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Key Questions for Decision-Makers

Protection of Plant Varieties under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights

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Preface

Today's decision-makers are faced with implementing a myriad of international legal obligations that are relevant to the conservation, use and development of plant genetic resources. These obligations arise from international legal treaties and instruments with diverse and – if not implemented rationally – potentially conflicting objectives. These include, for example, liberalizing trade, conserving wetlands, conserving biodiversity and ensuring equitable benefit-sharing derived from its sustainable use, and mitigating the effects of, and ultimately halting, climate change. IPGRI's legal and policy work aims to provide decision-makers with practical analysis and tools to guide them in formulating responsive policy and legislation that is consistent with their national objectives and the sustainable management of plant genetic resources.

This volume is part of an ongoing body of work that IPGRI hopes will assist decision-makers with the complex task of discerning the many issues of relevance to the conservation and management of plant genetic resources and devising a coherent and consistent policy and legislative response. It is our hope that decision-makers and those wishing to influence the decision-making process will find this volume to be a useful tool to help understand implementation options under Article 27.3(b) of the TRIPs Agreement and their potential implications for their country's objectives relevant to plant genetic resources. We would welcome feedback from readers on the usefulness of this tool including suggestions on how the general approach might be improved and other areas where some type of decision-making tool would be useful.

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The Fundamentals

1. What is TRIPS?

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO) is Annex 1C of the Marrakech Agreement, which came into force on 1 January 1995. This international agreement is binding upon all members of the WTO and sets certain minimum standards for the implementation of intellectual property rights (IPR) at national level.

Under Art. 27 of TRIPS, members of WTO are required to provide patent protection for inventions in all fields of technology, whether products or processes, provided that they are new, involve an inventive step and are capable of industrial application. However, Article 27.3(b) of TRIPS allows for certain exclusions from patent protection and states:

"Parties may also exclude from patentability: (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbio-logical processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by a combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement."

WTO Members were obliged to apply all the provisions of the TRIPS Agreement from 1 January 1996, with the following exceptions:

1. Developing country members and, under certain conditions, members in the process of changing from a centrally planned to a market economy, may delay until 1 January 2000.

2. Least-developed countries have until 1 January 2006 with the proviso that where there are sufficient grounds to warrant a further, delay this 10-year grace period may be extended.

The TRIPS Agreement calls for the review of Article 27.3(b) after four years, i.e. in 1999. The review has consisted of gathering information with the input almost exclusively consisting of replies to a list of questions on how plant and animal inventions are handled under domestic laws.

TRIPS Article 27.3(b) provides sufficient flexibility for countries to design a system that best fits their circumstances and meets their goals and objectives.

2. What is a *sui generis* system?

The Latin term *sui generis* means 'of its own kind'. However, as the TRIPS Agreement does not define what an effective *sui generis* system is, nor does it refer to any specific existing rights regime or treaty, the term *sui generis* can mean different things to different people. For example, to some indigenous communities it signifies a new system of legal rights encompassing concepts such as traditional resources rights and the right to self-determination. To others, a *sui generis* system balances the traditional objectives of Intellectual Property Rights (IPR) with sustainably conserving and using biodiversity through a mixture of IPR and other instruments. In this document *sui generis* is used in its narrow sense to signify a system of IPR for the protection of plant varieties.

3. What are the basic requirements under TRIPS?

Compliance with Article 27.3(b) entails the following minimum requirements:

- Members have to implement some form of intellectual property protection for plant varieties whether through patents, a *sui generis* system or a combination of the two. In other words, members need to provide for a legally enforceable right either to exclude others from unauthorized use of a protected plant variety, or to obtain remuneration for its use.
- Nationals of other member states have the same rights as those granted to nationals of the country concerned.
- Any advantage, favour, privilege or immunity granted to nationals of any other country has to be granted immediately and unconditionally to nationals of all other member states, i.e. most-favoured-nation treatment.
- A juridical procedure must be in force to permit action against any infringement of *sui generis* rights.
- In contrast to Article 4 of the 1978 UPOV Act, the TRIPS Agreement does not specify the number of species or genera for which varieties have to be protected. Some argue that by not explicitly limiting its application, article 27.3(b) requires members to provide some form of protection for all plant species and botanical genera.

The term "*sui generis*" is subject to both broad and narrow interpretation. Without a clear understanding, this can cause confusion in discussions on implementation options.

4. What are the options for plant variety protection under TRIPS?

There are three main approaches members can take under the TRIPS Agreement:

(a) patent plant varieties

(b) create a *sui generis* system for plant variety protection (PVP), such as that provided by the conventions of the International Union for the Protection of New Varieties of Plants (UPOV) or any other tailor-made system

(c) devise an approach that combines both a patent and a *sui generis* system.

Under all options, plants could be excluded from patentability; indeed, there is no obligation under TRIPS to provide IPR for plants. For countries concerned about broad IPR claims, excluding plants from patentability could prevent claims to bring plant varieties and plant groupings beyond plant varieties under exclusive control.[1] Under options (b) and (c) members could provide different types of protection systems for plant varieties. They may decide, for example, to offer patent as well as *sui generis* protection for plant varieties. Alternatively, they may choose to provide one form of protection for varieties of a specific species and a different form of protection for other species.

[1] Defining and legally interpreting "plant variety" is not necessarily simple. The question arises of how a "plant variety" can be distinguished from a "plant" and whether a transgenic plant is a plant or a plant variety. UPOV 1991 defines a plant 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 breeder's 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 said characteristics; and considered as a unit with regard to its suitability for being propagated unchanged."[Article 1(vi)].

5. What does combining a sui generis and a patent system imply?

Most countries have mixed agricultural economies. Incentives for plant breeding therefore should be relevant to the type of agricultural production. For example, an IPR suitable for an industrialized system of agricultural production, geared towards export, is unlikely to be appropriate for an agricultural sector characterized primarily by subsistence farming. Since both these systems of production may exist within a country, it is worthwhile exploring how options can be mixed and matched (and ultimately administered) to allow different needs and goals to be addressed.

A country may wish to attract foreign investment and capacity by the presence of strong IPR protection for plant biotechnology, while at the same time encourage plant breeding by farmers and the enhancement of traditional varieties. In such cases, a system could be created which contains different levels of protection for different plant varieties.[2]

The main problem with this is that a clear line needs to be drawn between the different systems in order to avoid unwanted overlaps that will favour holders of stronger, i.e. more exclusive, rights to the disadvantage of holders of weaker rights.

Options available to avoid overlap include:

(a) Prohibiting double protection This may be an attractive option in countries where there is no real overlap between varieties used by the commercial and non-commercial sectors. However, it could raise a problem when varieties of a species are used for traditional farming and industrial crops.

[2] A dual system is consistent with TRIPS and UPOV 1978. If the weaker standard does not comply with the minimum requirements of UPOV 1991, the system would not be in compliance with UPOV 1991.

(b) Providing diverse levels of protection for the same variety or different varieties of the same species, depending on their intended use. In contrast to the first option, this would allow different protection levels for the same variety of a species. This may be preferable in countries where plant varieties of the same species are used in traditional and industrial agriculture.

Most countries have mixed agricultural economies and therefore may wish to use different instruments in accordance with the needs and goals of each sector of their agro-economy.

6. Is the TRIPS Agreement flexible?

There is flexibility under the TRIPS Agreement for establishing both patents and a *sui generis* system, thus allowing decision-makers to design a system which best meets their country's circumstances, goals and objectives. For instance, there is nothing to prevent a country from modifying its patent law or creating a *sui generis* patent-like system in order to include exemptions for farmers and/or breeders (see III.5 & 6). Neither does the TRIPS Agreement prevent the development of additional protection systems or the protection of additional subject matter.[3]

Specifically, the TRIPS Agreement does not define:

- a plant variety
- the requirements for protection, such as novelty, distinctness, uniformity and stability
- the scope of protection, i.e. whether a right should extend to vegetative, reproductive and harvested material, or to the export of the protected material
- the duration of the right
- the relationship between a *sui generis* right and other IPR such as patents.

The TRIPS Agreement does not prevent the development of additional protection systems or the protection of additional subject matter.

[3] For example, a country could include indigenous knowledge as a subject matter to be covered by the *sui generis* system or it could set up a separate system for the protection of farmers' rights as part of the PVP system. Providing that the additional conditions do not contradict other TRIPS requirements, their addition to PVP legislation should not run foul of TRIPS. (UPOV would apply only if the state is a member of UPOV.)

7. How can PVP fit in with national and international needs and interests?

National interests

TRIPS is an international agreement that sets minimum requirements for IPR for its members; it is not an international patent system. Any patent or *sui generis* system created for PVP is established at the national level. It must satisfy various national interests such as those of farmers and local communities as well as the seed sector and biotechnology industries. Such groups are likely to have very different views on IPRs.

In addition, these interests have to be balanced against other national policy objectives such as those relating to trade, the environment and development. PVP is just one piece of an overall policy package that will ultimately reflect a balancing of both narrower and larger objectives.[4]

International obligations

Although legislation under TRIPS only provides coverage at national level, its implementation is relevant to national obligations stemming from international agreements. For example, decision-makers devising a *sui generis* system will be faced with issues that affect a wide range of problems relating to biodiversity; therefore, obligations contained in the Convention on Biological Diversity (CBD) are of direct relevance.

Decision-makers need to be aware of the potential relationships between any PVP system being devised and other relevant areas, including, inter alia:

1. national regulations on access to genetic resources (CBD Article 15);
2. national legislation relating to the rights of indigenous and local communities, including the issue of farmers' rights (CBD Article 8j), and
3. the International Undertaking on Plant Genetic Resources currently under revision.

International obligations should be kept in mind when devising a system for PVP in order to avoid conflicts among objectives and obligations, and to pursue synergies where possible.

Implementation of Article 27.3(b) is relevant to national obligations stemming from other international agreements such as the Convention on Biological Diversity.

[4] Bragdon, S.H. and D. Downes. 1998. Issues in Genetic Resources No. 7. Recent Policy trends and developments related to the conservation, use and development of genetic resources. IPGRI, Rome.

II National Conditions, Obligations and Objectives

1. Is there a best system for the protection of plant varieties?

Countries are characterized by a broad array of socioeconomic, agricultural, cultural and other conditions. Hence, their diverse needs and objectives also are diverse. Even within countries these factors mix to form a multitude of different combinations. There is, therefore, no ideal system that will serve all interests or fit all countries. Deciding which alternative is best depends on a country's current situation and priorities, and its objectives for the future.

There is not one ideal *sui generis* system that will suit the needs of all countries.

2. What should decision-makers know before devising a system of protection?

Before determining the most suitable IPR options for a country, decision-makers need to know the answers to key questions about the current situation of their agricultural economy and their objectives for the future. The following factors need to be considered:

- What kind of domestic seed industry exists?
- What kind of public breeding sector exists?
- What kind of seed-supply system is in place?
- To what extent is farm-saved seed used in the country?
- What is the current capacity of breeders?
- What do local breeders want to do in the next 5-10 years?
- Are external inputs to agriculture low or high?
- What are the country's production needs and objectives?
- What is the country's biotechnology capacity?
- What are the goals and realistic expectations of the biotechnology sector?
- What kinds of strategic alliances will the country want to enter into in the next 5-10 years and how involved will other countries be?

3. What is the status of the agricultural economy?

A country's agricultural economy is often mixed. It may consist of large-scale agriculture with an active private plant-breeding sector and an advanced capacity in biotechnology, as well as an agricultural sector geared towards domestic markets carried out mainly by traditional, small-scale, mostly subsistence farmers. If each of these two situations is considered as ends of a continuum, countries will be found all along this line with different sectors of their agricultural economies at different places.

Industrialized agriculture

A country with an agricultural economy oriented towards markets, particularly export markets, needs to consider the legal and policy tools desirable – and in many cases necessary – to support this sector of the economy. Requirements will include easy access to improved plant varieties and the possibility to sell agricultural products in the global marketplace. Both of these involve agricultural trade and can be blocked in the absence of compliance with the TRIPS Agreement.[5] In such countries, or in those countries which aspire to this and already have a minimum infrastructure and capacity, a patent or a strong *sui generis* system, the same as, or similar to, that of the main importing countries will:

- facilitate exports by providing protection comparable to that of the importing country,
- facilitate exports of harvested products as the IPR system of many importing countries prevents the import of harvested products derived from varieties subject to IPR protection unless the import is authorized by the holder of the IPR, *and*
- facilitate imports of propagating material, as breeders may be reluctant to sell any (non-hybrid) material to countries which do not provide protection.

Small-scale mainly subsistence farming

Countries whose agricultural economy is mainly geared towards domestic markets and which depends largely on traditional varieties cultivated by small-scale, often subsistence, farmers will have less to gain from the introduction of strong PVP.[6] Unless a country has a minimum technical capacity and infrastructure for plant breeding, strong PVP is more likely to attract foreign companies and imports rather than build domestic capacity.

Rather than providing a strong IPR system which could increase imports, countries mainly reliant upon traditional varieties and plant breeding by farmers may prefer to elaborate on concepts: e.g. farmers' and community rights, benefit-sharing, equity, rights against misappropriations and promotion of on-farm conservation and landraces. A *sui generis* IPR system should be tailored so that it does not run counter to instruments elaborating on these concepts and goals. Countries may also wish to explore if, and how, a *sui generis* IPR system could provide incentives to support these goals.

Decision-makers should be aware that, in general, under patent law there is no farmers' exemption to allow the use of farm-saved seed for propagation purposes. Breeders and modern biotechnology companies often perceive the farmers' exemption as potentially reducing the profit, or the expectation of profit. Consequently, there may be strong opposition on the part of breeders and modern

[5] TRIPS provides procedures for enforcing its obligations. These include the potential for trade sanctions against non-complying members and are unprecedented in international intellectual property law.

[6] Traditional varieties are important to more than subsistence farmers. The conservation of genetic diversity – including that contained in traditional varieties – is a global concern (see CBD preamble). It is the foundation upon which plant breeding depends for the creation of new varieties and is, therefore, a critical aspect of food security.

technology companies to this exemption in countries where patent-like protection for plant varieties is being considered. UPOV 1991 does allow for countries to provide for a farmers' exemption. However, unlike UPOV 1978, where the exemption is implicit, the 1991 Act requires Parties to take an active step to recognize the exemption which is limited in scope compared with the exemption under the 1978 UPOV Act (see III.5).

Mixed agricultural economy
As already noted, the agricultural economy of most countries is composed of various sectors. In such cases, countries may wish to mix and match different forms of IPR in accordance with the needs and goals of each sector.

Countries considering establishing strong rights to encourage the industrial agricultural sector should note that under TRIPS, IPR applies to nationals as well as non-nationals (see I.3). Therefore, the granting of such rights may restrict the use and breeding of protected varieties at the domestic level. To protect both national production and export interest, a balance is needed. One option is a tiered system to reflect the different situations in countries where both the domestic and export markets are of importance.

Incentives for commercial breeding need to be balanced by increased efforts for the conservation, development and use of agrobiodiversity.

4. What is the status of plant breeding?

Traditional breeding
Countries relying primarily on the traditional breeding skills of farmers may not find classic PVP, with its requirements for uniformity, stability, etc., well-suited to these breeding methods. Such countries need to consider how to tailor their PVP system to support the technological capabilities of their breeding sector and meet domestic requirements (see II.3).

Classical scientific breeding (excluding biotechnology)
Countries mainly reliant on a private breeding sector and the use of classical scientific breeding techniques may consider designing a *sui generis* system of PVP the same as, or similar to, that of UPOV. By setting up such a system countries can reward and encourage plant breeding while keeping plant varieties available for further breeding and, to some extent, allowing farmers to replant saved seed (see II.3). This will be of particular interest to:

- countries which rely primarily on classical plant-breeding methods because under patent protection access to germplasm is restricted and classical plant breeding depends on this access
- countries which rely on their public plant-breeding sector as this also requires access to germplasm to be successful.

However, given that "the chief contemporary cause of the loss of genetic diversity has been the spread of modern commercial agriculture"[7] such a protection system, by creating incentives for commercial breeding, may well contribute to genetic erosion.

[7] FAO. 1996. Report on the State of the World's Plant Genetic Resources, p. 13. FAO, Rome.

Incentives for commercial breeding should be matched by greater efforts to encourage the conservation and sustainable use of traditional varieties. In addition, countries need to assess their intentions, either now or in the future, to export agricultural products obtained from varieties protected in a country that may import such products (see II.3).

Countries wishing to encourage classical plant breeding should note that unlike UPOV 1978 and 1991, patent law does not include the breeders' exemption. Although this exemption is essential for conventional plant breeders, it could reduce profit prospects for the modern biotechnology sector, which may be more interested in receiving exclusive rights for new gene constructs or gene sequences (through patents) than in free access to plant varieties. Nevertheless, there is nothing in TRIPS to stop a country from devising a patent-like *sui generis* system that provides for breeders' and/or farmers' exemptions (see II.3).

Biotechnology plant breeding

In countries with a strong capacity in biotechnology there is likely to be significant pressure for a strong system of IPR, which is seen as a critical mechanism to protect investment in research and development, to facilitate alliances with companies in other countries, and to facilitate trade in biotechnology products. The biotechnology sector is primarily interested in obtaining protection for gene constructs and biotechnology processes. It is important to note that modern biotechnology does not replace plant breeding but ideally should complement it. The right balance must therefore be struck between the interests of breeders and those who develop biotechnology processes and gene constructs for use in plant breeding.

Strong intellectual property protection for biotechnology innovations could benefit:

- countries with a strong capacity in modern (plant) biotechnology
- countries with the infrastructure and skills required to build up domestic capacity (although they may also profit from the absence of such protection, see IV.1).

However, it should be borne in mind that:

- the presence of multinational plant breeding companies in a country with little internal capacity for breeding is unlikely to directly stimulate the development of domestic industry capacity
- the patenting of gene constructs, and plants carrying these, may have an adverse effect on the price of seeds and other propagating material

and

- the cost of administering patent applications in the field of plant biotechnology is likely to be more expensive than administering a PVP system (see II.6).

Public sector breeding

In general, PVP is more important when breeding activities are carried out by the private sector than by the public sector, at least as the latter has traditionally been conceived. If the role of the private sector in breeding activities increases, the public breeding sector will need strengthening in order to:

- keep alternatives available and promote competition
- focus on subsistence agriculture and marginal areas where there is likely to be little private-sector interest.

A strong private sector requires a robust public sector to keep options available and to focus on the needs of marginal areas.

5. What are the other national goals and objectives?

As noted earlier, decision-makers have to consider the relationship between a system of PVP and other national objectives and obligations. Many of these arise from concerns about diversity, the conservation of landraces and traditional varieties, and the related issues of benefit-sharing and farmer and community rights. Countries may wish to consider mechanisms that could be built into the PVP system to support these concerns. For example, a *sui generis* system could be designed to facilitate the sharing of benefits between users and providers of germplasm, thus supporting one of the objectives of the CBD. The following options are available, neither of which is incompatible with TRIPs:

- a requirement that applicants for IPR are obliged to disclose the source of material and provide evidence that prior informed consent was obtained
- a declaration as to where the genetic material used in the variety was obtained.

It should be noted, however, that a *sui generis* IPR system is probably not the best instrument to fulfil obligations for benefit-sharing under the CBD. This is because only a very small part of overall genetic diversity will ever reach markets in the form of products that can be protected as varieties under a *sui generis* system.

6. What will the system cost to administer?

Setting up a *sui generis* system for the protection of plant varieties will require new capacities in many countries.[8] For example, an institution must be created or adapted to examine applications for the protection of plant varieties in technical and legal terms. Setting up such an institution, and finding and training personnel skilled in technical and legal matters, may prove difficult, time consuming and costly. Consequently, it may be preferable to:

(a) use an existing national institution already dealing with seed registration and certification *and/or*

(b) a regional institution for legal examination and/or registration.

Option (b) is of interest to countries where national institutions for seed certification either do not exist or cannot be used to perform the tasks required. This is particularly the case in regions where countries share similar ecogeographic features such as climate, soils and important crops.

Setting up a PVP system is potentially costly. Countries may wish to look for possible avenues for regional cooperation.

[8] The TRIPS Agreement and Developing Countries. 1996. UNCTAD Secretariat, New York and Geneva 1996 UNCTAD/ITE/1.

7. How can equitable access to the system be ensured?

Whatever system of plant-variety protection is decided upon, care should be taken to ensure that access to IPR, and its enforcement, is available to all potential users whether they be a large multinational company, a small farmer or a traditional community. In this respect it should be noted that the more plant varieties included in a PVP system the more difficult it will be to implement and enforce.

Although it is beyond the scope of this paper to go into detail, some mechanisms that could be used to protect more vulnerable users are:

- the provision of legal aid
- ensuring that measures are in place to legally enforce IPR and protect the rights of small farmers
- establishing farmers' cooperatives to act on their members' behalf
- ensuring that the system allows for the reversal of what may prove to be bad decisions.

An effective system must also ensure that access and enforcement are available to all potential users.

III Key Provisions of PVP Systems

1. Does the variety have to be distinct?

A variety has to be distinct enough to identify it from other varieties. Without such a distinction, problems of multiple protection of one variety, protection for varieties already in use, and an infinite duration of rights over a variety would arise.

Thus, distinctness, as it is understood here, relates to what is known as common knowledge or as the "state of the art" in patent law. In patent law, inventions must not form part of the state of the art, i.e. they have to be novel. Under PVP laws, the variety usually has to be "distinct" from any other variety. Still, the extent to which a variety has to be distinct is open for definition by members. The 1978 UPOV Act requires the variety to be distinct "by one or more important characteristics", although "important" was not understood as to require a characteristic conferring an additional value to the variety. Consequently, the clause was deleted from the 1991 Act. It would be feasible, however, to require truly important characteristics, i.e. traits of agronomic or nutritional value to distinguish varieties.

Moreover, members are free to require distinctness from any other variety, as stipulated by the UPOV Acts, or only from a certain group of varieties, such as varieties under cultivation within the territory of the country. However, such "national distinctness" would invite breeders to apply for the protection of varieties which already fall in the public domain in other countries.

2. How should uniformity be defined?

Background and objectives

Current PVP usually requires that a variety has certain uniform identifiable characteristics, not because uniformity is an objective of PVP legislation but because it serves to clearly define the subject matter to be protected. Therefore, uniformity is only required for those characteristics that make the variety distinct from other known varieties and not for all characteristics. There is concern, however, about the effect of uniformity on biological diversity and its general inability to encompass landraces and traditional varieties.

Countries who wish to encourage heterogeneity, especially for genetic vulnerability, could do this by:

- modifying the general approach to uniformity taken by most PVP systems, *and/or*
- keeping traditional varieties and landraces outside the system but protecting them with non-IPR rights.

Replacing 'uniformity' with 'identifiability'

The present requirement for homogeneity / uniformity in PVP legislation is highly controversial and has been criticized for reinforcing trends towards genetic uniformity, thus leading to a higher degree of genetic vulnerability in farmers' fields. Replacing the requirement for 'uniformity' with 'identifiability' would encourage heterogeneity by making it possible to protect plant populations or landraces under a PVP system. As the term 'identifiable' emphasizes the legal need to identify the protected subject matter and not a plant's specific physical properties, it leaves considerable and explicit flexibility of interpretation.

Under UPOV, uniformity is only used to distinguish between varieties, but countries could also decide to apply uniformity or identifiability only to characteristics of economic or practical interest. It should be borne in mind, however, that such a definition might not be attractive to countries aiming to harmonize their PVP system with international standards. Furthermore, the long-term impact of the use of the term 'identifiable' on overall diversity is unclear, particularly as it may introduce into a market economy – and its corresponding system of incentives – landraces which may otherwise have stayed outside this system. On the other hand, insofar as it slows or deters the replacement of old by modern varieties, it may retard the erosion of agrobiodiversity

Maximum polymorphism in 'non-relevant' characteristics

As full uniformity is not required, there is room within the uniformity obligation to include requirements that encourage heterogeneity in 'non-relevant' characteristics. Countries may wish, for example, to explore the possibility of requiring maximum polymorphism in 'non-relevant' characteristics such as leaf shape or the colour of decorticated grain.

Other legislation related to uniformity

If diversity considerations are important in setting uniformity criteria, decision-makers should also examine national policies, laws and regulations that have direct implications for genetic uniformity, such as seed and marketing laws. National seed certification or marketing requirements are often less flexible than PVP legislation in this regard and provide for even stricter standards. Pressure for uniformity also arises from production systems, including the demands of grocery chain stores.

3. How can traditional varieties and landraces be protected?

There may be groups of people or communities claiming rights to traditional varieties and landraces. Decision-makers must therefore decide whether and how to determine entitlement to PVP rights in these cases. If a country decides to design its PVP system to encompass such varieties, it can provide for the registration of communities or specific groups as collective owners of PVP rights. The situation is analogous to existing systems where IPRs are owned by legal entities such as companies or a group of individuals.

It should be noted that it is inherently more difficult to delimit claims related to traditional varieties which are more heterogeneous than varieties produced through classical breeding. A system encompassing such varieties should be designed, therefore, to cope with potentially overlapping claims of rights holders. One option is to define minimum genetic distances with regard to the composition of the two varieties (e.g. the second variety may consist of the same genotypes only if the distribution is significantly different). Another is to define a maximum level of genotypes that can be shared by the first and second varieties.

A further difficulty in protecting landraces and other traditional varieties is the fact that many of these varieties have been in use for a considerable period of time and may therefore no longer qualify as "distinct". However, this problem may be addressed by the introduction of a grace period as is common under existing PVP protection regimes and under the patent laws of some countries. "Grace period" means a period within which the variety can be sold, or otherwise disposed of, prior to the date of application. The UPOV Acts incorporate this grace period in their definition of novelty and WTO members are free to grant even longer periods to encompass landraces and other traditional varieties.

In addition, certain acts carried out in relation to the variety, such as its customary use in a restricted area or at community level, could be established as not being prejudicial to the protection of the variety.

However, before introducing or modifying legislation in order to encompass landraces and traditional varieties, decision-makers should carefully examine possible implications on the conservation and availability of landraces and other traditional varieties. There may be more direct and stronger way of conserving and developing these resources and defending the rights of indigenous and local communities in relation to them. It is not clear whether or not the protection of such varieties would have any positive impact on their conservation or stimulate breeding activity, nor would protection serve the purpose of strengthening the rights of communities and traditional farmers over their resources. In considering new PVP systems, or modifications to the existing PVP system, decision-makers may also wish to pursue non-IP means for the conservation and development of traditional varieties and the protection of the rights of indigenous and local communities. One means may be through the use of legislation on access to genetic resources pursuant to the CBD. Another may be through the protection of knowledge related to such resources.

Other types of protection for traditional varieties and landraces

It is not clear what the long-term effects of including landraces and traditional varieties in a system to protect plant varieties will have on their conservation and use. Consequently, decision-makers may choose to keep these varieties outside an IPR system and confer other types of rights to promote their conservation

and use[9]. These range from establishing rights against misappropriation of the varieties, to rights relating to the traditional and customary use of resources encompassed under the term 'traditional resource rights'[10] (see parts II.3 and III.2).

Decision-makers wishing to conserve agrobiodiversity need to look beyond PVP legislation and also consider other instruments and pressures such as seed and marketing laws.

4. What should be the strength of rights conferred under PVP?

Countries may choose from a number of options, ranging from the strongest form of IPR, i.e. patents, to the weakest, such as the PVP seal. In general it is assumed that:

- Countries with a more industrial-agricultural base will opt for strong exclusive rights such as patent protection and/or a *sui generis* system close to the scope of UPOV 1991.
- Countries with a more traditional agricultural base will opt for comparatively weak rights such as those of a PVP seal for specific varieties.
- Countries with mixed agricultural economies and consequently various objectives may wish to strike a balance between their different interests by:
  - making an overall compromise and providing a medium level of protection for plant varieties;
  - setting up a system with different levels of protection which could be applied either on a species or variety-specific basis, or according to the use of the variety. For instance, protection similar to patents for ornamentals and high-value export crops, and a *sui generis* system based on UPOV 1978 or PVP seals for other species.

Under the latter option, the possibility of shifting species from one level to the other would give considerable flexibility for the future. Although problems may arise in cases where a species is cultivated for different economic purposes, the level of protection for a variety, or for different varieties of the same species, could vary according to their intended use.

[9] Similarly (and as an overall part of establishing a *sui generis* system under TRIPS), decision-makers will want to consider benefit-sharing mechanisms and means to ensure equity both within and outside the PVP system. See discussion in section II.5.

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

The duration of a right is an important factor in balancing the competing interests of breeders, biotechnologists, farmers and others affected by, or with a stake in, PVP. For example, an exclusive right can be weakened substantially by reducing the duration of the right. In contrast, a weak right is strengthened by being granted for a long time. This factor should be carefully considered regardless of how rights are defined. UPOV 1991 and patent protection under TRIPS require that rights be granted for at least 20 years. TRIPS 27.3(b) does not specify a required period of duration under a *sui generis* system.

Decision-makers need to consider what rights farmers should retain, notwithstanding the IPR granted to the plant breeder.

5. What rights should farmers retain?

Member states need to consider what rights farmers should retain notwithstanding the IPR granted to the plant breeder. By only concentrating on the commercial marketing of propagating material, many PVP laws implicitly allow for the production of propagating material of a protected variety for non-commercial purposes. However, the actual scope of this farmers' exemption varies from country to country.[11] Some countries only allow their farmers to plant-back seeds and exchange limited amounts 'over the fence' on a strictly non-commercial basis,[12] while others interpret the farmers' exemption so as to allow farmers not only to plant-back seeds but also to sell limited quantities for reproductive purposes 'brown bagging'.

In determining the rights a country may wish to retain for its farmers under its PVP system, a decision-maker must consider the status of the traditional agricultural base within a country and its reliance on farm-saved seed. The closer the agricultural base is to the traditional farming sector the more need there is to retain the farmers' exemption. Weaker rights for breeders, such as a PVP seal, leave more room for farmers' activities in relation to the protected material. However, this kind of system is not likely to fully satisfy commercial breeders.

Countries that decide to create a patent-like system for plant varieties can still provide for a farmers' exemption (see II.3). This may provide a mechanism for balancing the interests of the biotechnology industry with those of farmers.

[11] Under UPOV 1991 Act, member states may "within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder" allow farmers to propagate saved seed on their farm. Farmers may only propagate 'on their own holdings' the product of the harvest obtained by planting the protected variety 'on their own holdings'. Therefore, the 1991 UPOV Act clearly prohibits the practice of farmer-to-farmer exchange which is officially supported in many developing countries.

[12] As recently as January 1995, the US Supreme Court held that under the farmers' privilege foreseen in the Plant Variety Protection Act, a farmer may sell for reproductive purposes only such seed as he has saved for the purpose of replanting his own acreage.

6. What rights should breeders retain?

The breeders' exemption
Member states need to consider what rights breeders should retain, notwithstanding the IPR granted for the plant variety. Countries need to balance their interest in keeping material available for breeding, and hence improvement, and the rights to be conferred to the PVP right-holder. This is particularly true where strong exclusive rights are conferred through a patent or patent-like system for plant varieties and is most likely to occur in countries with a more industrialized agricultural economy.

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, are common practices in most countries today. It is possible for a patent-like system for PVP to explicitly include an exemption for breeders or to include this under a general research exemption. Acts to be exempted from the patent-like right should be clearly defined. For example, it may state that varieties subject to patent protection may be used freely as an initial source for breeding new varieties, provided the new variety does not include, or express, any of the patent-specific genes or characteristics.

The principle of essential derivation
Under UPOV 1991, the right-holder's authorization is not required to use a variety to breed another variety, nor for its commercialization, unless the resulting variety is essentially derived from the protected variety. This concept aims to prevent breeding a new variety basically the same as the original except for a few minor changes – 'cosmetic' breeding.

Countries with a strong classical breeding sector but with capacity in biotechnology and a corresponding patent system, may wish to consider adopting the concept of essential derivation in order to:

- protect traditional breeders from a patent system that could potentially restrict their access to germplasm;
- ensure that traditional breeders continue to be rewarded for their innovations by sharing in any benefits to be had from the exploitation of a variety based on genetic engineering essentially derived from a classically bred variety protected by PVP.

However, decision-makers should be aware of the following problems in applying the principle of essential derivation.

Acceptable genetic distances
These vary between species and have to be determined for each species separately. The commercial varieties of some species are so closely related that it is difficult not to define them as being essentially derived even with the use of new molecular techniques.

Applying essential derivation
This requires technical knowledge and investment, and is more likely to be introduced in countries with a more industrial agricultural base.

IV Patents and a *Sui Generis* System

A critical issue facing decision-makers is how to handle the interface between a *sui generis* system and an existing patent system in the country. This is particularly true for countries with biotechnology capacity wanting to balance incentives for plant-breeding innovations using biotechnology with incentives for traditional plant breeding.

The interface between a patent system and a PVP system will need to be clear in order to avoid conflict and confusion.[13] It will also have to be carefully managed to ensure that incentives are present to encourage plant breeding under both a patent and a PVP system. For example, a country wishing to encourage both classical breeding and the development of transgenics will need to clearly delineate the rights of each kind of innovator. Innovators/breeders, whether 'classical' or 'modern', need clarity if they are to be assured of their rights in the products of their work.

1. Is there flexibility in implementing TRIPS' patent requirements?

Decision-makers must consider to what extent TRIPS requires the granting of patent protection for innovations which may be relevant for the use and reproduction of plant biotechnology innovations. In considering options, decision-makers should bear in mind that there is some flexibility under TRIPS to allow countries to encourage biotechnology innovation by providing or not providing protection for some types of innovation. It can be argued that not providing protection could encourage innovation, as this would allow domestic companies to benefit from foreign developments, which, if they were protected, could not be used or could only be used if the domestic company could pay the licence fee.

When there is a strong private sector role in breeding activities, public sector breeding needs to be kept strong to:
(1) keep alternatives available and promote competition, *and*
(2) focus on subsistence agriculture and marginal areas.

[13] The advantage of avoiding overlaps and contradictions of different forms of protection is demonstrated by the following example. If a patented gene is inserted into a plant protected by a plant breeders' right similar to that of UPOV, the question arises as to 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.

2. How can plant biotechnology innovations relate to the patentability of genes?

Under the TRIPS Agreement plants other than microorganisms may be excluded from patentability irrespective of the methods used to obtain them. Although it does not state whether or not genes may be excluded from patent protection it can be argued that because TRIPS allows for the exclusion of plants from patentability, the exclusion of parts of plants, such as plant genes, is also allowed.[14] This argument would imply that the situation may be different for genes originating from microorganisms, as TRIPS explicitly prohibits the exclusion of microorganisms and products directly obtained from patented biotechnology processes from patentability.[15]

However, countries can determine, in accordance with well-established principles of patent law, that substances that exist in nature are simply a discovery and not an invention. The TRIPS Agreement only requires patent protection with regard to 'inventions' without defining this term. Hence, members are free to exclude from patentability biological matter, including cells and genes isolated from nature.[16] Under specific circumstances, plant genetic innovations, such as genes, sequences, vectors or processes may also fall under the optional exclusion from patentability of "inventions, the prevention of the commercial exploitation of which is necessary to protect ordre public or morality".

Whether or not patent protection has to be granted under TRIPS for parts of plants, members are certainly free to limit the scope of protection of a gene patent so that it does not extend to plants into which the patented gene has been inserted. In other words, they may ensure that the scope of patents claiming genetic material does not extend to subject matter that is excluded from patentability.

3. Is there a balance between patents and PVP?

Decision-makers need to consider whether allowing patent protection for genes is desirable, and if so, how to manage the relationship between gene patents and the protection system for plant varieties. In general, PVP was developed to encourage classical plant breeding at a time when advanced biotechnology breeding techniques were not in use. Consequently, the traditional system of PVP was not designed to encourage this kind of activity and does not provide incentives for biotechnologists to isolate genes or develop transformation systems to allow the insertion of a new gene in a plant cell from which plants may be regenerated. A country with biotechnology capacity wanting to encourage the development of transgenic crops may wish to consider developing a system to allow the patenting of genes, while supporting plant breeders by creating a *sui generis* patent-like or other *sui generis* system for plant varieties.

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[14] See Leskien, D. and M. Flitner. 1997. Intellectual Property Rights and Plant Genetic Resources: Options for a *Sui Generis* System. Issues in Genetic Resources No. 6, pp. 18-20. IPGRI. Rome.

[15] With a patented biotechnology process (not product) competitors are allowed to make the same product only if they employ a different process.

[16] South Center. 1997. The TRIPS Agreement - A Guide for the South. Geneva.

4. What is the scope of protection under patents?

TRIPS does not define in detail the scope of protection of patents for biological material and biotechnology processes. Therefore, it is not clear whether members providing patent protection for genes have to ensure that protection also extends to plants produced by propagation or multiplication without using the invention.

Patenting genes but not the plant in which the gene is contained

This may be an attractive approach in countries where there is a strong national breeding programme, but a minimum capacity for biotechnology to adapt biotechnology products to local conditions. Such an approach may favour the traditional breeder at the expense of biotechnology development. Countries that decide to exclude plants from patentability should make it clear that:

- the protection of a gene patent does not extend to plants into which this gene has been inserted
- patents for genetic material do not extend to subject matter excluded from patentability.

Patenting genes and the plant containing the gene

Should the option of patenting genes and the plant containing the gene be chosen, exemptions could be made for broad experimental use or research. In many nations, in situations where experimental use is stimulated by the potential for ultimate commercialization, the experimental or research exemption may not apply. There is no reason, however, why a developing nation should not permit such experimental or research use, while still requiring the patent-holder's consent for the commercial use of resulting products, providing that use is within the scope of the patent.

Allowing the free use of patented plant material

This option could be chosen providing that the resulting plant variety does not express or even contain the patented gene or show any features/traits claimed by the patent. This alternative has the advantage of encouraging the continued use of the material for further development by breeders while giving biotechnologists considerable protection with regard to their research results. This may be an attractive option for countries seeking a balance between their breeding and biotechnology sectors, and the general objective of improving and making new plant varieties available.

Not allowing patents for plants or parts of plants

The option of not allowing patents on either plants (including plant varieties) or parts of plants (such as genes) may be most suitable in:

- countries reliant primarily on subsistence agriculture with a weak formal breeding sector which does not expect to benefit from biotechnology
- countries which have the desire and capacity to imitate innovations patented elsewhere but not the capacity to undertake top-level research and development.

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