter of any PBR system, but they create incentives for unnecessary and sometimes dangerous uniformity and they tend to exclude any heterogeneous groupings of plants, which is problematic with regard to the conservation and sustainable use of agricultural genetic diversity. However, the criteria of distinctness and homogeneity / uniformity can be (and under specific circumstances should be) interpreted much less strictly in technical terms than at present. Different possible interpretations are reflected in the wording of several national PBR laws, even if they are not applied as they potentially could be (see 4.2.2.2).

It might be even possible to completely replace the requirements of 'uniformity' and 'stability' by the requirement of 'identifiability', hence Distinctness and Identifiability (DI) instead of DUS. The term 'identifiability' emphasizes the legal need to identify the protected subject matter instead of the specific physical properties a plant variety has to have. A typical combination of a few characteristics may in many cases suffice for the assignment of a right. This term leaves considerable and explicit flexibility for interpretation.

A lot of the technical 'fine-tuning' can and should be left up to the respective national competent authorities. Much of today's very narrow limits of accepted heterogeneity are not due to the wording of the UPOV Convention or national laws but rather to the Test Guidelines set up by UPOV and similar guidelines and related practices of national competent authorities.

It is very important in this context to be aware of the links to National Seed Certification Schemes regulating the placing of seeds on the market. The protection of farmers from unwanted heterogeneity / diversity in their fields – one of the historical reasons for the development of seed legislation – cannot be achieved solely through rigid regulations excluding large parts of (traditional) agricultural diversity from the public sphere. Special registers and respective labelling requirements may be a much better solution than certification schemes which simply ban everything from the market that does not comply with the DUS requirements. Switzerland, for example, has recently set up a 'second register' for highly heterogeneous groupings of cereals ('landraces') (Blümlein 1996).

4.2.3.2 Different protection for heterogeneous and 'local' varieties

As they presently stand and are interpreted, the UPOV requirements for protection are clearly an impediment to the protection of 'landraces' or 'local' varieties. Still, if the different elements mentioned above are combined, it is possible to define groupings of plants that are quite heterogeneous with enough precision to allow assignment of a property right to them. In fact, some open-pollinated varieties (e.g. rye varieties) that have been protected in Europe for decades are hardly less heterogeneous than many of today's 'landraces' in many developing countries. These varieties were neither uniform nor stable, but they could nevertheless be clearly identified. Again, it may be useful to set up a special unit within the competent authorities to judge, in a practical way, whether a certain 'landrace' shall be considered sufficiently defined to be eligible for protection.

However, the protection of such varieties certainly implies the possibility of broader property claims than allowable under the UPOV Acts. A property right tailored to protect highly heterogeneous populations should not confer on its holder the same rights as provided for by the UPOV Acts.

A *sui generis* system may nonetheless provide different forms of protection for heterogeneous and less heterogeneous plant varieties. It is conceivable to have two separate protection and / or certification registers that confer different rights to different levels of uniformity / stability (see 5.5). In the United States, for instance, the Plant Patent Act (PPA) for vegetatively propagated varieties, and the Plant Varieties Protection Act (PVPA), for sexually reproduced varieties relate – at least historically – to different standards of uniformity.

4.2.3.3 National novelty

As far as the requirement of novelty is concerned, member states may consider defining commercial novelty in a way that allows for the protection of those varieties which have been sold or otherwise disposed of to others on a (defined, restricted) local basis only and / or over a certain period of time. Similarly, member states are free to treat plants as novel as long as they have not been offered for sale in the territory of that member state. Such definition would, however, be in conflict with the requirement of absolute novelty as required by both UPOV Acts (see 4.2.1).

4.2.3.4 Agro-economic priorities

Thought should be given as to how additional requirements could allow national authorities to tailor a PBR system according to their own specific agricultural policy aims. This could be achieved by adding an additional requirement that directs incentives, provided for by the PBR system, to the needs and circumstances of a particular member state.

Prior to the UPOV Convention (1961) some of the few existing PBR systems (e.g. the German *Saatgutgesetz* of 1953) included an additional requirement for a variety to be eligible for protection: the requirement of 'usefulness', or 'Value for Cultivation and Use' (VCU, "landeskultureller Wert").

No notion of utility/usefulness was included in the UPOV requirements for protection because it was felt that the VCU requirement, which refers to national or local priorities, would cause problems of compatibility between Union members. The introduction of the VCU requirement is especially critical in relation to the novelty requirement. If a variety is denied plant variety protection on grounds of lacking VCU in country A, but is granted protection and finally placed on the market in country B, the plant variety will no longer be deemed to be new in country A after a certain period of time.[15] Thus, even if after some years the plant variety turned out to fulfil the VCU requirement in country A, it would still have to be denied protection on grounds of lacking novelty, having been on the market in country B for more than a certain period of time. For this reason UPOV decided not to include the VCU requirement (UPOV 1974).

However, this problem could be solved by including a provision by which the fact that a variety has been tested and placed on the market in another country at a time when it did not fulfil the requirement of VCU under the first country's law, shall not be deemed relevant to its novelty.

It should also be noted that VCU could only create this sort of problem at an international level. The TRIPS Agreement, however, does not require any internationally harmonized *sui generis* system.

The introduction of VCU as an (additional) protection requirement may thus be considered useful in certain cases as it allows countries to provide for incentives to fit their specific (economic/ecological) priorities in plant breeding. For example, some of the High Yielding Varieties (HYVs) developed in Centres of the Consultative Group on Agricultural Research (CGIAR) or by multinational corporations have been criticized on the basis that they were poorly adapted to specific agro-ecological situations or existing agricultural practices in developing countries. The VCU requirement offers an instrument to tackle this problem. Its concrete implementation, however, should be left to a national council in which different interest groups are represented and which readjusts at regular intervals the VCU requirement to agricultural development, and agro-economic, political and cultural aims. The VCU requirement should be implemented on a sector-specific and species-specific basis. While it might be advisable to stick closely to the common criteria in the field of, for example, cut flowers, other sectors or species (e.g. staple food crops, minor crops) may require a VCU requirement implementing specific need-oriented and 'adapted' criteria.

A *sui generis* system which requires compliance with certain quality standards of cultivation and use may be linked quite smoothly with a liberal seed registration scheme. Instead of providing for very general incentives and strictly regulating the placing of seeds on the market – as is presently done in most European countries – member states may find it preferable to allow for the marketing of a very wide array of varieties but to grant the *sui generis* privilege in respect to only those varieties that fit their agricultural policy, which may for instance include encouraging the conservation and sustainable use of genetic diversity.

[15] UPOV 1991 Act: Six years for trees and vines, four years for all other varieties (Art. 6).

4.2.3.5 Breeding activity

As already mentioned, JUNAC Decision 345 specifically excludes non-cultivated plant groupings, i.e. wild (sub)species or botanical *varietates*, in its definition of protectable subject matter. Only "sets of cultivated botanical individuals" are protectable under Decision 345. In contrast to this, the UPOV Acts do not require the cultivation of a plant variety, nor do they require any breeding activity to be carried out on a plant variety.

Whether truly wild plant groupings, which have neither been bred nor cultivated, should be eligible for protection under a *sui generis* system does not only depend on the scope of protection of such a system. It may also depend on a country's general policy in relation to access to genetic resources. If this policy aims at the free utilization of naturally occurring plants, it seems that such plants should rather be excluded from any exclusive rights imposing restrictions on their use. If, however, the knowledge and skills necessary to find and identify such wild (or semi-wild) plant groupings or 'varieties' are also to be rewarded by the *sui generis* right, it may be recommendable also to grant protection for such groupings / varieties or even all botanical *varietates* (Shiva 1996).

4.2.3.6 Declaration of origin/PIC

Apart from creating a direct reward system for farmers and indigenous communities by making 'landraces' eligible for protection under a *sui generis* system, members may require the applicants for a patent and / or a *sui generis* right to identify the provider of the genetic material from which a patent or a *sui generis* right has been derived. For this purpose, members may add as a further protection requirement the 'declaration of geographical origin' of the genetic material constituting the raw material of the new variety.

Several authors (e.g. Gollin 1993) have proposed that the sharing of benefits between users and providers of germplasm be facilitated by making it an obligation to specify the geographical origin of used materials in any application for IPR. However, as pointed out earlier, an equitable sharing of benefits can certainly not be achieved by using IPR as the only trigger point for negotiations on benefit-sharing (see 3.5.2).

It may nevertheless be very useful to require information about the geographical origin of materials used in the breeding process of varieties to be protected. Even if this information is not itself used to conclude agreements on the sharing of benefits with the providers of germplasm, it can still help to monitor and verify whether such agreements exist. It may, for instance, be helpful in verifying whether the PIC of the providers of the material has been obtained.[16]

It is important, however, that any such provisions requiring information about the place of origin of materials are workable. A number of possible problems need to be addressed by any conforming legislation. The geographical origin of some of the materials used may be either unknown or not revealed. In many cases, material may originate from more than one country. Even if it seems feasible, thanks to the latest molecular techniques, to identify the (genetic and geographical) origin in many cases, this would often be difficult, costly and time-consuming. These difficulties may explain why, in JUNAC Decision 345, the provision requiring information about the geographic origin of the material was not made a legal requirement for protection but was made a technical formality to which applications should comply.

[16] Comparable provisions have been integrated in the rules of the filing procedure in the JUNAC Decision 345.

Table 3 compares the protection requirements under the TRIPS *sui generis* option to those of the UPOV Acts of 1978 and 1991 and the JUNAC Decision 345.

Table 3. Overview: protection requirements

	TRIPS *sui generis*	UPOV 1978 Act	UPOV 1991 Act	JUNAC Decision 345
Novelty	required [1]	required	required	required
Distinctness	required	required	required	required
Uniformity	optional	required	required	required
Stability	optional	required	required	required
Identifiability	required	not sufficient	not sufficient	not sufficient
Additional requirements	optional	inadmissible	inadmissible	not foreseen

[1] No absolute novelty required; transition periods possible.

4.3 Scope of protection

The required effectiveness of a *sui generis* system does not depend on its requirements for or the level of protection. However, as an IPR, a *sui generis* system has to provide legally enforceable rights either to exclude others from certain acts in relation to the described subject matter and/or to obtain a remuneration in respect of certain uses of the described subject matter (see 2.2). Furthermore, the *sui generis* system has to provide for a right not available under other forms of intellectual property covered by the TRIPS Agreement.

4.3.1 Protected material

Insofar as the *sui generis* system aims at the protection of plant varieties, the physical elements covered by the system will have to be the material representing the variety. Countries seem to have at least two alternatives here. Firstly, they may choose between granting protection in respect of acts concerning propagating material only, or in respect of acts concerning the harvested material, as well. Secondly, they may choose between granting protection in respect of acts concerning reproductive or vegetative propagating material, or in respect of both. There are examples for all of these options (Table 4).

Table 4. Overview: protected material

Coverage of:	TRIPS *sui generis*	UPOV 1978 Act	UPOV 1991 Act	US Plant Patent Act
Vegetative propagating material	optional [1]	required	required	required
Reproductive propagating material	optional [1]	required	required	not foreseen
Harvested material	optional	optional [2]	required [3]	not foreseen [4]
Products directly obtained from harvest	optional	optional	optional	not foreseen

[1] Either vegetative or reproductive propagating material, or both.

[2] Coverage required for ornamental plants when used for commercial propagating purposes.

[3] Provided that the harvested material has been obtained through the unauthorized use of propagating material and the breeder has had no reasonable opportunity to exercise his right in relation to the propagating material.

[4] Disputed, see OTA 1989.

4.3.1.1 Propagating material and/or harvested material

According to the UPOV Act of 1978, reproductive and vegetative propagating material shall be subject to the exclusive right conferred on the holder. Member states can, however, grant more extensive rights in respect of certain botanical genera or species, including the possibility to extend the right to the marketed product.

The UPOV 1991 Act defines material as propagating material of any kind, harvested material, including entire plants and parts of plants, and any product made directly from the harvested material. However, acts in respect of harvested material will require the right-holder's authorization only in cases where the harvest has been obtained through the unauthorized use of protected material and the breeder has had no opportunity to exercise her/his right in relation to that material. Whether acts in relation to products made directly from such harvested material will require the holder's authorization depends on the decision of each contracting party. The EU Regulation on Community Plant Variety Rights No 94/2100, as well as the US PVPA Amendments of 1994, provide for such an extension of the plant variety right.

JUNAC Decision 345 defines material in accordance with the UPOV Act of 1991 as "reproductive or vegetative multiplication material in any form; harvested material, including whole plants and parts of plants; any product made directly from harvested material". Whether the scope of covered material should be rather broad or narrow is dependent on the question of which acts relative to this material shall require the authorization of the holder of the right.

4.3.1.2 Reproductive and/or vegetative propagating material

While the UPOV Convention as well as the laws modelled after it, including the JUNAC Decision 345 and the US Plant Variety Protection Act, cover acts both related to vegetative and to reproductive propagating material, the US Plant Patent Act adopted in 1930 allows for the protection of asexually propagated varieties other than tuber-propagated plants only and, thus, exclusively covers acts in respect of vegetative propagating material. The PPA was the only form of protection available for plant varieties in the United States until 1970 when the UPOV-style Plant Varieties Protection Act was adopted. Given the fact that only a limited number of plant varieties are propagated vegetatively (irrespective of the technical feasibility), the scope of protection of a *sui generis* would be severely limited if only acts in respect of vegetative material have to be authorized by the holder of the right (RAFI 1995).

4.3.2 Acts requiring the holder's prior authorization

As set out above, the *sui generis* system has to accord a right either to exclude others from certain acts in relation to the protected variety and/or to obtain a remuneration in respect of certain uses of the variety. Furthermore, the *sui generis* system has to provide for a right not available under other forms of intellectual property foreseen in the TRIPS Agreement. Therefore, the protection of the name of a plant variety would barely fulfil the minimum standard of a *sui generis* system, since such a right would already be available under the TRIPS section on trademarks (Arts. 15-21). The same applies *mutatis mutandis* to the use of trade secrets, which may be relevant, for example for materials or technologies involved in the breeding process.

The scope of protection of a *sui generis* system may be as broad as that under patent law; in which case, however, member states may also provide for the protection of plant varieties by not excluding plants from patentability. On the other hand the *sui generis* system could

only provide for an exclusive right to market material of a variety under some form of PVP seal exclusively available for plant varieties complying with certain requirements. Between these different options, member states have a range of possibilities in determining the acts in respect of material of a protected plant variety which require the right-holder's authorization.

Member states may also consider modelling the scope of protection of their *sui generis* system on the UPOV Acts. Like other conventions in the field of IPR, the UPOV Convention defines the scope of the right which member states have to grant by establishing certain acts which shall require the authorization of the right-holder. At the same time the UPOV Convention also defines specific acts which member states must or may exempt from the acts requiring approval. Such UPOV-specific exemptions are the so-called farmers' exemption and the breeders' exemption.

The different models presented below may be combined with each other. This is but a selection of a number of possible models.

4.3.2.1 The patent model

The rights conferred by a patent on the holder have been described earlier (see 1.8 and 1.9). According to the TRIPS Agreement, a patent shall confer on its owner rights which are, in principle, of absolute exclusiveness.

While it is clear that any *sui generis* system conferring patent-like rights to the holders of rights would be compatible with the TRIPS Agreement, it is also clear that such a broad scope of protection would have severe consequences for plant breeders, as well as for the application of modern biotechnologies. Given the fact that the overwhelming majority of developing countries lag behind the developments in modern biotechnology and that, so far, many of them do not have the infrastructure necessary for attracting foreign investors active in this field of technology, not many developing countries are likely to benefit from a *sui generis* system for plant varieties conferring patent-like rights. It should also be noted that the use of propagating material which consists of or includes patented subject matter may be held to require the patentee's authorization. Patent law does not provide for any farmers' exemption, nor does it foresee a breeders' exemption. Members could, however, incorporate such exemptions into their patent laws.

4.3.2.2 The UPOV Act 1991 model

The scope of the right foreseen by the UPOV Act of 1991 goes far beyond that required by the UPOV 1978 Act. In fact, the 1991 revision has brought the Convention more into line with patent law. The 1991 Act requires the authorization of the right-holder for production or reproduction, conditioning for the purpose of propagation, offering for sale, selling or other marketing, exporting or importing, and stocking for any of these purposes.

These acts require the authorization of the breeder in respect of propagating material and of harvested material (including entire plants and parts of plants), provided that the harvested material has been obtained through the unauthorized use of propagating material and that the breeder has had no reasonable opportunity to exercise his right in relation to the propagating material. Finally, authorization of the right-holder is also required for the use, for any of the above purposes, of material of varieties (i) whose production requires the repeated use of the protected material, (ii) which have been essentially derived from a protected variety, or (iii) which are not clearly distinguishable from a protected variety. While following for the most part the UPOV Act of 1991, JUNAC Decision 345 leaves it up to the member states of the Andean Pact to decide whether

protection should extend to varieties essentially derived from protected varieties. By its Decree No. 533, Colombia has taken a decision in favour of such an extension.

In line with patent law, the UPOV Act of 1991 exempts from the breeders' right acts done for experimental purposes as well as acts done privately and for non-commercial purposes. In contrast to patent law, however, neither is the holder's authorization required for acts for the purpose of breeding another variety nor the commercialization of that other variety, unless the other variety is essentially derived from the protected variety (breeders' exemption). Furthermore, member states may also "within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder" allow farmers to propagate on their farm seed saved and retained on their farm. Whether, under Art. 17 (2) of the UPOV Convention, farmers planting back saved seed have to remunerate the right-holders, is the subject of some controversy. While EU Regulation No. 2100/94 requires farmers, except small farmers, to pay an equitable remuneration to the holder which shall be sensibly lower than the amount charged for the licensed propagating material, no comparable provisions may be found in the US Plant Varieties Protection Act of 1994.

While any *sui generis* system which is modelled (as to the scope of the right) on the UPOV Act of 1991 would, as to the level of protection, comply with the TRIPS Agreement, it should be noted that the farmers' exemption as permitted by the 1991 Act does not allow farmers to exchange saved seed with other farmers for propagating purposes. Farmers may only propagate "on their own holdings" the product of the harvest which they have obtained by planting the protected variety "on their own holdings". Given the fact that many farmers in developing and also in industrialized countries exchange seed for propagating purposes on a regular basis, and that this practice of seed exchange facilitates crop rotation as well as variety rotation, the farmers' exemption as permitted under the UPOV Act of 1991 does not meet the needs of many countries. It may also be questioned whether this provision on seed exchange is completely in line with the CBD's explicit aim to "protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements" (Art. 10 (c) CBD), and to promote their "wider application" (Art. 8 (j) CBD)).

The concept of 'essentially derived' varieties

The concept of 'essential derivation' of plant varieties aims at the prevention of so-called cosmetic plant breeding, i.e. the 'take-over' of varieties with irrelevant changes. It is important to note that the concept as foreseen by the UPOV Act of 1991 is not based on the idea that those who have been conserving genetic resources over the past centuries should also benefit from the utilization of these resources in modern plant breeding. Under UPOV 1991, only those plant varieties that have been derived from a **protected** variety will be considered as being essentially derived from the original variety. The fact that a variety has been (partially) derived from genetic resources falling under the sovereign right or ownership of a state is not an issue under the UPOV Act of 1991.

Today, there are still many problems in applying the principle of dependency in plant breeding as laid down in the UPOV Act of 1991. 'Acceptable' genetic distances vary strongly between species, so they will have to be determined for each species separately. In some species most commercial varieties are so closely related that it is difficult not to define them as 'essentially derived' even with recent molecular techniques. Furthermore, it seems unclear how to treat two very similar varieties, one of which was bred while the original variety was still protected and the other after the protection for the original variety had run

out. The former would no doubt be essentially derived, while the latter apparently would be independent.

It is conceivable that the principle of essential derivation could be used to create returns for varieties that are available in the public domain when they are used as original varieties for further plant breeding. The use of such varieties, no matter whether they were publicly bred or stem from collections, could be made subject to authorization and/or payments in cases where the resulting variety is 'essentially derived' (H. Ghijsen, pers. comm.). Again, the more variability that is found in the original variety, the less likely it is that derived varieties could be termed 'essentially derived'. And, as set out above, if the principle of essential derivation is applied to encompass cases of comparably large genetic distance, it seems most likely that the availability of plant breeding material would be severely hampered.

4.3.2.3 The UPOV Act 1978 model

Under the 1978 UPOV Act, member states have to grant rights with the effect that the right-holder's authorization shall be required for the production for purposes of commercial marketing, the offering for sale and the marketing of propagating material. Moreover, the repeated use of the new plant variety for the commercial production of another variety, and the commercial use of ornamental plants or parts thereof as propagating material in the production of ornamental plants and cut flowers, shall require the right-holder's authorization.

By focusing on the commercial marketing of propagating material, the UPOV Act implicitly allows the production of propagating material of a protected variety for non-commercial purposes. However, the scope of this so-called farmers' exemption or farmers' privilege is far from clear. While it is interpreted by some UPOV member states as only allowing farmers to plant back seeds and to exchange limited amounts of them 'over the fence' on a strictly non-commercial basis, other member states, especially the United States, interpreted the farmers' exemption as allowing farmers not only to re-plant seeds but also to sell limited quantities of them for reproductive purposes ('brown bagging'). As recently as January 1995, the US Supreme Court held in *Asgrow Seed Co. vs. Winterboer et al.* that under the farmers' privilege foreseen in the PVPA, a farmer may sell for reproductive purposes only such seed as he has saved for the purpose of replanting his own acreage (Rappert 1995).

The UPOV Act of 1978 also provides for an explicit breeders' exemption, according to which the use of a protected variety as an initial source of variation for the purpose of creating other varieties, and the marketing of such varieties (unless the repeated use of the protected variety is necessary for the commercial production of another variety), are allowable without the right-holder's authorization.

It is obvious that the protection as required by the UPOV Act of 1978 is considerably weaker than that foreseen in patent law and the UPOV Act of 1991. The 1978 Act does not restrict the use of protected plant varieties for breeding purposes; the farmers' exemption leaves considerable flexibility, as 'brown bagging' in the United States clearly shows. However, it is also clear that the farmers' exemption as provided for in the UPOV Act of 1978 cannot be interpreted as allowing the selling and marketing of unlimited amounts of saved seed for propagating purposes. Thus, the implementation of the UPOV Act of 1978 will always require national legislators to draw a dividing line between allowable marketing acts and those that require the right-holder's authorization.

4.3.2.4 The plant variety protection seal model

The concept of granting a right to use for marketing purposes a specific seal or certificate for seeds of a specified variety goes back to the historical roots of plant variety protection laws and seed certification schemes. The holder of a PVP seal has the exclusive right to use this seal for material of a specified, registered variety in combination with its registered denomination. A PVP seal would definitely confer more rights than a breeder could receive by registering the name of a variety as a trademark. It would give holders the exclusive right to use the PVP seal certifying that the variety complies with the requirements as laid down in the national *sui generis* legislation when selling, offering, exposing or exchanging seeds of the variety.

In contrast to the acts requiring the right-holder's authorization under the UPOV Acts of 1978 and 1991 and under patent law, the right to the use of the PVP seal would not relate to the material of the variety as such. Thus, the **material** of a protected variety would remain absolutely free. Only the use of the PVP seal in combination with the registered denomination and the material of the variety would be the exclusive right of the holder and those who have obtained that holder's authorization.

The advantages of such a PVP seal are obvious: farmers could continue to expose and sell saved seed; they could also use the plant variety's denomination insofar as it is not in some way restricted by a trademark. Yet the exclusive right to use the PVP seal for a specific, registered variety would still give right-holders a substantial competitive advantage, especially if the protection requirements that plant varieties have to fulfil are adapted to the needs and expectations of farmers.

Since the PVP seal would not affect the use of the material of the protected varieties as such, any exceptions to the right to use the PVP seal would seem to be unnecessary. In addition, the duration of such a right could be substantially longer than foreseen in the UPOV Acts or for patents in the TRIPS Agreement, thus corresponding better to the time horizon of informal breeders and indigenous innovations in general (cf. Tewolde 1996).

Table 5 compares the effect of protection under the TRIPS *sui generis* option with those of the UPOV Acts of 1978 and 1991 and the JUNAC Decision 345.

Table 5. Overview: effect of protection

Authorization required for:	TRIPS *sui generis*	UPOV 1978 Act	UPOV 1991 Act	JUNAC Decision 345
Production and reproduction	optional	required	required	required
Offering for sale, selling [1]	optional	required	required	required
Exporting and importing [1]	optional	optional	required	required
Conditioning stocking [1]	optional	optional	required	required
Possible additional acts	optional	optional	optional	optional
Breeder's exemption	optional	required	restricted [2]	restricted [3]
Farmer's exemption	optional	required	restricted	required

[1] For one of the above purposes.

[2] Not foreseen for essentially derived varieties, see text.

[3] Not foreseen for essentially derived varieties where their commercialization requires the authorization of the breeder of the original variety.

4.4 Duration

The TRIPS agreement does not specify the duration of rights under a *sui generis* system.

The duration of such rights should certainly be related to their scope. A strong and exclusive right should not have the same duration as a weaker right with many exceptions. If, for example, the *sui generis* right does not protect the material of a variety as such, as is the case with the PVP seal, a limitation of the duration of the right does not seem to be necessary. In this case, a long period of protection may in fact well correspond with the time frame of informal breeding, if the protection of 'landraces' is intended (cf. Muzio 1996).

If, however, the *sui generis* right restricts the free use of the material of plant varieties it should be granted for a fixed period only. While the UPOV Act of 1978 provides a minimum period of protection of 15 years (18 years for certain other plants, such as vines and fruit trees), the 1991 UPOV Act provides a minimum period of 20 years (for trees and vines, 25 years).

4.5 Interface with other IPR

Whatever form of a *sui generis* system member states choose to establish, the interface of this system with other Intellectual Property Rights is of the utmost importance.

The UPOV Act of 1978 leaves each state party to the Act free to grant protection to new varieties of plants by means of a 'special title of protection' – that is, a title specially created for plant varieties – or a patent. However, member states whose national laws admit protection under both these forms may provide only one of them for one and the same botanical genus or species. This ban on double protection was not included in the 1991 Act.

The rationale behind the ban on double protection is that problems may arise wherever two forms of protection with different scopes overlap. If some varieties of one and the same species are patented, while others are protected by UPOV-type PBR, the situation would be quite confusing for breeders, since the latter varieties could be used freely for breeding purposes while the use of the former varieties would infringe the patent. Farmers would also have to face the same insecurity if under the *sui generis* system the planting back of saved seed was allowable, while under the patent it was forbidden.

The need to avoid such overlaps and contradictions of different forms of protection is also demonstrated by the following example. If a patented gene is inserted into a plant which is protected under a UPOV type breeders' right, the question arises whether the plant may be used freely under the breeders' exemption as an initial source for breeding a new variety, or whether such use would infringe the patent on the inserted gene. The answer to this question is actually far from clear. While some argue that the plant should be freely utilizable for breeding purposes, others argue that any use of the plant would also make use of the patented gene and thus require the patent holder's authorization. Between these two positions, one may also argue that the use of the plant is allowable without the patent-holder's authorization, as long as the new variety does not contain the gene, or, if it contains the gene, does not express it. Whatever solution is chosen, it is obvious that the overlap of patents and weaker forms of protection tends to afford privilege to the patent-holder and complicates the legal situation of the holder of the weaker right considerably.

Member states establishing a *sui generis* system for the protection of plant varieties should therefore consider carefully the interface between the *sui generis* rights and other forms of protection. While under the TRIPS Agreement plant genes may be excluded from patentability, this may not be the case with genes isolated from microorganisms, as

members are not allowed to exclude microorganisms from patentability. Because it is currently very common to transfer genes which have been isolated from microorganisms to plants, the interface between the *sui generis* right and patents definitely has to be addressed. To this end, it might not be enough just to stipulate that plants are unpatentable, but also that the scope of protection of a gene patent does not extend to plants into which this gene has been inserted. It should be ensured that the scope of patents claiming genetic material does not extend to subject matter which is excluded from patentability (see 1.8).

4.6 Balancing plant breeders' rights

In order to balance the privilege being granted to plant breeders by whatever form of IPR, other provisions may be introduced in the *sui generis* or other IPR legislation or separate laws, which implement TRR, for example.

Access regimes with their much broader coverage (or case-by-case material transfer agreements) may contain provisions that reserve rights to the providers of germplasm and related knowledge. As an example, the Guatemalan Acuerdo Ministerial 177 of September 1995 requires that varieties containing any genetic material collected in Guatemala be available for local use in Guatemala without any restrictions. This obligation has to be passed on by collectors to any third parties requesting the material. Furthermore, member states may consider to set up community gene funds, registers or provide for public defenders.

4.6.1 Community gene funds

The establishment of community gene funds which could be financed either by fees or by a royalty of some percent of the gross value of seeds sold may be used for the benefit of the conservers and donors of 'landraces', directly if the origin of the variety can be clearly traced back, or indirectly, through a fund administered jointly by representatives of local farming communities and indigenous peoples. Where the origin of the useful genetic material cannot be clearly identified, the royalties credited to the gene fund may be used to strengthen the *in situ* conservation activities of local communities in areas threatened with genetic erosion (Swaminathan 1995).

Such solutions may be particularly well-suited where there is a large seed market and/or important plant breeding activities in the country (e.g. India). Elsewhere it may be difficult to generate funds large enough to have any nation-wide impact at community level.

It has also been proposed that the assistance received by a country under international arrangements such as the FAO International Fund could accrue to such community gene funds (Swaminathan 1996).

It can be added that neither the levying of a tax on seed sales nor international measures to support local communities need to be related to a *sui generis* right.

4.6.2 Registers

An additional element that could facilitate the sharing of benefits with indigenous and farming communities is the establishment of registers (RAFI 1994; Singh Nijar 1995; Swaminathan 1995; Tewolde 1996).

There are several mutually supportive options, ranging from national registers for local communities and registers of folklore or informal innovation to an international database to trace germplasm. Such registers or databases may *inter alia* help to identify contributors to

pedigrees of plant varieties or other innovations. They may also be helpful in avoiding what has been called "intellectual piracy" from indigenous or farming communities, in securing that methods and materials in customary use cannot be declared as novel (Shiva 1996).

4.6.3 Public defender

Finally, an (internationally recognized) office for a 'public defender' to intervene in unequal relationships between communities and governments or between states and multinational corporations may be helpful in many of the proposed models (Crucible Group 1994; Posey and Dutfield 1996). Even strong legal positions can be difficult to defend effectively in cases where one lacks financial means, the procedures are time-consuming and legal expertise is out of reach.

5. Shaping the *Sui Generis* System

Summary

In shaping the *sui generis* system some general aspects merit specific attention.

Firstly, since some of the elements discussed in the previous chapter exclude each other while others do not, it is necessary to match the different elements of a *sui generis* system with each other.

A second important question is whether a country aims at UPOV membership or not. Several of the elements proposed in Chapter 4 are not compatible with the UPOV Acts of 1978 or 1991. While UPOV membership may have advantages like the right of priority or technical and administrative cooperation, the advantage of national treatment among UPOV members may have become irrelevant after the entry into force of the TRIPS Agreement.

The third point to ponder is the need to create incentives for private investment in plant breeding. If a country has the necessary infrastructure and capacities, a strong legal protection of plant varities may attract additional investment; if not so, the attractivity of strong exclusive rights may be much lower.

Finally, while IPR are certainly not an effective instrument to conserve biological diversity or promote its sustainable use, the potential impact of the different elements, in particular the protection requirements, should be borne in mind when designing a new system. Furthermore, the *sui generis* system might be helpful in facilitating benefit-sharing agreements or verifying the compliance with provision in a country's access legislation.

One example for the countless possible combinations of the different elements as set out in Chapter 4 concludes the study. It represents a two-level approach corresponding to the strong dichotomy in the agricultural economy of many countries.

5.1 Coherency

As has been shown in the previous chapter, there is a variety of elements that can be included in a *sui generis* system for plant varieties. Most of these elements are, however, extremely interdependent, which means that a decision on a *sui generis* right will have to be a package one, rather than several isolated decisions on single elements.

Many of the elements discussed above do not exclude each other but are mutually supportive; others do exclude each other. In order to achieve a coherent and smoothly working *sui generis* system it will be necessary to match the different elements with each other.

A basic rationale, reflected in all intellectual property legislation, should also apply to the *sui generis* right as required by the TRIPS Agreement: the more extensive the right conferred on the holder, the stricter the requirements for obtaining the right should be. This should be taken into account by all member states, regardless of which option they go for under the TRIPS Agreement.

A further principle of IPR which should be taken into account is keeping a proper balance between the sometimes diverging interests of the individual right-holders on the one hand and society as a whole on the other. This requires a careful examination of each single element and the consequences of its inclusion into the proposed system of protection. However, the fact that for example a certain protection requirement is considered to have undesirable side effects does not necessarily mean that this element has to be eliminated outright. Instead, it may be possible to counterbalance the negative side effects by modifying the scope or the duration of the *sui generis* right, or by adding other supporting measures.

5.2 UPOV compatibility

The design of a *sui generis* system will inevitably depend on whether a country wishes to join UPOV. It should be noted that as long as the UPOV Act of 1991 has not entered into force, developing countries may accede to the Act of 1978. From a legal perspective, the main advantage of being a UPOV member seems to be that under both UPOV Acts member states have to afford the same treatment as their laws provide for their own nationals only to the nationals and residents of the other UPOV member states. Thus, breeders may benefit from their country's UPOV membership if they intend to apply for protection in other UPOV member states. Under the UPOV Act of 1978, member states may even limit the right to apply for protection of a variety to nationals or residents of those other member states which also apply the Act to the genus or species to which the variety belongs (reciprocity rule).

However, the advantage of national treatment among UPOV members might have become irrelevant after the entry into force of the TRIPS Agreement. If it is correct that the TRIPS principle of national treatment is applicable to all IPR covered by the Agreement, including the *sui generis* system (see Chapter 1.3), this would imply that the UPOV member states already have to accord the nationals of other WTO members treatment no less favourable than that which they accord to their own nationals with regard to the protection of plant varieties. Thus, from the perspective of national treatment, UPOV membership would seem less attractive than before the entry into force of the TRIPS Agreement.

5.3 *Sui generis* system as an incentive

There seems to be no reliable method of assessing the effects of the legal protection of plant varieties on private investment in plant breeding. The results from studies in the United States are contradictory, to say the least (Butler and Marion 1985; Kloppenburg 1988; RAFI 1994). A recent study on several Latin American countries showed that under conditions of shrinking public sector investment, the introduction of PBR "seems to have prevented reduction in R&D expenditure" rather than having stimulated additional private investment in domestic plant breeding (Jaffé and van Wijk 1995). It seems that if a country has the necessary infrastructure and scientific capacities, the legal protection of plant varieties can attract private investments in plant breeding to a certain extent. For member states that mainly rely on public breeding and wish to continue to do so, the legal protection of plant varieties seems to be less interesting. They may consider granting TRIPS-compatible protection for plant varieties through 'less exclusive' forms of protection, such as the PVP seal.

5.4 Conservation of and access to genetic resources

It is often argued that the value being attributed to plant genetic resources by making plant varieties eligible for intellectual property protection would contribute to the conservation of those resources. This argument, while it seems plausible at first glance, does not take into account that the reason for the loss of genetic diversity is not simply that these resources are regarded as useless. It is unrealistic to expect that the loss of genetic resources could be prevented simply if plant breeding became more profitable. First of all, no more than a minimal part of plant genetic resources will ever fit into commercial breeding programmes or even end up on the market in the form of plant varieties (Swanson *et al.* 1994). Secondly, the loss of overall biodiversity through the global expansion of today's uniform varieties is several orders of magnitude bigger than any possible positive ecological effects of a growing private plant breeding business. Thus, the granting of IPR for products of modern plant breeding is certainly not an effective instrument to conserve biological diversity. In strictly ecological terms, incentives to speed the spread of industrial-style agriculture are rather counter-productive and should be properly balanced with other legal or economic measures limiting their destructive effects.

While IPR are not an effective means of promoting the sustainable use of biodiversity, it is important to bear in mind the potential impact of every element of an IPR system when designing a new system. Careful consideration should be given in particular to the protection requirements and the links with seed legislation.

IPR laws, including any *sui generis* system, also do not offer an effective means to control access to a country's genetic resources. As the TRIPS Agreement stipulates 'national treatment', WTO member states may not discriminate applicants for patents or *sui generis* rights on grounds of their nationality. Thus states which provide for the legal protection of plant varieties will have to grant such protection notwithstanding the WTO member nationality of the applicant and notwithstanding the place of origin of the material used for the creation of the new plant variety. Still, states may use specifically tailored IPR laws, including the *sui generis* system, as a tool to facilitate benefit-sharing agreements or to verify the compliance with certain provisions in their access legislation. They may also use non-IPR legislation, including product legislation and seed certification schemes.

5.5 An example of a *sui generis* system

It is outside the scope of this study to discuss the countless possible combinations of the different elements of a *sui generis* right and to assess all their advantages and disadvantages. More importantly, the pros and cons of particular combinations cannot be objectively defined. The effect of a specific combination depends to a large extent on a country's economic situation, its agricultural and industrial policy and its overall development strategy.

Factors that may have a decisive impact include the importance of agricultural exports, the state of the art in domestic plant breeding, the role of public research and the special needs of small farmers as well as the situation of indigenous peoples. Even under very similar situations, for example a combination of small domestic market, high importance of agricultural exports and poorly developed private plant breeding, very different conclusions among different policy-makers might result when deciding on the elements of a *sui generis* system. Some may see the introduction of plant patents as a useful means to attract investment for the construction of a biotechnology industry, others may focus exclusively on the needs of small farmers, protecting their achievements and strengthening public plant breeding efforts.

Thus, the example given in Figure 1 is but one possible way to bring the different elements together. By no means is it the 'one-size-fits-all' solution. However, it is not completely arbitrary that this example represents a two-level approach. Many member states, especially those which may have to protect plant varieties for the first time from the year 2000 or 2005 onwards, are characterized by a strong dichotomy in their agricultural economy. A modern sector aiming at global markets, on one hand, is often contrasted by a 'traditional sector' mainly focusing on subsistence or local markets on the other. For many member states it is neither realistic nor desirable that either of the two very different sectors disappears in the near future.

Consequently, a high degree of institutionalized flexibility and two different levels concerning the requirements and the scope of protection, both connected at a procedural level, are the main features of our example.

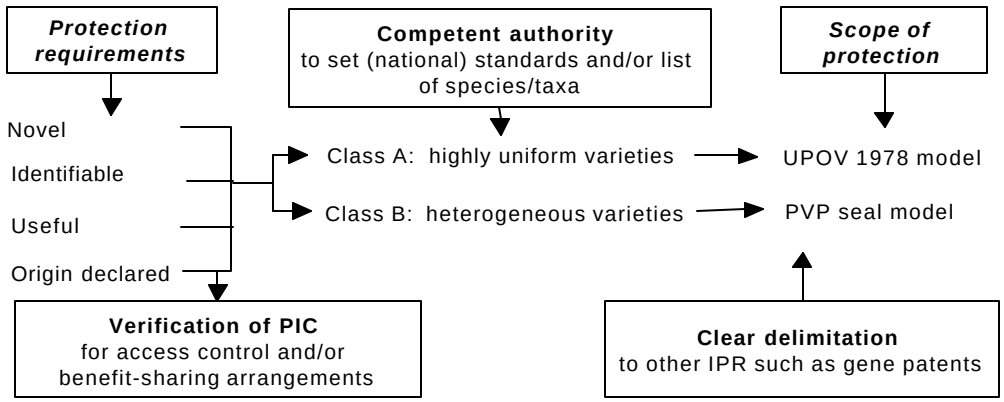

Fig. 1. Example of a two-level *sui generis* design.

References

Ajai, O. 1995. Regulating Access to Nigeria's Genetic Resources: Issues in the Emergent Law and Implications of Article 15 of the Convention on Biological Diversity for National Legislation. Paper presented at the Global Biodiversity Forum, Jakarta, 4-5 November.

Axt, J.R. *et al.* 1993. Biotechnology, Indigenous Peoples, and Intellectual Property Rights. Congressional Research Service, Report for the Congress. Washington DC, USA.

Barber, C.V. and A. La Viña. 1995. Regulating Access to Genetic Resources: The Philippine Experience. Paper presented at the Global Biodiversity Forum, Jakarta, 4-5 November.

Barton, J.H. and W.E. Siebeck. 1994. Material Transfer Agreements in Genetic Resources Exchange - the Case of the International Agricultural Research Centres. Issues in Genetic Resources No. 1, May 1994. IPGRI, Rome, Italy.

Bent, S.A. *et al*. 1987. Intellectual Property Rights in Biotechnology Worldwide. New York N.Y.

Berg, T. 1996. Dynamic Management of Plant Genetic Resources: Potential of Emerging Grass-Roots Movements. Studies in Genetic Resources No. 1. FAO Plant Production and Protection Division, Rome.

Bernhardt, R. 1995. Interpretation in International Law. Pp. 1416-1426 *in* Encyclopedia of Public International Law, Vol. 2 (R. Bernhardt, ed.). Elsevier Science B.V., Amsterdam.

Blümlein, G. 1996. Biologische Vielfalt fuer den oekologischen Landbau oder oekologischer Landbau fuer die biologische Vielfalt, epd-Endwicklungspolitik-Materalien 1/96.

Bronckers, M.C. 1994. The Impact of TRIPS: Intellectual Property Protection in Developing Countries, CML Rev., pp. 194-205.

Brush, S.B. 1994. Providing Farmers' Rights through *In Situ* Conservation of Crop Genetic Resources. Background Study Paper No. 3. November 1994. FAO Commission on Plant Genetic Resources, Rome.

Bruzzone, R. 1993. The Research Exemption: A Proposal. P. 52 *in* AIPLA Vol. 21.

Butler, L. and B. Marion. 1985. The Impacts of Patent Protection on the US Seed Industry and Public Plant Breeding. North Central Regional Research Publishing 304. University of Wisconsin, Madison.

Cameron, J. and Z. Makuch. 1995. The UN Biodiversity Convention and the WTO TRIPS Agreement. Gland.

CHR. 1979. UN Commission on Human Rights, Sub-Commission on Prevention of Discrimination and Protection of Minorities. Study on the Rights of Persons belonging to Ethnic, Religious and Linguistic Minorities. Special Rapporteur F. Capotorti. E/CN.4/Sub.2/384/Add. 1-3 ("Capotorti-Report").

CHR. 1992. Commission on Human Rights, Sub-Commission on Prevention of Discrimination and Protection of Minorities, 44th session. Intellectual Property of Indigenous Peoples: Concise Report of the Secretary-General, E/CN.4/Sub.2/1992/30.

CHR. 1993. Commission on Human Rights, Sub-Commission on Prevention of Discrimination and Protection of Minorities, 45th session. Report of the Working Group on Indigenous Populations on its eleventh session, E/CN.4/Sub.2/1993/29, including Annex I, p. 50, Draft declaration as agreed upon by the members of the Working Group at its eleventh session.

Cooper, D., J. Engels and E. Frison. 1994. A Multilateral System for Plant Genetic Resources: Imperatives, Achievements and Challenges. Issues in Genetic Resources No. 2, May 1994. International Plant Genetic Resources Institute, Rome, Italy.

Correa, C.M. 1994a. The GATT Agreement on Trade-Related Aspects of Intellectual Property Rights: New Standards for Patent Protection EIPR:327-335.

tCorrea, C.M. 1994b. Sovereign and Property Rights over Plant Genetic Resources, FAO Background Study Paper No. 2. Commission on Plant Genetic Resources - First Extraordinary Session, Rome, 7-11 November.

Crucible Group. 1994. People, Plants, and Patents. International Development Research Centre, Ottawa, Canada.

Downes, D. 1993. New Diplomacy for the Biodiversity Trade: Biodiversity, Biotechnology, and Intellectual Property in the Convention on Biological Diversity. Touro J. Transnational Law 4:1-46.

Downes, D. 1995. The Convention on Biological Diversity and the GATT. Pp. 197-252 *in* The Use of Trade Measures in Selected Environmental Agreements (R. Housman *et al.*, eds.). Geneva.

Dubey, M. 1996. An Unequal Treaty - World Trading Order After GATT, New Delhi.

Elena Rosselló, J.M. 1994. The UPOV Convention - The Concept of Variety and the Technical Criteria of Distinctness, Uniformity and Stability. Pp. 57-68 *in* Seminar on the Nature and Rationale for the Protection of Plant Varieties under the UPOV Convention, Buenos Aires, 26-27 November 1991. UPOV, Geneva.

European Commission. 1995. Commission of the European Communities, Proposal for a European Parliament and Council Directive on the Legal Protection of Biotechnological Inventions, COM (95) 661 final.

European Communities. 1990. Draft Agreement on Trade-Related Aspects of Intellectual Property Rights (MTN.GNG / NG11 / W / 68).

Flitner, M. 1995. Sammler, Raeuber und Gelehrte: Die politischen Interessen an pflanzengenetischen Ressourcen, 1895-1995. Frankfurt / New York.

Fowler, C. and P. Mooney. 1990. Shattering. Food, Politics and the Loss of Genetic Diversity. University of Arizona Press, Tucson.

GATT Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods. 1990. Status of work in the negotiating group, Chairman's report to the GNG (MTN.GNG / NG11 / W / 76)

Glowka, L. *et al.* 1994. A Guide to the Convention on Biological Diversity. IUCN, Gland / Cambridge.

Gollin, M.A. 1993. An Intellectual Property Rights Framework for Biodiversity Prospecting. Pp 159-198 in: Biodiversity Prospecting: Using Genetic Resources for Sustainable Development (Walter Reid *et al.*, eds.). WRI, Washington DC, USA.

GRAIN. 1995. Towards a Biodiversity Community Rights Regime. Seedling 13:2-14.

Greaves, T. 1996. Tribal Rights. Pp. 25-40 *in* Valuing Local Knowledge: Indigenous Knowledge and Intellectual Property Rights (Stephen Brush and Doreen Stabinsky, eds.). Washington DC; Covelo, CA.

Hendricks, F., V. Koester, and C. Prip. 1994. Access to Genetic Resources: A Legal Analysis. Pp. 139-156 *in* Biodiplomacy - Genetic Resources and International Relations (V. Sanchez and C. Juma, eds.). Environmental Policy Series No. 4. African Centre for Technology Studies (ACTS), Nairobi, Kenya.

Hitchcock, R.K. 1994. International Human Rights, the Environment, and Indigenous Peoples. Colorado J. Int. Environ. Law and Policy 5:1-22.

ICCBD. 1994. Intergovernmental Committee on the Convention on Biological Diversity, 2nd session, Nairobi, 20 June-1 July 1994. Farmers' Rights and rights of similar groups. The rights of indigenous and local communities embodying traditional lifestyles: experience

and potential for implementation of Article 8 (j) of the Convention on Biological Diversity. Note by the Interim Secretariat. UNEP / CBD / IC / 2 / 14.

Independent Commission on International Humanitarian Issues. 1987. Indigenous Peoples: A Global Quest for Justice. Washington DC, USA.

IPGRI. 1996. Access to Plant Genetic Resources and the Equitable Sharing of Benefits - a Contribution to the Debate on Systems for the Exchange of Germplasm. Issues in Plant Genetic Resources No. 4. IPGRI, Rome.

Jaenichen, H-R and A. Schrell. 1993. Die "Harvard-Krebsmaus" im Einspruchsverfahren vor dem Europaeischen Patentamt. GRUR Int. pp. 451-452.

Jaenichen, H-R. 1993. The European Patent Office's Law on the Patentability of Biotechnological Inventions. Cologne; Berlin; Bonn; Munich.

Jaffé, W. and J. van Wijk. 1995. The Impact of Plant Breeders' Rights in Developing Countries: Debate and Experience in Argentina, Chile, Colombia, Mexico and Uruguay. IICA; University of Amsterdam.

Jaffee, S. and J. Srivastava. 1994. The Roles of the Private and Public Sectors in Enhancing the Performance of Seed Systems. The World Bank Research Observer 9, 1:97-117.

Keystone. 1990. Final Consensus Report of the Keystone International Dialogue Series on Plant Genetic Resources - Madras Plenary Session, Second Plenary Session, 29 January-2 February, Madras, India.

Kloppenburg, J.R. 1988. First the Seed. The Political Economy of Plant Biotechnology 1492-2000. Cambridge.

Kohona, T.B. 1994. Dispute Resolution under the World Trade Organisation, JWTL No. 2:23-47.

Lange, P. 1996. Patentierungsverbot für Pflanzensorten. GRUR Int., pp. 586-591.

Leskien, D. 1996. Gentechnologie und Patentrecht. Zum neuen Richtlinienvorschlag der Europaeischen Kommission. ZUR 7(6):299-306.

Leskien, D. and Flitner, M. 1996. Farmers' Rights Now! Agriculture and Rural Development 3(1):20-23.

Lesser, W.H. 1994. Attributes of an Intellectual Property Rights System for Landraces. Pp. 247-279 *in* Biodiversity: Politics and Law in the Light of Sustainable Development (Salazar, R.; J.A. Cabrera Medaglia and A. Lopez Mora, eds.). Fundacion AMBIO, San Jose, Costa Rica.

Moufang, R. 1988. Genetische Erfindungen im gewerblichen Rechtsschutz. Koeln *et al.*

Moufang, R. and J. Straus. 1992. Die Hinterlegung biologischen Materials. Baden-Baden.

Muzio, G. 1996. Brazil: Collective Intellectual Rights and Control of Access to Biological Resources. Pp. 1-6 *in* Intellectual Property Rights, Collective Rights, Biodiversity. Occasional Papers No. 1, Paper 6. Institute for Sustainable Development, Addis Ababa.

OECD. 1996a. Saving biological diversity: economic incentives. Paris.

OECD. 1996b. Intellectual Property - Technology Transfer and Genetic Resources. Paris.

OTA. 1989. New Developments in Biotechnology: Patenting Life. Washington DC.

Otten, A. 1996. Viewpoint of the WTO. Pp. 44-50 *in* Agrobiodiversity and Farmers' Rights: Proceedings of a Technical Consultation on an Implementation Framework for Farmers' Rights (M.S. Swaminathan, ed.). M.S. Swaminathan Research Foundation. Madras.

Pacon, A.M. 1995. Was bringt TRIPS den Entwicklungslaendern, GRUR Int. pp. 875-886.

Posey, D. and G. Dutfield. 1996. Beyond Intellectual Property Rights. Toward Traditional Resource Rights for Indigenous Peoples and Local Communities. IDRC, Ottawa.

RAFI. 1994. Conserving Indigenous Knowledge: Integrating Two Systems of Innovation. UNDP, Geneva.

RAFI. 1995. Sixty-five years of U.S. Plant Patent Act (PPA). RAFI Communique Sep/Oct 1995. Ottawa.

Rappert, B. 1995. The US extension of plant variety protection: a critical evaluation. Science and Public Policy 22(2):95-105.

Reichman, R.H. 1993. The TRIPS Component of the GATT's Uruguay Round: Competitive Prospects for Intellectual Property Owners in an Integrated World Market. Fordham Intellectual Property, Media and Entertainment Law Journal :171-194

Roberts, T. 1995. Plant Biotechnology - Patentability of plants under the EPC. EIPR D-188.

Ruiz, M.M. 1995. A Genetic Resources Access Regime for the Andean Pact Countries: Issues and Experiences. Paper presented at the Global Biodiversity Forum, Jakarta, 4-5 November.

Schrell, A. 1995. Anmerkung zu Pflanzenzellen/ PLANT GENETIC SYSTEMS. GRUR Int., pp. 986-987.

Sedjo, R.A. 1988. Property Rights and the Protection of Plant Genetic Resources. Pp. 293-314 *in* Seeds and Sovereignty (J.R. Kloppenburg, ed.). Durham and London.

Seide, R. and F. Smith. 1995. Intellectual Property and Biotechnology. New York State Bar Journal, May/June.

Shelton, D. 1995. Fair Play, Fair Pay. Research Report. WWF, Gland.

Shiva, V. 1996. A New Partnership for National Sovereignty: Intellectual Property Rights, Collective Rights and Biodiversity. *In* Intellectual Property Rights, Collective Rights, Biodiversity. Occasional Papers No. 1, Paper 3. Institute for Sustainable Development, Addis Ababa.

Singh Nijar, G. 1994. A conceptual framework and essential elements of a rights regime for the protection of indigenous rights and biodiversity. TWN, Penang.

Singh Nijar, G. 1995. Developing a "Rights Regime" for Control of Biodiversity and Indigenous Knowledge. Pp. 225-265 *in* Prospects in Biodiversity Prospecting. Proceedings of a Workshop held in Kuala Lumpur, Malaysia, 9-10 November 1994 (A.H. Zakri, ed.). Genetics Society of Malaysia, Kuala Lumpur, Malaysia.

Stoll, P-T. 1994. Die WTO: Neue Welthandelsorganisation, neue Welthandelsordnung. ZaoeRV, pp. 241-339

Straus, J. 1987. Gewerblicher Rechtsschutz fur biotechnologische Erfindungen, Cologne; Berlin; Bonn; Munich.

Straus, J. 1993. The Biodiversity Convention and Intellectual Property. IIC 24:602-615.

Straus, J. 1996. Bedeutung des TRIPS für das Patentrecht. GRUR Int. pp. 179-205.

Swaminathan, M.S. (ed.). 1995. Farmers' Rights and Plant Genetic Resources - Recognition and Reward: A Dialogue. Madras.

Swaminathan, M.S. (ed.). 1996. Agrobiodiversity and Farmers' Rights: proceedings of a Technical Consultation on an Implementation Framework for Farmers' Rights. M.S. Swaminathan Research Foundation, Madras.

Swanson, T., D.W. Pearce and R. Cervigni. 1994. The appropriation of the benefits of plant genetic resources for agriculture: An economic analysis of the alternative mechanisms for biodiversity conservation. Background Study Paper No. 1. FAO Commission on Plant Genetic Resources, Rome.

Tewolde, B.G.E. 1996. A Case for Community Rights. Pp. 1-33 *in* Intellectual Property Rights, Collective Rights, Biodiversity. Occasional Papers No. 1, Paper 2. Institute for Sustainable Development, Addis Ababa.

UNEP. 1995. Conference of the Parties to the Convention on Biological Diversity, 2nd meeting, Jakarta, 6-17 Nov 1995. Access to genetic resources and benefit-sharing: Legislation, administrative and policy information. UNEP/CBD/COP/2/13.

UNESCO. 1989. Recommendation on the Safeguarding of Traditional Culture and Folklore. Adopted by the General Conference at its 25th session. Paris, 15 Nov 1995.

UNESCO/WIPO. 1985. Model Provisions for National Law on the Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions. Paris, Geneva.

UPOV. 1974. Actes des Conférences Internationales pour la Protection des Obtentions Végétales, 1957-1961, 1972. Geneva.

UPOV. 1979. Revised General Introduction to the Guidelines for the Conduct of Tests for Distinctness, Homogeneity and Stability of New Varieties of Plants (TG/1/2). Geneva.

UPOV. 1992. Records of the Diplomatic Conference for the Revision of the International Convention for the Protection of New Varieties of Plants. Geneva.

UPOV. 1995 [1985]. Plant Variety Protection Laws and Treaties. Compiled by the International Union for Protection of New Varieties of Plants. 2 Volumes. Geneva.

UPOV. 1996. Administrative and Legal Committee. Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement") and Plant Variety Protection. CAJ/36/2.

Verma, S.K. 1994. Intellectual Property: International Aspects. *In* Intellectual Property Law (P.S. Sangal and K. Ponnuswami, eds.). Delhi.

Verma, S.K. 1995. TRIPS and Plant Variety Protection in Developing Countries. EIRR:281-289.

Winter, G. 1992. Patent Law Policy in Biotechnology. J. Environmental Law 4(2):167-187.

WRI, IUCN, UNEP. 1992. Global Biodiversity Strategy. A Policy-makers' Guide. Washington DC, USA.

WTO. 1995. Environment and TRIPS, WT/CTE/W/8.

0Zakri, A.H. 1995. Formalising Access to Genetic Resources: The Malaysian Experience.

List of Acronyms

BGHZ	Bundesgerichtshof, Entscheidungen in Zivilsachen
BPatG	Bundespatentgericht
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
CGRFA	Commission on Genetic Resources in Food and Agriculture
CHR	Commission on Human Rights
DUS	Distinctness, Uniformity, Stability
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
FAO	Food and Agriculture Organization
GATT	General Agreement on Tariffs and Trade
GRAIN	Genetic Resources Action International
GRUR	Gewerblicher Rechtsschutz und Urheberrecht
GRUR Int.	Gewerblicher Rechtsschutz und Urheberrecht International
IARC	International Agricultural Research Centre
ICCBD	Intergovernmental Committee on the Convention on Biological Diversity
IIC	International Review of Industrial Property and Copyright Law
ILM	International Legal Materials
ILO	International Labour Organisation
IPGRI	International Plant Genetic Resources Institute
IPR	Intellectual Property Right(s)
IUPGR	International Undertaking on Plant Genetic Resources
JUNAC	Junta del Acuerdo de Cartagena
MTA	Material Transfer Agreement
OECD	Organisation for Economic Co-operation and Development
OTA	Office of Technology Assessment
PBR	Plant Breeders' Rights
PIC	Prior Informed Consent
PPA	Plant Patent Act
PVP	Plant Variety Protection
PVPA	Plant Varieties Protection Act
RAFI	Rural Advancement Foundation International
TRIPS	Agreement on Trade Related aspects of Intellectual Property Rights
TRR	Traditional Resource Rights
UNCED	United Nations Conference on Environment and Development
UNEP	United Nations Environment Programme
UNESCO	United Nations Education and Science Organisation
UPOV	Union pour la Protection des Obtentions Végétales [International Union for the Protection of New Varieties of Plants]
USPQ	United States Patent Quarterly
VCU	Value for Cultivation and Use
WIPO	World Intellectual Property Organisation
WRI	World Resources Institute
WTO	World Trade Organisation
ZUR	Zeitschrift fuer Umweltrecht