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TRIPS-Related Patent Flexibilities and Food Security

Options For Developing Countries

Policy Guide

By Carlos M. Correa

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About the Author
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This Policy Guide may be downloaded from www.quno.org/economicissues/food-sustainability/foodLinks.htm#QUNOPUB or http://ictsd.org/programmes/ip/

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QUNO and ICTSD welcome feedback and comments to this document. These can be sent to Caroline Dommen (cdommen@quno.ch) or Ahmed Abdel Latif (aabdellatif@ictsd.ch).

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ABBREVIATIONS AND ACRONYMS

CBD	Convention on Biological Diversity
CGN	Centre for Genetic Resources
ECJ	European Court of Justice
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
FAO	UN Food and Agriculture Organization
FTA	Free-trade agreement
IP	Intellectual property
IPR	Intellectual property rights
ITPGRFA	Treaty on Plant Genetic Resources for Food and Agriculture
MAS	Marker-assisted selection
PVP	Plant variety protection
R&D	Research and development
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UPOV	International Union for the Protection of New Varieties of Plants (UPOV)
WTO	World Trade Organization

PREFACE

The Quaker UN Office and ICTSD started working on the ways that international intellectual property policy can affect food and sustainability in the late 1990s. Since then, each organization has undertaken a range of activities, including commissioning publications in which examine a subject of importance in the international intellectual property regime, highlight key issues they see arising and make recommendations for policymakers. The aim is to contribute to greater understanding of the impact of intellectual property policy upon people's lives and thus to better inform debate and policy.

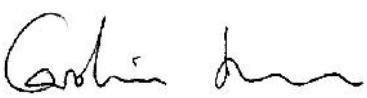
This Policy Guide is designed for negotiators and policymakers in the areas of intellectual property, agriculture and food policy as well as breeders, farmers and other members of civil society. We also intend for it to be a useful tool for providers and recipients of technical assistance in the areas of intellectual property and agriculture.

This Policy Guide proceeds from the observation that there is insufficient awareness of the flexibilities available for each country to implement the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in a way that is consistent with its food, agriculture and development priorities. These priorities may differ significantly from one country to another, depending on the nature of each country's agriculture sector and environmental and developmental priorities. The Policy Guide recalls how important the free flow of genetic material and knowledge has been throughout history for progress in plant breeding. The Guide also emphasizes that the flexibilities incorporated in the TRIPS Agreement are an integral part of the agreement. This Guide focuses on patents (as opposed to plant variety protection or plant breeders' rights). It draws on the wide experience in this area in countries that implement the patent flexibilities discussed, most notably the European Union (EU).

Promoting agricultural innovation is key to address food security. At the same time, ensuring that the benefits of such innovation are widely diffused, especially in developing countries, is equally important. It is for each country to strike the necessary balance to achieve this taking into account its specific needs and priorities.

We sincerely hope you will find this publication useful particularly at a time when food security has become such a pressing global challenge which requires urgent responses.

Ricardo Meléndez-Ortiz
Chief Executive, ICTSD



Caroline Dommen
Representative, Global Economic Issues, QUNO

1. INTRODUCTION

Achieving food security[1] is a major objective of the international community. The effort to reduce the number of people suffering from food insecurity faces many obstacles, including underinvestment in agriculture and rural development, substantial increases in food prices and poverty.

A number of factors related to the production of seeds and control over plant materials and technologies can also impair attainment of food security. The field related to the development and production of commercial seeds is highly concentrated. There is a growing orientation of research and development (R&D) toward commercially attractive crops and varieties, while traditional seed supply systems are eroded. The spread of commercial plant varieties has significantly reduced the genetic variability and increased the vulnerability of agricultural production. In addition – and this is the focus of this Guide – some forms of intellectual property rights (IPRs) can create barriers to the free flow of information and materials (e.g. through farmers' exchange of seeds), which is essential to sustained levels of food production as well as development of new varieties.

IPRs were originally conceived for innovations in manufacturing (such as new machinery, industrial products and processes) and artistic creations (such as literary works or music). More recently, IPRs have been applied to biological processes and products, including living organisms.

The expansion of IPRs to plant materials and food has given rise to concerns about the possible implications for food security.[2] IPRs generally grant exclusive rights. This means that the right holder can exclude, for a period of time, anyone from using the protected subject matter, unless the national law provides for specific exceptions or limitations. Thus, IPRs remove competition and enable the right holder to charge the price that the market will bear. Hence, the granting of IPRs affects access to protected products and their affordability. Higher prices for seeds and other agricultural inputs may be detrimental to small farmers and increase the concentration of agricultural production for food.

In addition, IPRs may have an impact on what agricultural research is done and on the sustainability of agriculture. In this respect, concerns include the:

- growing orientation of R&D toward commercially attractive crops and varieties;
- erosion of traditional seed supply systems that are a source of economic independence and resilience in the face of threats such as pests, diseases or climate change;[3]
- loss of crop diversity due to the uniformisation resulting from the spread of commercial varieties.[4]

Although various factors[5] may contribute to these effects, IPRs – particularly patents - may amplify them. Indeed, changes in intellectual property (IP) legislation and jurisprudence have made it possible in some countries to patent plant genetic materials, whether natural or modified.

The growing use of patents to protect innovations in plants, as a result of the obligations arising from the TRIPS Agreement and from bilateral and regional free-trade agreements (FTAs) entered into by a number of developed and developing countries[6], may drastically transform the paradigm related to the free flow of knowledge and materials (e.g. through farmers' exchanges of seeds) under which agriculture developed over the past centuries.

Although the TRIPS Agreement provides WTO Members with flexibilities for implementing its provisions in ways that are consistent with their agriculture and food policy objectives, such flexibilities have received little attention so far. In fact, many WTO Members have not used them or have done so only to a limited extent. This contrasts with the situation in the area of public health, where a large range of measures has been debated and adopted nationally and internationally to ensure access to medicines.[7]

Countries could do much more to develop systems of IP protection that, while being consistent with the TRIPS Agreement, would be adapted to local conditions and reward innovation as well as promote food security.

When designing and implementing IP regimes, therefore, crucial choices need to be made about the type and scope of IPRs conferred on plant materials and food.

This Policy Guide describes the flexibilities contained in the TRIPS Agreement and how they can be used at the national level to promote and support food security policy objectives. It provides recommendations and options for policymakers and officials in developing countries, taking into account relevant precedents from developing and developed countries.

This Guide focuses on flexibilities related to patents as applied in the area of plant materials. Issues related to possible options for implementing plant variety protection, such as in the context of the International Union for the Protection of New Varieties of Plants (UPOV), are not considered here.[8]

Progress in plant breeding for food has historically been based on open flows of materials and knowledge. The exchange of seeds and knowledge about them has traditionally taken place among farmers. Food crops also moved from their places of origin to distant places around the world where they were adapted and improved. Recognizing the importance of keeping such flows unrestricted for research and breeding is one of the main objectives of the UN Food and Agriculture Organization (FAO) Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).[9]

Granting patents on plant varieties and plant components (such as genes) may impede access to genetic resources needed to ensure the continued development of diverse[10], adapted and improved plant varieties.

The analysis and recommendations of this Guide are based on the assumption that achieving food security requires a legal system that preserves a free flow of knowledge and plant materials, so as to permit a continuous process of improvement and adaptation of plant varieties through research and breeding, the availability of a diversity of materials to respond to local needs and changing conditions (including those generated by climate change), and the diversification (as opposed to concentration) of the supply of technologies and seeds. It is also based on the assumption that patents may encourage innovation in some sectors only when certain contextual conditions exist (such as a solid scientific and technological infrastructure, risk capital and adequate industrial policy), and that it will be up to national governments to decide how to strike a balance between promoting access to, and diffusion of, innovations, on the one hand, and the granting of exclusive rights through IP, on the other.[11]

After briefly considering the history and different modalities of IPRs applicable to plants, the Policy Guide examines the flexibilities available in relation to the

- exclusions from patentability;
- scope of protection when patents are granted; and
- extent of exclusive rights granted.

2. INTELLECTUAL PROPERTY PROTECTION OF PLANTS: BRIEF HISTORY AND OPTIONS

Plant-related IPRs are not new. The Plant Patents Act was enacted in 1930 in the United States to respond to the demands of the nascent seed industry. It allowed for the protection of asexually reproduced cultivars[12] (except tubers) under a system of special "plant patents." The Netherlands was the first country to introduce, in 1942, a new *sui generis* form of IPR for plant varieties – known as plant variety protection (PVP) – and Germany followed suit in 1953[13]. PVP evolved, after intense debates, as an alternative to patents in an effort to capture the specific characteristics of innovation in the plant breeding industry,[14] namely the fact that a plant variety can only be the outcome of incremental innovation.

The PVP model was eventually enshrined in the UPOV Convention signed in 1961 and subsequently revised in 1978 and 1991. The UPOV Convention initially banned double protection by PVP and patents,[15] but the 1991 revision permits both. This change reflects the growing trend toward granting patents on plants and their components.[16] Currently, PVP and patent protection covering plant DNA and cells and, in some cases, complete plants and plant varieties, coexist in most countries.

Only a small number of countries[17] have implemented *sui generis* regimes different from UPOV. There is a significant body of literature and a large number of proposals for the design of such regimes, largely triggered by the wording of Article 27.3(b) of the TRIPS Agreement. The notion of Farmers' Rights – first mentioned in 1983 in the FAO International Undertaking on Plant Genetic Resources for Food and Agriculture[18] and incorporated later into the ITPGRFA[19] – and the principles of benefit sharing, as contained in the Convention on Biological Diversity (CBD),[20] decisively contributed to shaping those regimes.

It is worth noting that "trade secrets" (a form of protection recognized by Article 39 of the TRIPS Agreement) may also apply to innovations in plant breeding, particularly in the case of the production of hybrid seeds. Commercial breeders do not make the parental lines used to generate hybrids available in order to avoid reproduction by third parties.

There are significant differences between patents and PVP protection. In the case of the latter, there are also differences depending on whether UPOV 1978, UPOV 1991 or another system applies.[21]

It is important to note that PVP protects materials that actually exist: in some countries samples thereof must be submitted to the competent authorities; in others, they must be available for as long as the protection is in force. In the case of patents, however, there is no need to provide evidence of the actual existence of the subject matter, but only the possibility of obtaining it.

The main elements of farmers' rights as understood in the ITPGRFA are:

- the right to participate in the sharing of the benefits of the use of genetic resources
- the protection of traditional knowledge
- the right to participate in decision-making

In some countries, such as Australia, Japan or the US, the subject matter of protection covered by patents and plant breeders' rights may be a plant variety as such.[22] However, most countries exclude the patentability of plant varieties, as allowed by the TRIPS Agreement.

The rights provided under PVP and patents are similar, but PVP legislation contains two important exceptions: the "breeder's exception" and the "farmers' privilege" that most countries do not recognize under patent law. This question is further elaborated below, in section IV.

3. EXCLUSIONS FROM PATENTABILITY

Food security may be negatively affected by the appropriation of plant genetic resources, as it may prevent further research and breeding or limit the possible sources of supply of seeds. Article 27.3(b) allows WTO Members considerable policy space to define national laws in this area.

Some of the available options relate to the exclusion from patentability of

a) plants
b) essentially biological processes, and
c) plant varieties.

3.1. Plants

Article 27.3(b) allows (but does not oblige) WTO Members to exclude plants from patent protection. However, it is important to note that, in the absence of any definition in TRIPS itself, the exclusion for plants can be interpreted in broad terms, inclusive of plants as such as well as plant varieties and species. In addition, countries that opt to implement this exception may exclude plants, whether obtained through conventional breeding processes or through the use of genetic engineering.

A large number of national laws provide for the exclusion of plants in general, or plant varieties, with a variety of legal formulations.[23] Some countries' (such as Brazil, Cameroon, Colombia, Cuba and Guatemala) laws also exclude DNA sequences and amino acid sequences corresponding to the peptides or proteins produced by a naturally occurring organism.[24]

The TRIPS Agreement requires that microorganisms be granted patent protection. Under a literal interpretation of the Agreement,[25] the obligation to protect microorganisms is limited to organisms that are not visible to the naked eye, such as bacteria, viruses or fungi, provided that they constitute an "invention" that meets the patentability requirements. The obligation does not extend to microorganisms found in nature, even if isolated. Also, it does not extend to cells or genes, which "are naturally occurring entities that are there to be discovered, like new species or new planets."[26]

In some jurisdictions, such as Europe and the US, isolated genes for which a function has been identified have been deemed patentable. This approach has influenced patent legislation and practices in many countries. However, it has been increasingly questioned in recent years. In 2010, a US district court[27] rejected claims on isolated DNA or complementary DNA (cDNA) on the grounds that genes are a product of nature and therefore not inventions, even if isolated from their natural environment.[28] If finally confirmed, this decision may have a broad impact in different fields of biotechnology.[29]

An important question is whether the possibility of prohibiting patents on plants may be understood, under the TRIPS Agreement, as applicable also to plant cells, genes and other sub-cellular components.[30] It could be argued that none of those components are "plants" and, therefore, that they are not covered by the exclusion provided for in Article 27.3(b). But patenting of such components (even if modified) may be equivalent to patenting the plant as such, since the patent owner may prevent commercial acts[31] relating to any plant that contains the patented subject matter and thereby nullify, in practice, the exclusion relating to patents for plants. This might be the case even where one single modified gene or an artificial gene construct is incorporated into a plant (whose genotype may contain several thousands of coding genes).[32]

The possibility of broadly excluding plants and parts thereof from patentability is limited or completely ruled out in countries that have signed FTAs with the US,[33] where there is an obligation to grant patents for plants or to make efforts to do so.[34]

Recommendation:

It may be important for food security to exclude plants from patentability. Excluding plants or plant varieties from patentability is effectively circumvented if national laws allow parts or components of a plant to be patented, since control over the latter leads to control over the former.

Countries should therefore consider excluding plants from patentability, whether or not they are genetically modified and excluding from patentability parts and components of plants, including genes, even if isolated.

3.2. Essentially Biological Processes

TRIPS Article 27.3(b) allows the exclusion from patentability of "essentially biological processes" for the production of plants. The meaning of "essentially biological processes" – a concept drawn from the European Patent Convention (EPC) – has been examined in many European Patent Office (EPO) decisions and given a rather narrow interpretation. For instance, in Decision T320/87, *Lubrizol* (1990), the EPO held that "a novel combination of traditional plant breeding techniques that results in plants and seeds" is patentable.

A growing number of applications claim IP protection over conventional breeding methods. According to one study, "in 2008 nearly 25 percent of all patent applications at the EPO related to plants developed by conventional breeding. Some years before, patent applications centred on conventional breeding processes had been the rare exception."[35] In 2010, about 200 patents on seeds with and without the use of genetic engineering were granted by the EPO, and 100 applications were received on plants bred without using genetic engineering.[36]

The use of marker-assisted selection (MAS) explains the rise in patent applications involving conventional breeding methods. MAS permits breeders to identify genes of particular interest in the plant genome. Then, by means of genetic markers, they can select the plant lines containing the desired trait. This method allows the expression of desired traits without the insertion of genes that are not naturally present in the plant's genome, thereby avoiding the costly testing that is required for the approval and release of transgenic varieties.

An important issue is whether the use of MAS can be considered an "essentially biological process" excludable from patent protection.

In considering patents EP 1069819 relating to broccoli and EP 1211926 relating to tomatoes, the Enlarged Board of Appeal of the EPO ruled on 9 December 2010 that the mere use of molecular markers did not render the selection and breeding methods patentable.[37] While this decision – still on appeal – seems to confirm the non-patentability of conventional breeding methods (even when based on modern techniques) under European law, it leaves open the possibility of patenting the obtained plants as such.[38]

Recommendation:

Plant breeding methods must be available for unrestricted use to produce new varieties and ensure diversity in the field.

National laws should not allow for the patentability of conventional methods for plant breeding, even where selection is assisted by genetic markers. The use of such markers should not be deemed a sufficient ground to grant patents on the products obtained as such.

3.3. Plant Varieties

The TRIPS Agreement mandates the protection of plant varieties, allowing several options: "patents, an effective *sui generis* regime or a combination of both." This was one of the most controversial provisions in the TRIPS negotiating process. The initial proposals by the US, Japan, the Nordic countries and Switzerland aimed at broad patent coverage for plants and living organisms. In contrast, most developing countries rejected such an approach.[39] Meanwhile, EU countries wanted to preserve the freedom to exclude plant varieties (and animal races) from patentability, as provided for in the EPC.

According to TRIPS, therefore, national laws may provide for patents, a combination of PVP with patents and/or *sui generis* forms of protection, whether or not modelled on the UPOV Convention. In choosing the modality of protection, patents can be excluded for plant varieties as currently is the case for a large number of countries that follow the EPC approach.[40]

The patentability requirements (particularly the inventive step) seem not only unsuited to plant varieties, but also, given the scope of rights generally granted under patents, they may deter further research and breeding on protected materials and erode the rights of farmers to save and reuse seeds.

Recommendation:

Countries should assess the different options they have to provide protection for plant varieties in a manner that suits their national agriculture policy and food security objectives. Whether agricultural production in a particular country is essentially based on commercial or on farmers' varieties, protection of plant varieties under patents is not advisable, as they may restrict further breeding and farmers' saving and sharing of seeds.

3.4. Ordre Public And Morality

Article 27.2 of the TRIPS Agreement provides for the possibility of refusing patents for inventions the commercial exploitation of which is "necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law."

Ordre public or moral grounds to prevent the grant of patents relating to plants have been invoked in some circumstances in national courts, but not admitted so far. In *Plant Genetic*

Systems, the Board of Appeal of the EPO found that the invention (a genetically modified plant) was not improperly used, and it had not had destructive effects.[41]

In 1999, a legal challenge was brought in the US against a patent granted to a US citizen on the "ayahuasca" vine, which is native to the Amazonian rainforest. The Coordinating Body of Indigenous Organizations of the Amazon Basin (COICA) and other indigenous and environmental groups objected to the patent because it purported to appropriate for a US citizen a plant that is not only well-known, but also sacred, to many indigenous peoples of the Amazon.[42]

The patent was objected to, not on *ordre public* or moral grounds, but because it allowed a US citizen to appropriate a plant that was considered sacred to many indigenous peoples of the Amazon.

Although Article 27.2 is likely to be relevant in only a limited number of circumstances, it may be applied, for instance, when the diffusion of a certain plant technology, such as the sterilization of seeds, may have negative effects on agricultural production or the environment.

Recommendation:

Patents should be denied based on *ordre public* or moral grounds in cases where food security or the environment are put at risk, for instance, when the dissemination of certain genes may negatively affect particular crops or ecosystems.

4. PROLIFERATION OF PATENTS ON PLANT MATERIALS

Although the patenting of plant materials raises a number of concerns from the perspective of food security, many countries do allow such patenting. Patents are routinely granted in many developed and developing countries (such as China, Chile, India and South Africa) on genetically modified plants, plant cells, genes and other sub-cellular components as well as on enabling plant biotechnologies.[43]

In these cases, countries can use a number of flexibilities to limit the possible negative impact of patents on agriculture and food security. These flexibilities are examined in this section.

4.1. Multiplicity Of Patent Claims

The wide range of possible claims in connection with a single plant component or trait often leads to situations where a multiplicity of patents applies to one and the same plant. There may be a patent on promoters, another on terminator sequences and others on sequences used for "transportation" and "reporter genes" needed for the genetic transformation of a plant, and in the case of transgenic plants and agrobiotechnology products, each of their numerous components and processes, each may be protected by an IPR.[44] This leads to "[t]he development of large patent portfolios of more or less overlapping claim files ('patent thickets')."[45]

The presence even of one single patented component in a plant or plant variety may create a barrier against the utilization of the latter, including for research and breeding. For instance, a patent on a peptide transit used in GA 21 (a genetic construct that makes maize resistant to an herbicide) may prevent the incorporation of this construct in plants, even if the genetic construct as such is in the public domain.

The proliferation of patents explains the difficulties that researchers face:[46] "a web of proprietary claims now envelops the transfer and use of patented agricultural biotechnologies, thereby limiting the freedom to operate of public and private agencies alike."[47] A telling example is provided by the obstacles found for the use of agrobacterium – the most widely used tool to genetically transform plants – by researchers both in the private and public sectors, due to the complex set of patents relating to this technology.[48] Even in cases where a patent (e.g. on a promoter gene) is not in force in the country where a research entity operates, if a product were developed containing patented components, exports to countries where the patent does exist could be prevented by the patent owner.

The proliferation of patents is the result of a number of convergent factors, namely the erosion of the traditional distinction under patent law between "inventions" and "discoveries," and the relaxation of the patentability requirements.

4.2. Distinction Between Invention And Discovery

Although patent law has traditionally relied on a basic distinction between what is merely discovered as opposed to what has been invented, this distinction has become extremely thin or has disappeared. Under many laws (e.g., Australia, EC, Japan and the US), a biological material isolated from its natural environment may be considered an invention even if it previously occurred in nature.

Recommendation:

Allowing appropriation of plant materials found in nature through an IP right (even if the patent claimer has done work to isolate them or identify their properties) creates barriers that may negatively affect agricultural research. The TRIPS Agreement does not oblige WTO Members to confer patents on natural biological materials.

National laws should establish a clear-cut distinction between "invention" and "discovery" and consider that an "invention" does not exist where a natural substance, such as a gene, has been isolated or the properties or a function thereof identified.

4.3. Novelty

Patents were originally intended to reward new technical contributions to the existing pool of knowledge, and not just the mere disclosure of what already existed. Despite this, some countries' patent legislation allows patenting of pre-existing subject matter provided it has not been previously disclosed or made available to the public. For instance, under the European approach, a biological material may be considered an invention even if it previously occurred in nature. Thus, in *Interferones Alfa-Biogen* the EPO held that the availability of DNA sequences in a DNA library did not destroy novelty.[49]

While in most jurisdictions "novel" is understood as not being disclosed before the date of filing of the application anywhere in the world, the US has applied until recently[50] a relative standard of novelty that allowed a number of patent grants on genetic resources or traditional knowledge used in foreign countries but not disclosed in written form. A typical example was the case of US Plant Patent No. 5.751 (1986) relating to a variety of Ayahuasca found in a private garden in the Amazon, whose validity was confirmed despite a formal legal challenge.[51] Although new patents may not be obtained in the future in similar cases, patents already granted will remain in force until their expiry, as discussed below.

Recommendation:

Maintaining access to genetic resources for use and improvement is crucial for agricultural development and food security. National laws should apply an absolute concept of novelty and consider that a substance found in nature is not "novel" even if its composition, properties or characteristics have not been previously described.

4.4. Inventive Step

Another problem that may have serious implications for further research and breeding and for the availability of multiple sources of supply of genetic resources – and, hence, for food security – is the low standard often applied to assess the level of inventive step (or non-obviousness) of patent applications relating to plants. This is a more general problem, as it also affects inventions in other fields of technology,[52] notably in pharmaceuticals.

A telling example of the implications of lax standards of patentability was the US Patent 5894079 (known as the enola patent) granted on 13 April 1999 on a "new field bean variety that produces distinctly coloured yellow seeds."[53] The patent owner had purchased a bag of commercial bean seeds in Mexico and selected the yellow seeds for several generations through conventional methods until he obtained a "uniform and stable population" of yellow seeds. Until the patent was judicially declared invalid, after almost ten years of litigation,

it was used to prevent imports of the yellow bean from Mexico and subjected US production of that kind of bean to the patent owner's control.

A low level of inventive step may also lead to the grant of patents on minor variants of existing products, such as a change of amino acids in a gene construct to modify plants.[54] If accepted by patent offices, this kind of applications may generate uncertainty and eventually restrict the availability of generic versions of genetically modified plant varieties after the expiry of the original patent. As noted by a report of the Centre for Genetic Resources (CGN), "[P]atents on genetic properties of plants are too easily granted through careless application of the criteria (the inventiveness test, in particular)."[55] "DNA sequences for functional genes can still almost automatically be patented while the technique has meanwhile become state of the art and hardly contains innovative elements."[56]

Recommendation:

A low standard of inventive step may reduce the sources of supply and limit research and breeding. Patent offices should apply rigorous criteria to establish inventive step in plant-related innovations, so as to grant patents only when the invention is not obvious for a person, or a team of persons, with high technical qualification and experience in the field.

5. SCOPE OF EXCLUSIVE RIGHTS UNDER PATENTS

Given the particular nature of plant-related inventions, the extent of the rights conferred under a country's national law constitutes a key issue for researchers, breeders, farmers and consumers.

5.1 Scope Of Claims In Gene Patents

Few patent laws[57] address issues related to inventions consisting of or based on living materials or genetic resources. This remains a largely unregulated area in most countries, including those strongly dependent on agricultural production.

In the case of patents covering genes, an important issue is whether the exclusive rights extend to any possible utilization of the gene. If this were the case, nobody could use the patented gene even for functions not discovered or disclosed by the patent owner. An absolute protection of this kind is likely to discourage further research on and prevent other possible uses of a patented gene until the patent expires. Even if research is allowed under a "research exception" – as permitted under many national laws[58] – a product that contains the patented gene could not be commercialized without the patent owner's authorization until the expiration of the patent.

This problem may be addressed in different ways. One would involve the grant of a compulsory license due to patent dependency, as permitted by Article 31(l) of the TRIPS Agreement. However, the conditions set out by this provision are quite burdensome, as it may be necessary to demonstrate that the invention claimed in the second patent involves an important technical advance of considerable economic significance in relation to the invention claimed in the first patent.

Another way would be to limit the scope of the patent claim to the functions of the gene that were actually discovered by the applicant[59] so as not to interfere with third parties' research and use of the gene for other functions.

This second alternative has been suggested by the European Parliament,[60] and implemented in Germany but with regard to human DNA only.[61] French patent law more broadly stipulates that the scope of a claim is limited to that part of the sequence directly linked to the function specifically disclosed in the specifications, and that such a claim cannot be enforced against a subsequent claim on the same sequence that discloses another specific application thereof.[62] In a case related to a plant gene construct that provides resistance to glyphosate, the European Court of Justice (ECJ) interpreted, along the same lines, that the European Directive on the Protection of Biotechnological Inventions (Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998) "makes the patentability of a DNA sequence subject to indication of the function it performs" (paragraph 45).[63]

Recommendation:

Broad patent claims related to genetic materials may generate a disproportionate power for patent owners to prevent research or production based on functions/uses they have not discovered, thereby limiting the options for seed producers and farmers. If patents are allowed on genes, they should be limited to the function or use identified by the patent owner.

5.2. Unintentional Infringement

The presence of a trait in a plant protected by a patent may or may not be intentional, as a patented gene trait may disseminate by natural means and appear in plantations unintentionally. A telling example where the legal effects of this situation were considered was the *Monsanto Canada Inc. v. Schmeiser* case, where Monsanto sued Schmeiser, a Canadian canola breeder and grower, who had harvested and saved from one of his fields canola seed containing Monsanto's patented transgene that conferred resistance to glyphosate. The Canadian Supreme Court ruled that Schmeiser had infringed Monsanto's patent despite the fact that the presence of the patented gene in the defendant's field was deemed to be unintentional.[64]

However, patent laws may exclude liability in cases of *bona fide* infringement, as stipulated in Article 44.1 of the TRIPS Agreement. Significantly, Article 9(f) the Swiss patent law, incorporated in 2007, stipulates that a patent does not extend to biological material that was obtained in the agricultural domain by chance (*au hasard*) or when it is technically inevitable.[65]

Recommendation:

National laws should exempt from liability unintentional infringement caused by the dissemination of patented genetic materials.

5.3. The Farmers' Privilege

A few patent laws[66] clarify the rights conferred with regard to reproductive materials, such as seeds. French law, for instance, makes it clear that plant material can be multiplied or reproduced where it has been legally put on the market by the patent holder or with his or her consent, where this was the purpose for which the material has been marketed; the obtained material, however, cannot be subsequently used for further reproduction or multiplication.[67]

As noted above, under the UPOV system, a farmer can be allowed to save and reuse seed obtained from cultivation of a protected variety.[68] However, under patent law, the protection of a component present in a plant variety (e.g. a gene construct that introduces resistance to an herbicide) may be sufficient to prevent such acts.[69]

Patent laws may include exceptions to allow farmers to save and reuse seeds, in a manner similar to the farmers' privilege under PVP regimes. This is illustrated by Article 11 of the European Directive on the Protection of Biotechnological Inventions, under which those acts are admissible although subject to payment of remuneration to the breeders (small farmers do not have to pay such remuneration).[70] The exception could be equally provided for without remuneration independently of the farms' sizes. This would be a key component of a legal regime sensitive to food security policies, since it would reduce costs of production and promote the diversification of the sources of supply of seeds.

Recommendation:

National patent laws should, where plants and/or their components are patentable, introduce exceptions equivalent to the farmers' privilege under PVP.

5.4. Research And Breeding

PVP regimes allow the use by breeders of a protected plant variety for research and breeding (the breeders' exception). This is a mandatory exception under the UPOV Convention and a key feature of PVP regimes.[71]

This exception "optimizes variety improvement by ensuring that germplasm sources remain accessible to all the community of breeders."[72] Progress in agriculture is indeed based on the use and improvement of existing genetic materials. To encourage such progress, PVP permits a breeder to derive a new variety from a third party's protected variety. Importantly, the new derived variety can be commercialized without the consent of the owner of the original variety, provided the repeated use of the variety is not necessary for the commercial production of another variety.[73] Under UPOV 1991, however, if the variety is deemed to be an "essentially derived variety,"[74] its commercialization may be subject to the authorization of the owner of the initial variety (Article 14).

In principle, when patent protection exists, the patent owner can prohibit the use, production, sale or offer for sale of any biological material (including a plant variety) that contains the patented subject matter (e.g. a gene). Patent laws may, however, allow exceptions for research and breeding.[75] In the US, for instance, the patent law is interpreted as meaning that a variety protected by a plant patent can be used by a third party without authorization as a parent in a commercial breeding program, since infringement will exist only when the accused variety was derived asexually from the protected variety.[76] Article 22.V of the Mexican Law on Industrial Property includes a broadly worded exception allowing third parties, in the case of patents related to living material, the use of the patented product as an initial source of variation or propagation to obtain other products, except where such use is made in a repetitive manner. French Law stipulates that the exclusive rights conferred by a product or process patent on a biological material do not extend to the acts accomplished with a view to creating or discovering and developing other plant varieties.[77] Similarly, Swiss law stipulates that the rights conferred by a patent do not extend to the use of a biological material for selection or discovery with the purpose of developing a plant variety.[78]

These exceptions to patent law may not be fully equivalent to the breeders' exception under PVP. Although, arguably, selection, crossing, etc. of a variety could be legally done without the patent owner's authorization, the commercialization of a newly obtained variety that contains the patented subject matter may be considered as infringing the patent. Of course, there might be little incentive for third parties to do research and breeding if the outcome thereof cannot be commercialized, unless the time of remaining protection is short. For this reason, the Dutch seeds association, Plantum NL, has suggested an exception, stipulating that the use and exploitation of plant varieties protected by patent rights "should be free, in line with the 'breeders' exemption of the UPOV Convention."[79]

The compatibility of an exception under patent law – equivalent in its scope and effects to the breeders' exception – with the TRIPS Agreement (Articles 28 and 30) has not been tested yet.

Recommendation:

The continuous improvement of plant varieties requires freedom to undertake research and breeding where patented materials are involved. Exceptions to this effect should be adopted even where a country opts not to grant patents on plants (or plant varieties). Even if it opts not to do so, such exceptions should be included if the patentability of plant components is permitted. National laws may permit the commercialization of the newly obtained varieties, on the basis of non-remunerative exceptions. However, the compatibility of an exception of this kind with the TRIPS Agreement has not been tested.

5.5. Compulsory Licenses

As an alternative to an uncompensated exception equivalent to the breeders' exception, patent laws could provide for a remunerative exception based on a compulsory license: a breeder who might be prevented from legally commercializing a new plant variety because it contains one or more third parties' patented components, may be entitled to obtain a compulsory license on the relevant patent/s. It is important to note in this connection that the TRIPS Agreement does not limit the grounds for the grant of compulsory licenses.

Article 12 of the European Directive on the Protection of Biotechnological Inventions provides an example of compulsory licenses for situations of coexistence of patents and PVP, subject to a number of conditions:

a) The breeder has applied unsuccessfully to the holder of the patent for the right to obtain a contractual license;

b) The breeder can show that his variety "constitutes a significant technical progress of considerable economic interest" (Article 12.3(b)) with regard to the patented invention.

c) The owner of the relevant patent/s can obtain a "cross license" on the plant variety.

The European Directive, conversely, allows a company owning patents on a gene or other components to obtain a compulsory license on a third party's plant variety that incorporates such a gene or components (Article 12.2).

Swiss patent law (Article 36a), as amended in 2007, also introduced the right of a breeder to request a compulsory license when he cannot obtain or exploit his title without infringing a patent under conditions similar to those established by the referred to European Directive.

The burden of proof imposed on the breeder for obtaining a compulsory license under these provisions is problematic, since it relies on the comparison of subject matters of very different nature. A plant variety, as such, cannot represent "significant technical progress" with regard, for instance, to a patented gene; rather, the incorporation of the latter may improve a plant variety, for instance, by enhancing its resistance to pests, drought or herbicides. Compulsory licenses may be provided for in national laws subject to less stringent conditions, consistent with Article 31 of the TRIPS Agreement.

Recommendation:

National patent laws should provide for compulsory licenses in cases where the exploitation of a protected plant variety would infringe a patent. A cross-license may be granted to the patent owner with regard to the concerned variety.

6. CONCLUSIONS

There is significant room under existing international law for countries to decide whether or not to grant patent protection for plants (including plant varieties) and their parts and components. Available options include:

- Exclude plants (whether genetically modified or not), plants varieties and essentially biological processes for the production thereof from patent protection.
- If patents are granted, introduce the following features:
    - Clear distinction between discovery and invention;
    - Rigorous examination of novelty and inventive step;
    - Use-bound protection covering only the function of the gene specified in the claim;
    - Research and breeding exemption, including the commercialization of a new variety;
    - Allow farmers to save and reuse seeds.
- Address the interface between patent and PVP through compulsory licenses.

The sharing of information and materials has historically allowed for the continuous innovation by breeders and farmers and contributed to a sustainable supply of seeds. While there is no evidence suggesting that patents may provide an important incentive for agricultural innovation, food security can be put at risk by the appropriation of plant genetic resources under patent rights. Governments may opt to use the flexibilities examined above to avoid or mitigate the possible impact of patents in this field. While discussing which options would be most suitable for a particular national situation is beyond the scope of this study, a wide range of alternatives is available and can be applied consistently with existing international rules.

ENDNOTES

1 Food security is defined as "when all people, at all times, have access to sufficient, safe and nutritious food to meet their dietary needs and food preferences for an active and healthy life". Article 1 of the 1996 Rome Declaration on World Food Security.

2 See Special Rapporteur on the right to food, De Schutter, O. (2009), *Seed Policies and the Right to Food: Enhancing Agro-biodiversity, Encouraging Innovation*, Report (A/64/170) presented at the 64th session of the UN General Assembly (21 October 2009), available at: www.srfood.org/images/stories/pdf/officialreports/20091021_report-ga64_seed-policies-and-the-right-to-food_en.pdf

3 Special Rapporteur on the Right to Food, op. cit. p. 4.

4 See, e.g., Chiarolla, C. (2011), *Intellectual Property, Agriculture and Global Food Security. The Privatization of Crop Diversity,* and Jackson, L.A. (2000) "Agricultural Biotechnology and the Privatization of Genetic Information. Implications for Innovation and Equity" 3 *The Journal of World Intellectual Property*; Blakeney, M. (2009) *Intellectual Property Rights and Food Security*, Wallingford, Oxon, CABI.

5 Thus, seed certification laws may encourage the planting of a limited number of commercially developed varieties, while discouraging the diffusion of farmers' varieties better adapted to local conditions. The possibility of obtaining, in many cases, higher yields and increased income than with farmers' varieties also favours the diffusion of the former.

6 The TRIPS Agreement (Article 27.3(b)) obliges WTO members to provide some form of IP protection for plant varieties (although not necessarily patents), whereas FTAs, particularly those with the US, require actions to grant patents over plants.

7 As exemplified by the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the 4th WTO Ministerial Conference in November 2001.

8 For discussions of UPOV, see Dutfield, G. (2011), *Food, Biological Diversity and Intellectual Property - The Role of the International Union for the Protection of New Varieties of Plants (UPOV),* QUNO, available at: www.quno.org/geneva/pdf/economic/Issues/UPOV%20study%20by%20QUNO_English.pdf. See also Eaton, D. et al. (2006), *Intellectual Property Rights for Agriculture in International Trade and Investment Agreements: A Plant Breeding Perspective,* available at: siteresources.worldbank.org/INTARD/Resources/Note11_IPR_Agri.pdf

9 For a number of crops important for food security. Article 12.3(d) of ITPGRFA stipulates that Parties are not allowed to assert IPRs on plant genetic resources and their parts and components obtained through the ITPGRFA System "in the form received."

10 The reduction of genetic diversity is a major determinant of food insecurity. The lack of genetic diversity in potato, for instance, was responsible for the 'Great Irish Famine' in 1845. A plant disease ('late blight') led to massive crop failure, widespread famine, and a million deaths.

11 Evidence on the impact of different forms of IP on agricultural innovation is particularly elusive, despite some efforts to identify and quantify their effects. See, e.g., Dutfield, G. (2003) *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History*. Burlington, VT: Ashgate, and Boldrin, M. and Levine, D. (2007) *Economic and*

Game Theory Against Intellectual Monopoly, available at: http://levine.sscnet.ucla.edu/general/intellectual/against.htm (particularly chapter 4).

12 A cultivar is a race or variety of a plant that has been created or selected intentionally and maintained through cultivation. Asexual reproduction is the reproductive process that involves only one organism and results in two or more organisms, which can preserve unaltered certain desired traits (e.g. disease resistance, flavour, etc).

13 See Van Overwalle, G. (1999), "Patent Protection for Plants: A Comparison of American and European Approaches," *IDEA – Journal of Law and Technology* 39(2), p. 161.

14 See Dutfield, G. (2003), *Intellectual Property Rights and the Life Science Industries,* Ashgate, London, p. 186.

15 UPOV 1978, Article 2(1).

16 See Dutfield, G. (2011), *op. cit.*

17 Notably India, Thailand and Malaysia. See also *African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources* approved by the Organization of African States in 2000, available at: www.opbw.org/nat_imp/model_laws/oau-model-law.pdf

18 Available at: www.fao.org/ag//CGRFA/iu.htm

19 Available at: ftp://ftp.fao.org/docrep/fao/011/i0510e/i0510e.pdf.

20 Available at: www.cbd.int/convention/convention.shtml

21 For a comparison of the scope of rights conferred under patents and UPOV 1978 and 1991, see Jördens, R. (2002), *Legal and Technological Developments Leading to this Symposium: UPOV's Perspective*, WIPO-UPOV Symposium on the Co-Existence of Patents and Plant Breeders' Rights in the Promotion of Biotechnological Developments, WIPO-UPOV/SYM/02/2, p. 3.

22 For a legal definition of 'plant variety' see, e.g., Article 1(vi) of UPOV.

23 For a more detailed analysis of national legislations, see WIPO (2009), *Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights*. Document prepared by the Secretariat, SCP/13/3; WIPO, and Barbosa, D. and Grau-Kuntz, K. (2010) Exclusions from Patentable Subject Matter and Exceptions and Limitations to the Rights - Biotechnology, SCP/15/3, 2010, available at: www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex3.pdf

24 Boettiger, Graff, Pardey, Van Dusen and Wright, op. cit.p. 1093.

25 As mandated by Article 31 of the Vienna Convention on the Law of the Treaties.

26 Nuffield Council on Bioethics (2002), *The Ethics of Patenting DNA. A discussion paper,* London, p. 23.

27 *American Molecular Pathology, et. al., v. U.S. Patent and Trademark Office*, et. al., available at: http://graphics8.nytimes.com/packages/pdf/national/20100329_patent_opinion.pdf.

28 In support of this interpretation, an *amicus curiae* brief of the US Department of Justice argued that '[T]he chemical structure of native human genes is a product of nature,

and it is no less a product of nature when that structure is 'isolated' from its natural environment than are cotton fibers that have been separated from cotton seeds or coal that has been extracted from the earth' (available at: http://graphics8.nytimes.com/packages/pdf/business/genepatents-USamicusbrief.pdf).

29 On March 26, 2012, the U.S. Supreme Court remanded the case to the Court of Appeals for the Federal Circuit for further consideration in light of its decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc*.

30 Some national laws refer to living organisms, 'in whole or in part', thereby preventing the patenting of any components of plants. See WIPO (2009), op. cit.

31 As defined in Article 28.1 of the TRIPS Agreement.

32 The rice plant, for instance, has about 50.000 genes.

33 Twenty countries (most of them developing countries) have signed FTAs with the US. See http://www.ustr.gov/trade-agreements/free-trade-agreements.

34 For instance, the US FTAs with Chile, Peru, Colombia and CAFTA-DR include 'best endeavor clauses' to make available patents for plants, while other FTAs (e.g. with Morocco) contain a straightforward obligation to make patents available for plants.

35 Then, C. and Tippe, R. (2009), *The Future of Seeds and Food Under the Growing Threat of Patents and Market Concentration*, available at: www.no-patents-on-seeds.org/images/documents/report_future_of_seed_en.pdf, p. 14.

36 Then, C. and Tippe, R. (2010), *Seed Monopolists Increasingly Gaining Market Control Applications and Granting of Patents in the Sphere of Animal and Plant Breeding in 2010*, available at: www.no-patents-on-seeds.org/sites/default/files/news/patente_report_2011_final_en.pdf, p. 2.

37 Cases G 2/07 and G 1/08.

38 See Then, C.and T., Ruth (2010), op. cit, p. 3.

39 See for instance UNCTAD-ICTSD, (2005) *Resource Book on TRIPS and Development. An Authoritative and Practical Guide to the TRIPS Agreement*. New York: Cambridge University Press. p. 391.

40 See WIPO, Barbosa, D. and Grau-Kuntz, K. op. cit.

41 PLANT GENETIC SYSTEMS/Glutamine synthetase inhibitors: T 356/93, 5 EUR. PAT. OFF. REP. 357, 360 (1995).

42 See CIEL, *The Ayahuasca Patent Case*, available at: www.ciel.org/Bio/ayahuascapatentcase.html.

43 See Boettiger, Graff, Pardey, Van Dusen and Wright (2004), 'Intellectual Property Rights for Plant Biotechnology: International Aspects,' in Paul Christou and Harry Klee (eds.), *Intellectual Property Rights for Plant Biotechnology: International Aspects. Handbook of Plant Biotechnology*, John Wiley and Sons, Chichester. p. 1093.

44 See Kowalski, S.P., Ebora, R.V., Kryder, R.D., and Potter, R.H. (2002), "Transgenic Crops, Biotechnology and Ownership Rights: What Scientists Need to Know," *Plant Journal*, Aug; 31 (4):407-21.

45 Louwaars, N., Dons, H., van Overwalle, G., Raven,H., Arundel, A., Eaton,D., and Nelis, A. (2009), *Breeding Business. The future of Plant Breeding in the Light of Developments in Patent Rights and Plant Breeder's Rights,* Centre for Genetic Resources, (CGN) Wageningen, p. 52.

46 See, e.g., Atkinson, R.C., Beachy, R.N., Conway, G., Cordova, F.A., Fox, M.A., Holbrook, K.A., Klessig, D.F., McCormick, R.L., McPherson, P.M., Rawlings, H.R. Rapson, R., Vanderhoef, L.N., Wiley, J.D., Young, C.E. (2003), "Intellectual Property Rights: Public Sector Collaboration for Agricultural IP Management," *Science,* July, 11;301(5630), p. 174-5.

47 Nottenburg, C., Pardey, P.G., and Wright,B. D. (2002) "Accessing Other People's Technology for Non-profit Research' 46 *Australian Journal of Agricultural and Resource Economics* 389 at 391-92.

48 See Roa-Rodriguez, C. and Nottenburg, C. (2003) Agrobacteriummediated transformation of plants. CAMBIA, www.bios.net/Agrobacterium; Chung, S.M., Vaidya, M. and Tzfira, T. (2005) "Agrobacterium is Not Alone: Gene Transfer to Plants by Viruses and Other Bacteria," *Trends in Plants Science,* available at www.cambia.org/daisy/bios/1381/version/live/part/4/data.

49 Decision T 46 A of February14, 1989.

50 This aspect of the legislation has been changed by the 'America Invents Act' (Bill HR 1249) signed by the US President on September 16, 2011.

51 CIEL, op. cit.

52 See, e.g., Jaffe, A. and Lerner, J. (2004), *Innovation and Its Discontents: How Our Broken Patent System is Endangering Innovation and Progress, and What to Do About It, Princeton University Press; and Federal Trade Commission (2003), To Promote Innovation: the Proper Balance of Competition and Patent Law Policy*, available at: www.ftc.gov/os/2003/10/innovationrpt.pdf.

53 See, e.g., Shashikant, S. and Asghedom, A. (2009), 'The 'Enola Bean' dispute: patent failure & lessons for developing countries', *TWN Info Service on WTO and Trade Issues* (Aug09/11), Third World Network, www.twnside.org.sg.

54 For instance, AR P040100492, which claims EPSPS tolerant to glyphosate by mutations of aminoacids in positions 102 and 106.

55 Louwaars,N., Dons, H., van Overwalle, G., Raven, H., Arundel, A. Eaton, D., and Nelis, A. op. cit. p. 53.

56 Id.

57 The European legislation is noticeable in this regard.

58 See Correa, C. (2005), *International Dimension of the Research Exception*, SIPPI Project, AAAS, Washington D. C., available at: http://sippi.aaas.org/intlexemptionpaper.shtml.

59 These claims are generally known as 'use-bound' claims.

60 Available at: www.europarl.europa.eu/sides/getDoc.do?type=TA&reference=P6-TA-2005-0407&language=EN.

61 *Patent Act* of December 16, 1980, as last amended by the Law of February 28, 2005

62 Article L613-2-1 of the French Industrial Property Code.

63 Case C-428/08, Monsanto Technology LLC v Cefetra BV et al. More specifically, the ECJ General Advocate held that 'Directive 98/44 permits and, in fact, requires an interpretation to the effect that, in EU territory, the protection conferred on DNA sequences is a 'purpose-bound' protection (paragraph 29). See http://curia.europa.eu/jurisp/cgi-bin/gettext.pl?where=&lang=es&num=79899690C19080428&doc=T&ouvert=T&seance=CONCL#Footnote7.

64 [2004] 1 S.C.R. 902, 2004 SCC 34, available at: http://csc.lexum.umontreal.ca/en/2004/2004scc34/2004scc34.html.

65 A bill was also introduced in California (US) to exempt from infringement a farmer who did not know he was planting seeds containing an infringing material, when he acted *bona fide*, or when a patented genetically modified organism (GMO) was found at insignificant levels. See www.infogm.org/spip.php?article3705.

66 See, e.g. article 22.VI of the Mexican patent law; article L613-2-4 (as incorporated in 2004) of the French patent law; article 8.1 of the European Directive on Biotechnological Inventions 98/44.

67 French patent law, article L613-2-4 (as incorporated in 2004).

68 While the farmer's privilege is automatic under the 1978 version of UPOV, it is an optional exception to breeders' rights, and subject to conditions, under UPOV 1991. The application of this exception may be subjected to payment of compensation to the breeder. See, e.g. the Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights, available at: www.cpvo.europa.eu/documents/lex/394R2100/EN394R2100.pdf.

69 For instance, in a decision by the US Court of Appeals of the Federal Circuit in *Monsanto v. McFarling* (302 F.3d 1291, Fed. Cir., May 2007), a farmer was condemned to pay a fixed compensation per bag of saved seed. See www.cafc.uscourts.gov/opinions/05-1570.pdf, and Correa, C. (2009), *Trends in Intellectual Property Rights Relating to Genetic Resources*, Commission on Genetic Resources for Food and Agriculture, Rome: Background Study Paper No. 49, Rome, available at: ftp://ftp.fao.org/docrep/fao/meeting/017/k533e.pdf.

70 See also http://eurlex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31994R2100&model=guichett.

71 See UPOV, *Access to Genetic Resources and Benefit-Sharing. Reply of UPOV to the Notification of June 26, 2003, from the Executive Secretary of the Convention on Biological Diversity (CBD)* (adopted by the UPOV Council at its session number 37, on 23rd October 2003), available at: www.upov.int/export/sites/upov/en/news/2003/pdf/cbd_response_oct232003.pdf).

72 Jördens (2002), op. cit., para. 12.

73 See, e.g, article 5(3) of the UPOV Convention (1978).

74 An 'essentially derived variety' would exist, for instance, when a gene construct is inserted in an existing variety. The concept is defined in article 14(5)(b) of UPOV 1991.

75 See Henson-Apollonio, V. (2002), *Patent Protection for Plant Material*, WIPO-UPOV Symposium on the Co-existence of Patents and Plant Breeders' Rights in the Promotion

of Biotechnological Developments, Geneva, October 25, available at: www.upov.int/en/documents/Symposium2002/pdf/wipo-upov_sym_02_4.pdf.

76 Based on *Imazio Nursery v. Dania Greenhouses*, 69 F.3d 1560, 36 USPQ2d 1673, CAFC 1995.

77 Article L613-5-3 (as amended in 2004).

78 Any agreement that limits or nullifies the exception would be deemed null and void.

79 *Plantum NL position on patents-and plant breeders' rights,* adopted 6 May 2009. See also a similar proposal in Louwaars, N., Dons, H., van Overwalle, G., Raven, H., Arundel, A., Eaton, D., and Nelis, A. op. cit., p. 57.

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The TRIPS Agreement provides WTO Members with flexibilities for implementing its provisions in a way consistent with their agriculture and food policy objectives. However such flexibilities have received little attention so far. Many WTO Members have not used them or have done so only to a limited extent.

This policy guide describes the TRIPS-related patent flexibilities that may be desirable and necessary for supporting agriculture and food policy objectives and how they may be applied. It seeks to encourage developing countries to implement intellectual property policy in a way that is consistent with such objectives.

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