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IPDEV Work Package 6:

ASSESSING THE ECONOMIC IMPLICATIONS OF DIFFERENT MODELS FOR IMPLEMENTING THE REQUIREMENT TO PROTECT PLANT VARIETIES

LITERATURE REVIEW AND COMMENTARY ON LEGAL REGIMES AND MODELS FOR PROTECTING PLANT VARIETIES

Produced with support of the European Commission's 6th Framework Programme for Research as part of the project "Impacts of the IPR Rules on Sustainable Development" (IPDEV)

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Date: September 2006

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Introduction

Article 27 (3) (b) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) states that "Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof". The question arises of how countries can best implement this provision in pursuit of their national economic development objectives.

This review first assesses the way that various international agreements deal with plant genetic resources for food and agriculture and plant varieties. These are TRIPS, the International Convention for the Protection of New Varieties of Plants (the UPOV Convention), the Convention on Biological Diversity (CBD), and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA or IT). It then assesses the compatibility of these treaties. The second part of the paper analyses the TRIPS requirements concerning plants from a development perspective. The third and fourth parts address the application of patent and plant variety protection to plant genetic resources including plant varieties. The fifth and sixth parts consider the evidence concerning the economic and environmental implications of patents and plant breeders rights. The seventh part focuses on developing countries, assessing the impacts, both positive and negative, of PBRs for such nations. The eighth part considers the types, basic features and likely effects of alternative proposals for *sui generis* plant variety protection.

1/ Treaties dealing with plant genetic resources (PGR)

Plant genetic resources have certain characteristics that make them difficult to value and to appropriate, whether by governments or by industry (Srinivasan 2003). First, locating plants containing useful genetically-coded traits can be very difficult. In other words, resources are hard to find. Second, a new variety may descend from dozens of varieties from many dispersed locations. The value of each individual resource, whether we talk of a gene construct or a plant variety, is likely to be very hard to estimate but may be far lower than many people suppose. Other valuation problems lie in the difficulty in identifying the centres of origin of PGRs (Srinivasan 2003).

It is important not to overstate the case, though, that PGRs are hard to value. One study on the use and value of landraces for rice breeding in India estimated that rice landraces acquired from India and overseas contributed 5.6 percent, or US$75 million, to India's rice yields (Evenson 1996). Assuming that landraces contribute equally to other countries where rice is cultivated, the global value added to rice yields by use of landraces can be estimated at US$400 million per year.

And in qualifying the argument that the value of plant genetic resources for food and agriculture tends to be quite low, it is arguably increasing. If so, this is due to (a) the need for more food as a result of global population growth; (b) the limited amount of new land being opened up for food production; and (c) the increasing adoption of new biotechnologies (Brush 1994), which allow gene transfer between more distantly-related organisms, thereby expanding the pool of genes potentially available for the breeding of new crop varieties.

Crop breeders tend to use PGRs that are already in circulation in their breeding programmes rather than landraces and 'wild'[1] varieties, whose values may need first to be ascertained. Landraces may be a useful source of desirable single genes, but will not be adapted for a wide range of conditions. They may also require considerable effort to breed out extraneous genetic material. Breeders thus tend to use varieties held in their own collections and those bred in public institutions. Increased adoption of genetic engineering and other biotechnological techniques including transgenics is expected to further reduce dependency on exotic plant germplasm.

However, exotic germplasm is likely to be used when particular traits are sought, new breeding programmes are being started, or for long-term genetic enhancement, and also in the breeding of certain crops (e.g. potatoes). Indeed, even though a survey revealed that only 2.4 percent of germplasm used in the development of new varieties comes from wild species or landraces maintained in situ (see Swanson 1996), these resources are still important. Securing effective protection from diseases and pests in the long term is absolutely dependent on inputs of genes and traits that are new to the system in the sense of being undiscovered or known only to indigenous or traditional communities.

As for appropriation, this is made difficult by the capacity of plants to reproduce, and to the cumulative nature of plant breeding activities, drawing on innovations (through selection, crossings, or new techniques) of previous generations and from many sources. For governments, this may result in insufficient incentive to conserve plant genetic resources in in situ conditions. For businesses, without intellectual property protection there may be little incentive to invest in research and development directed to non-hybrid varieties.

Owing in part to the particularities of PGRs, the varying views on how they should best be managed, and the different economic interests involved, the approaches to PGR regulation in the relevant treaties are quite different if not actually conflicting. Some like the CBD are concerned with fair and equitable commercialisation founded upon the sovereign right to regulate access. The FAO ITPGR seeks to facilitate access. And UPOV and TRIPS are concerned with protecting innovation based on the use of PGRs. The issue of compatibility between diverse treaties and approaches is paramount.

Which agreement takes priority? The Vienna Convention on the Law of Treaties has often been invoked, with interpretations sometimes at variance. Thus, it is sometimes argued that the CBD, being a framework agreement in the field of environment, supersedes TRIPS where conflicts between the two arise. However, it is generally considered that a later treaty prevails over an earlier one dealing with the same subject matter, and that a specific treaty prevails over a general one. Thus, the TRIPS agreement, which is both posterior to the CBD and specific with regard to intellectual property, should not be seen as depending on the CBD. However, both treaties should be implemented in a harmonised manner. Helfer (2002) mentions paragraph 31 of the

[1] Overuse of the word 'wild' has come under criticism in some quarters. As Posey expressed it, there is a common but ill-informed tendency to presume 'that just because landscapes and species appear to outsiders to be "natural", they are "wild" and – therefore – unowned' (Posey 1996:55). Posey promoted the term 'non-domesticated resources' in place of 'wild resources' for this reason.

Doha Ministerial Declaration that contains a narrow mandate for harmonising Members' trade and environment obligations limited to "the relationship between existing WTO rules and specific trade obligations set out in multilateral environmental agreements". In contrast, paragraph 19 of the Doha Declaration mentions TRIPS Art. 7 and 8 (i.e. promoting social and economic welfare as one of the goals of the implementation of the TRIPS agreement, and taking into consideration public health and nutrition). According to Helfer, such a reference reduces the risks of challenge of domestic legislations implementing TRIPS Art. 27 (3) (b) under the WTO Dispute Settlement Understanding.

The FAO International Undertaking on Plant Genetic Resources was renegotiated after the adoption of the CBD in order to harmonise its provisions with the latter. The new International Treaty on PGR, which effectively replaces the International Undertaking, also takes into account the TRIPS agreement and the UPOV Convention, in a negative way, as its Article 12 (3) (d) specifies that intellectual property rights shall not be applied for in relation to PGR for food and agriculture or their components in the form received from the multilateral system instituted by the Treaty. This formulation is open to interpretation. As recalled by Helfer (2002), the US wanted the first phrase ("genetic parts or components") deleted and the second ("in the form received") maintained, whereas developing countries defended the opposite position. As IT Art. 22 provides that the patentability of genes isolated from germplasm could be submitted to arbitration or to the International Court of Justice (IT Art. 22), national laws should be amended accordingly, in particular in the US, Japan and Europe. Additionally, Helfer specifies that IT Art. 13.2 (d)(ii) is not necessarily incompatible with the TRIPS agreement, insofar as the latter nowhere prohibits Members from imposing fees or levies associated with the holding of patent rights (cf. those routinely imposed by patent offices).

The articulation between TRIPS and UPOV is not clear either. It has often been underlined (Leskien and Flitner 1997, Watal 2001, Rangnekar 2002, Mulvany 2003) that TRIPS Art. 27 (3) (b) does not explicitly refer to the UPOV Convention, whereas other provisions of the TRIPS agreement expressly cite the Paris, Berne and Rome Conventions and the Treaty on Intellectual Property in Respect of Integrated Circuits. As explained by Watal, in the course of the TRIPS negotiations a reference to UPOV 1978 was considered inadequate, and that to UPOV 1991, premature, as this Act was still open to signature. Thus, as shown by Rangnekar (2002), the pressure put on developing countries to join UPOV 1991 (as since 1998, it is the only Act still open to adhesion or accession[2]) is not justified by the wording of TRIPS Art. 27 (3) (b). Moreover, TRIPS Art. 27 (2) and Art. XX of GATT 1994 allow for exceptions, provided the necessity requirement is fulfilled (Leskien and Flitner 1997). The criterion enunciated by Art. 27 (2) for an exclusion from patentability is that the prevention of commercial exploitation is necessary. According to these authors, there is no obligation to show that the commercial exploitation is prevented by law, all the more as there is a time lag between a technological development and its legal

[2] Cf. UPOV, Council Document C/33/18 dated 16/11/2000, para. 6. The UPOV Council restates in this document that, pursuant to its decision adopted on April 29, 1997, the accession applications filed to the UPOV after April 24, 1998 (i.e. one year after the entry into force of the 1991 version of the UPOV Convention) are deemed to concern the 1991 version, unless an exception is made – as in the case of Brazil, Bolivia, China, India, Nicaragua, Panama and Zimbabwe.

regulation (indeed, the meaning of ordre public in specific cases is generally considered by courts).

Alternatively, it may be argued that the prohibition of commercial exploitation of an invention is insufficient in itself to render it unpatentable on ordre public or morality grounds, but is nonetheless necessary. Take the example of a pharmaceutical. Although drugs can be patented upon their initial discovery, their sale is normally prohibited until such time as their developers are able to demonstrate to a state drug regulator that they are safe and effective. So this provision cannot be used to reject a drug patent application or delay its grant because its safety and effectiveness have yet to be proven. Nor can it be used to revoke a patent if it subsequently turns out that the drug is unsafe or ineffective. On the other hand, to reject a patent application on ordre public or morality grounds for an invention whose exploitation is *not* prohibited by law or regulation would not be permissible.[3]

2/ TRIPS requirements concerning the protection of plant varieties

According to Article 27.3 (b), "Members may … 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 microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof."

Leskien and Flitner (1997) consider that the *sui generis* system has to be a form of intellectual property rights, like other rights mentioned in Sections 1 through 7 of Party II of TRIPS. Moreover, the TRIPS Council has asked Members to notify their *sui generis* laws under Art. 63 (2); thus, a farmers' rights approach can complement the *sui generis* system, but may not replace an IPR-like right. Still according to these authors, an effective *sui generis* system entails the protection of plants of all species and genera, national treatment and MFN principles, and enforcement procedures. As highlighted by these authors, the term "effective" is also used in the Preamble and in Article 41 of TRIPS, in both cases in reference to enforcement procedures.

Rangnekar (2003) explains that pursuant to TRIPS Art. 1.2, an intellectual property right is a right to exclude others from using the protected subject matter in certain types of transactions and/or to obtain remuneration from the use of this subject matter. Furthermore, Leskien and Flitner (1997) insist on the necessary compliance of IPRs with competition rules by quoting Art. 40 TRIPS, which allows measures to prevent or control licensing practices having an adverse effect on competition in the relevant market (exclusive grant-back conditions, conditions preventing challenges to validity and coercive package licensing). However, Rangnekar disagrees with the latter with respect to the coverage of such a *sui generis* right. Accordingly, the protection granted could be limited to the technological and economic territory that a breeder can control, and there could be a weaker scope of protection for open-pollinated and tuber-propagated food crops, in comparison to that offered to ornamental and high-valued export crops (Ghijsen 1998, IPGRI 1999). Likewise, differing biologically

[3] For further discussion, see Carvalho, N.P. de (2002).

determined appropriability conditions have already led in the context of the UPOV Convention to differing durations of protection (cf. vines and tress compared to other species). In any case, as well summarised by Rangnekar (2002), the coverage issue constitutes a grey area, to be clarified either through a Dispute Settlement Body (DSB) decision or an agreed interpretation by the TRIPS Council, although according to Dispute Settlement Understanding (DSU) Art. 3 (2), quoted by Leskien and Flitner (1997), "recommendations and rulings of the DSB cannot add or diminish the rights and obligations provided in the covered agreements." As to duration of *sui generis* rights, Leskien and Flitner (1997) insist on the fact that it is not addressed by the TRIPS Agreement.

3/ Patent protection for plants

Patent protection was generally not considered appropriate for plant genetic resources, on two counts. One concern was that patents could jeopardise food security (this was the rationale for the exclusion of tuber-propagated plants even from the specific regime created for plant innovations under the US Plant Patent Act of 1930). The second was that patent criteria had been elaborated with respect to mechanical inventions and did not apply easily to living material.

However, this needs to be qualified. In 1724, Thomas Greening was granted an English patent for "grafting or budding the English elm upon the stock of the Dutch elm". In 1785, Philip Le Brocq acquired a patent for "rearing, cultivating, training, and bringing to perfection, all kinds of fruit trees, shrubs, and plants; protecting their leaves, blossoms, flowers and fruits". Nonetheless, patenting activity relating to the structural and functional components of plants and the extension of the patent system to include plants and plant products themselves within their ambit are recent phenomena.

In Europe, the general rule prior to the Second World War was that plants could not be protected under IP law in any country. But the situation was not entirely clear, and patents were occasionally granted. In 1936, for example, the German Appeal Board accepted an application for a patent that claimed

> 1. Seed material of a race of lupinus mutabilis and lupinus Cruikshanksii which race is increased in fat content above 14 per cent and is made completely or almost completely free of alkaloid; 2. The use of the grain harvest from seed material in accordance with claim 1 for producing oils, fats, press-cakes, rubble and the like. (Quoted in Benjamin 1936:462)

Countries adopted a range of approaches during the 1940s and early 1950s, from denying all protection (for example, Britain and Denmark), to allowing patents (Italy from 1948, France from 1949, and Belgium from 1950), and creating specific IP systems for plant varieties. Examples of such systems included the Dutch Breeding and Material Seed Ordinance of 1941, the Austrian Plant Cultivation Law of 1946, and the German Law on the Protection of Varieties and the Seeds of Cultivated Plants of 1953, on which the UPOV Convention was partly modelled on.[4] Further afield,

[4] For brief descriptions of this law, see Heitz (1987:75-6) and Wuesthoff (1957:27).

South Africa followed the US example in modifying its patent law in 1952. In the Red Dove case of 1969, the German Supreme Court confirmed a rejection by the German Patent Office of a breeding method, but on the grounds that the method was not repeatable, not that it consisted in living material. In other words, the Court accepted the principle that animal breeding methods are potentially patentable.

Despite these initially divergent approaches, the relatively uniform climatic and agronomic conditions throughout much of Europe, and the post-war moves to enhance the integration of the west European economies, provided good reasons to harmonise patent legislation as soon as the appropriate form of protection could be agreed upon.

In 1963, the Council of Europe adopted the Convention on the Unification of Certain Points of Substantive Law on Patents for Invention, which contained certain language adopted with slight modification in both the European Patent Convention and TRIPS. The Convention had to accommodate wide differences in national patent rules relating to pharmaceuticals, food, agriculture and horticulture while encouraging states to harmonise their rules within a realistic time-frame at the level of the most expansive rights available at that time in any one country. Thus, contracting states not required to grant patents in respect of:

> (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes and the products thereof.

The terms ‘essentially biological’ replaced ‘purely biological’ from an earlier version of the text. The Council’s Committee of Experts on Patents, that was responsible for drafting the convention, changed the wording to broaden the exclusionary language to embrace such ‘essentially biological’ processes as varietal selection and hybridization methods even if ‘technical’ devices were utilized to carry out the breeding processes (Bent et al. 1987:66-7).

Article 53 of the European Patent Convention repeats certain exclusions in the 1963 Convention while making them mandatory rather than optional. Thus

> (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.

The rationale for this choice was the adoption of the UPOV Convention in 1961, which prohibited double protection for a given variety. However, the UPOV Convention did not exclude plant varieties from the scope of patent protection in general. Nevertheless, as plant breeders’ rights were not available in all EPC member States and the principle of uniform patent protection within the EPC territory had to be respected, it was considered simpler, for housekeeping reasons, to adopt such a ban when implementing both the UPOV and the Strasbourg Conventions.[5]

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[5] See paragraph 3.5 of the *Transgenic Plant/Novartis II* decision of the EPO Enlarged Board of Appeal of December 20, 1999.

"Essentially biological" continues to lack a precise and genuinely scientific meaning (Funder 1999:569), though the EPO has attempted to clarify its application. According to the EPO guidelines for examiners,

> The question whether a process is 'essentially biological' is one of degree depending on the extent to which there is technical intervention by man in the process; if such intervention plays a significant part in determining or controlling the result it is desired to achieve, the process would not be excluded.

And the EPO Technical Board of Appeal in a 1995 case (Greenpeace v. Plant Genetic Systems NV) affirmed that 'a process … comprising at least one essential technical step, which cannot be carried out without human intervention and which has a decisive impact on the final result' is not essentially biological and would thus be patentable. On the other hand, conventional plant and animal breeding methods and other techniques such as artificial insemination would not be (Warren-Jones 2001:122).

Between 1990 and 1995, 5,775 patents on biotechnological inventions were granted in the US, compared with 5,706 in Japan and 2,903 by the European Patent Office[6]. Not all of these are necessarily concerned plants; however, these figures tend to show the importance of patents in this field, including for plant transformation activities. For instance, there were no less than 2,755 patents granted by the USPTO for Bt recombinant genes as of 7 September 2004[7].

In the US, the availability of patents for plant-related inventions was not obvious, until the USPTO Board of Appeals' decision *in re Hibberd* in 1985[8]. Until then, patents were issued only for F1-hybrids (hybrids of first generation), which were excluded from protection by the PPA and the PVPA.[9] The USPTO decision had to be confirmed by the Supreme Court, which was achieved in the *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International Inc.* decision, rendered December 10, 2001. The ruling of this latter decision, adopted with two Justices dissenting, is based on the 1980 *Chakrabarty* decision, according to which "the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions". However, following the dissenting judges, in *Diamond*

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[6] According to figures cited by Carlos Correa in a FAO study paper (no 8/1999)

[7] The *Bacillus thuringiensis* (Bt) bacterium, capable of producing specific proteins called δ-endotoxines, makes a natural insecticide and numerous patents have been filed for its introduction in plants such as maize, cotton or rice. For a search of the USPTO databases, see http://www.uspto.gov/patft/index.html

[8] For an analysis of the decision, see The American Society of Agronomy *International Property Rights Associated with Plants* (1989). The claims were concerned with the isolation and manipulation of a particular corn mutant derived from cultured tissue of a particular hybrid corn line that possessed the advantages of regenerability and heritability, and directed to "mutant monocot seed" including seed of a "cereal crop" (later restricted to maize). As the authors underline, the patent contained no specification as to the relative location of the multiple loci involved, the frequency of mutation at the different loci or the number of gene copies available for mutations, and failed to disclose means for isolating a gene encoding an undisclosed enzyme. Owing to this description of the specification, one can but wonder whether the condition of sufficiency of disclosure and enablement (35 USC s.112) was fulfilled.

[9] Cf. footnote no 2 of ETC Group *Utility Plant Patents: A Review of the U.S. Experience (1985 – July, 1995)*, available at http://www.etcgroup.org, visited February 18, 2005.

v. Chakrabarty the Court considered whether the language of 35 U.S.C. section 101, "manufacture or composition of matter", included such living things as bacteria; it was not concerned with the "general coverage for matters to which the special plant statutes do refer (namely, plants)".[10] The Court recalls that it has in the past given effect to two overlapping statutes, so long as each reaches some distinct cases, and that both the 1930 Plant Patent Act (PPA) and the 1970 Plant Variety Protection Act (PVPA) contain no statement of exclusivity. While section 101 "is a dynamic provision designed to encompass new and unforeseen inventions", "[p]lant patents under the PPA thus have very limited coverage and less stringent requirements than section 101 utility patents"[11].

Nonetheless, as Mark D. Janis and Jay P. Kesan (2002a) argue[12], "there is very little law explaining how these prerequisites should be applied to patents that claim conventionally bred plants". The same authors explain that "the term 'variety' as used in the Plant Patent Act must be understood to encompass a single, individual plant", whereas in the PVPA, the "concept extends to a plant grouping"[13].

In 1983, the European Patent Office Technical Board of Appeal held in the *Ciba Geigy* decision[14] that the scope of the subject matter excluded under Article 53(b) was that which is protectable under the UPOV Convention, i.e. "all cultivated varieties, clones, lines strains and hybrids which can be grown in such a way that they are clearly distinguishable from other varieties, sufficiently homogeneous and stable in their essential characteristics." Thus, owing to these criteria, seeds chemically treated were not found to constitute new plant varieties, as new genetic material was not added to the seeds.

In the *Lubrizol* decision[15] rendered in 1988, the Technical Board of Appeal appraised "product-by-process" claims to hybrid plants and seeds in light of the UPOV definition of "plant variety". The Board decided that these hybrids lacked the required stability to be plant varieties. Therefore, they did not come under the plant varieties exclusion and could thus be patentable subject matter.

The line could no longer be drawn so easily after the European Community adopted in 1994 E.C. Regulation 2100/94 on Community plant variety rights. The Regulation is based on the 1991 version of the UPOV Convention,[16] which allows the concurrent protection of a plant variety by breeders' rights and by patent.

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[10] *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International Inc.* Dissenting opinion, I – paragraph 5. Available at http://supct.law.cornell.edu/supct/html/99-1996.ZS.html

[11] Ibid. Decision, II – A, paragraphs 5 and 9.

[12] Mark D. Janis and Jay P. Kesan 2002 (a), p. 1161-1164, at 1162. Another unanswered issue relates to the scope of protection and whether infringement can occur as a consequence of pollen drift.

[13] Mark D. Janis and Jay P. Kesan 2002 (b), p. 727-778, at 735.

[14] Decision T49/83, 23 July 1983. For a general discussion of the EPO decisions in this field, see Karen Blöchlinger *A Variety of Interpretations of "Plant Variety"*, in CASRIP Newsletter, Winter 2000, p. 10.

[15] Decision T320/87, 10 November 1988.

[16] Council Regulation 2100/94 creates a community title. As to national titles, they are governed by the national legislations implementing the version of the UPOV Convention which the countries have respectively ratified. In the 1991 version of the convention, Art. 31 organises the conflicts likely to arise in bilateral relations between members from the application of the national treatment principle to two different versions of the rights. Accordingly, a Belgian citizen in England will benefit from the

Nonetheless, the Technical Board of Appeal held in the *Plant Genetic Systems* instance that a plant variety corresponds to "any plant grouping within a single botanical taxon of the lowest-known rank which, irrespective of whether it would be eligible for protection under the UPOV Convention, is characterised by at least one single transmissible characteristic distinguishing it from other plant groupings and which is sufficiently homogeneous and stable in its relevant characteristics."[17] It thus led to a situation where some plant-related innovations could be ineligible for protection both under plant variety rights and under the patent regime (whereas it was made clear that plant cells as such could be patentable, as they do not fall under the definition of plant varieties).

The *Novartis* decision of December 20, 1999 of the Enlarged Board of Appeal of the European Patent Office partly clarifies the issue. The Enlarged Board first reminds us that "the term plant variety in Article 53(b) EPC had the same meaning as in the UPOV Convention and the excluding provision should only apply if such varieties were claimed *per se*"[18] (in a product patent). Moreover, according to established case law, "the protection conferred by a process patent is extended to the products obtained directly by the process, even if the products are not patentable *per se*". Thus, like in the U.S., the patent protection and plant breeders' rights may overlap.[19] Effectively, the ruling of the Enlarged Board is that a "claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC, even though it may embrace plant varieties". The Enlarged Board specifies that the exclusion applies irrespective of the way in which the plant varieties are produced and that thus, "plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are excluded from patentability".

This decision, which overrules the previous position held in the *Plant Genetic System* case, rapidly refers to two recitals of the E.C. Directive 98/44 on the protection of inventions relating to biotechnology[20] to justify the "more than one variety approach".

It is relevant to now turn to criteria of protection. These, which are enumerated under TRIPS Art. 27 (1), consist in novelty, inventive step and industrial application. Although TRIPS Art. 27 (1) states that there shall be no discrimination between technologies, the Supreme Court of Japan has rather recently shown in a landmark decision dated 29 February 2000[21] that the criterion of industrial application does not apply to living material as it does to mechanical inventions. This decision clarified

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scope of rights of the 1991 version, whereas an English citizen in Belgium will receive 1972 version breeders' rights.

[17] T356/93, 21 February 1995.

[18] See decision, respectively paragraph VIII of Summary of facts and submissions and paragraph 4 of Reasons for the decision. Available in UPOV gazette 87/200, pp. 29-38.

[19] Note that the protection conferred by the UPOV Convention covers the seeds ("propagating material"), just like patents do, but not the genes or combination of genes, nor the process.

[20] The EPC is an international convention and does not pertain to the E.C. legal system; however, the EPO takes into account the E.C. Directive, as many of its member States have to implement it. In its decision of 16 June 1999, the Administrative Council of the EPO inserted a new Chapter VI entitled "Biotechnological inventions" in Part II of the EPC Implementing Regulations and amended the wording of Rule 28(6) EPC – see Notice dated July 1, 1999 in OJ EPO no. 8-9 of August-September 1999, pp. 545-587.

[21] Case no 1998 (Gyo-tsu) 19. Japanese Supreme Court decisions can be retrieved from http://courtdomino2.courts.go.jp. For further comments, see Lightbourne (2005).

that the "possibility of repetition in the process of breeding in an invention for a 'method of breeding and multiplying new breed of a plant' (…) is sufficient, if people in the same business are able to reproduce the plant in a scientific way, and do not have to have a high probability of reproduction".

In indent (3) of the "Facts", the Supreme Court specified that "[i]n fruit plants, the mechanism of inheriting individual characteristics is such that the hereditary elements which form the basis of individual characteristics influence each other, and cannot necessarily be ruled by the Law of Mendel; reproduction of fruit plants with an identical genetic structure can be achieved only with a very low probability."

According to Leskien and Flitner (1997), should patentability criteria be strictly applied, only few plant-related innovations would qualify for protection. In particular, following these authors, the criterion of inventive step might be difficult to fulfil. Moreover, on the one hand, as the TRIPS Agreement does not make any obligation to Members to join the Budapest Treaty, many plant genetic innovations may be *de facto* excluded from patentability for lack of sufficiency of disclosure. Nevertheless, Rangnekar (2002) underlines that a reference to the Budapest Treaty is often included in TRIPS-plus treaties negotiated by the U.S. or the E.U. with developing countries. On the other hand, as shown by Watal (2001), under the patent system, the disclosure requirement (and in particular, the 'best mode' description under the US system) would involve not only the deposit of planting material, including hybrid parental lines, but also opening these to the public, unlike under plant variety protection.

As to the coverage of patent protection for plants, it seems that in the US, utility patents are concerned with inventions encompassing plant groupings larger than a variety, or discrete plant varieties as well as seeds, tissues, genes, plant extracts, or processes. Concerning genes, the USPTO Utility Examination Guidelines made clear that, only where the *"application discloses a specific, substantial and credible utility for the claimed isolated and purified gene"* [22] does it fulfil the criteria of utility. Moreover, in order to "satisfy the written description requirement of 35 USC 112 para. 1, the description must show that the applicant was in possession of the claimed invention at the time of filing."[23] However, according to Leskien and Flitner (1997), the scope of protection remains unclear. In particular, it is not clear whether those parts of plants which cannot be regenerated to whole plants can be excluded from patentability under 27(3)(b), and it is not certain that the protection granted has to extend to plants produced not by using the invention, but by propagation and multiplication. The Canadian Supreme Court has recently illustrated this point in the *Monsanto v. Percy Schmeiser* decision rendered on May 21, 2004. After specifying that 95-98% of Schmeiser's 1998 canola crop was Roundup Ready canola, the court declared that "the appellant's saving and planting seed, then harvesting and selling plants that contained the patented cells and genes appears, on a common sense view, to constitute 'utilization' of the patented material for production and advantage." However, "the lower court erred not only in construing the claims to extend to plants and seed, but also in construing 'use' to include the use of subject-matter disclaimed by the patentee, namely the plant (…) Since there is no claim for a 'glyphosate-

[22] US Government, "US Patent Office Utility Examination Guidelines," Federal Register, Vol. 66 No. 4, January 5, 2001.
[23] Ibid. p. 1095 *in fine*.

resistant' plant and all its offspring, saving, planting, or selling seed from glyphosate-resistant plants does not constitute an infringing use."[24]

What this case shows is that the Canadian Supreme Court chose a strict interpretation of the patent claims, differing from the solution offered by Article 9 of the European Directive 98/44 on the protection of inventions relating to biotechnology. Accordingly, the protection conferred by a patent directed to a product containing or consisting of genetic information extends to all material (except the human body or simply discovered elements thereof) in which the product is incorporated and in which the genetic information is contained and performs its function. Article 8 of the same Directive enunciates that the protection conferred by a patent on a biological material possessing specific characteristics as a result of the invention extends to any biological material derived from that biological material through propagation or multiplication, in an identical or divergent form, which presents the same characteristics. In the EU, the modified canola plant would thus be protected, as well as its progeny. As already explained, the Directive allows for the protection of some plant varieties by patents, where a plant grouping characterised by a specific gene encompasses plant varieties, but is not limited to such plant varieties. The Canadian Supreme Court considers that adopting a differing view is not necessarily in breach of TRIPS Article 27(1) that requires member States to make patents available for any invention without discrimination as to the technical field. In fact, the Canadian Supreme Court obviously thinks that a EU-like position creates discrimination when it quotes in this respect the Canadian Biotechnology Advisory Committee:

> "(…) granting the patent holder exclusive rights that extend not only to the particular organism embodying the invention but also to all subsequent progeny of that organism represents a significant increase in the scope of rights offered to patent holders. It also represents a greater transfer of economic interests from the agricultural community to the biotechnology industry than exists in other fields of science."[25]

At least in some jurisdictions, the scope of patent rights can be limited by specific exceptions to rights, such as research exemption, compulsory licences or the general public order exception.

There is no general statutory research exemption provision under US patent law. The US Congress enacted in 1984 an industry-specific experimental use exemption for the dual purpose of restoring terms of patents for pharmaceutical products eroded by lengthy marketing approval proceedings, and of promoting the production of generic medicines upon termination of patents. The Drug Price Competition and Patent Term Restoration Act of 1984 (or "Hatch-Waxman Act") provides a "safe harbour provision", codified as 35 U.S.C. 271 (e) (1). This provision was meant to overrule the solution reached in *Roche Prods, Inc. v. Bolar Pharm Co.*[26], according to which a generic drug producer could not start the trials required for obtaining a Food and Drug Administration marketing approval before the expiration of the patent on the original drug. Accordingly, in *Roche v. Bolar*, the common law experimental use exception,

[24] See the case (p. 4) at http://www.canlii.org, last visited April 25, 2005.
[25] Ibid., at indent 165.
[26] 733 F.2d 858 (Fed. Cir.), cert. denied, 469 U.S. 856 (1984).

first laid down by Justice Story in the early nineteenth century in *Whittemore v. Cutter* and *Sawin v. Guild*[27], was held to be "truly narrow".

This restrictive interpretation of the common law exception was reaffirmed by the U.S. Court of Appeals for the Federal Circuit when it held on October 3, 2002 in *John M.J. Madey v. Duke University* that "(…) regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and it is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative." Thus, the statutory research exemption is currently construed narrowly, and does not apply to plant breeding programmes. Moreover, the application of the common law experimental use exception to such programmes is rather unlikely as things stand.

In contrast, in Europe, member States have adopted research exemptions, inspired by Art. 27 (b) of the Community Patent Convention (1989 version), and whose scope is generally broader than that of the American one. At least in France and Germany, the purpose for which the research is conducted, be it a commercial one, is irrelevant. Art. L. 613-5 of the French Code of Intellectual Property exempts among others any act done privately and for purposes which are not commercial as well as acts done for experimental purposes relating to the subject-matter of the patented invention; this wording is exactly the same as Section 60 (5)(a) and (b) of the United Kingdom Patents Act 1977, although the interpretation in this latter country differs.

In *SmithKline & French Laboratories Ltd. V. Evans Medical Ltd.*[28], the Court stated that "what is or what is not an experiment must depend upon the facts of each case but can include experiments designed with a commercial view in end." In this instance, it was found that the experimental use defence could not be invoked in relation to the use of patented transgenic animals (i.e. a research tool).[29] Experiments made on the subject matter of the patent should be distinguished from those carried out with the subject matter. Moreover, for acts other than experimental, the courts have insisted on the cumulative conditions that the use be private *and* not having a commercial purpose.

Besides this, in the UK, Section 60(5)(g) grants a farmers' exemption under the patent regime similar to what exists in the field of plant varieties protection; new Art. L. 613-5-1 of the French Code of Intellectual Property, introduced by Law no 2004-1338 of December 8, 2004, on the protection of biotechnological inventions, provides accordingly.

As to compulsory licences, their use is now restricted by TRIPS Art. 31, in particular by the requirement that the invention claimed in the second patent involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent. Similarly, the public order exception is limited

[27] 29 Fed. Cas. 1120 (1813); 21 Fed. Cas. 554 (1813).

[28] [1989] FSR 513.

[29] "Research tools" designates quite a wide array of things, such as genomics databases, DNA chips, recombinant DNA technology, PCR, combinational libraries, genes and receptors, or transgenic animals. See OECD 2002, at 50 and 61.

by TRIPS Art. 27 (2), which states that such exclusion should not be made merely because the exploitation of the invention is prohibited by domestic law.

4/ UPOV Convention Acts (1978, 1991)

As stressed by Rangnekar (2002), the 1991 Act of the UPOV Convention widens the legal definition of plant variety and changes the earlier emphasis on phenotypic expression of physiological and morphological characteristics to one based on expression of characteristics arising from the genotype. The definition of plant varieties under the International Code of Nomenclature,[30] by referring to "cultivars" and "plants assemblages", differs from that of UPOV 1991, which first defines varieties in terms of "plant groupings" within a single botanical taxon of the lowest known rank (lower in any case than the ranks of genus and species), before specifying those susceptible of protection by breeders' rights (Leskien and Flitner 1997, Crucible II Group 2001). In contrast, the 1978 Act of the UPOV Convention does not provide any definition of plant varieties.

Moreover, whereas pursuant to the 1978 Act of the UPOV Convention the principle of reciprocity could be applied to nationals of other members of the UPOV Convention, as the coverage could be limited in terms of species, the 1991 Act provides that national treatment should apply (Leskien and Flitner 1997, Helfer 2002). Another difference between these two Acts lies in the fact that the 1978 Act implicitly protects varieties that have been discovered. Pursuant to Art. 6.1(a), a protected variety may result from a natural source of initial variation (Crucible II Group 2001, Helfer 2002). This is made explicit in the 1991 Act (cf. Art. 1(iv): "breeder"). Contrary to the previous Acts of the UPOV Convention, the 1991 Act allows the concurrent protection by a breeder's right and by a patent.

Protectable varieties are those that satisfy the following criteria of protection:

- Novelty (at the date of filing of the application, propagating or harvested material of the variety has not been sold or otherwise disposed of to others, by or with the consent of the breeder),
- Distinctness (the variety must bear a characteristic which has no equivalent in other varieties),
- Uniformity (a broad proportion of the seedlings of a sowing must be identical),
- Stability (the relevant characteristics must remain unchanged after repeated propagation).

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[30] The International Code of Nomenclature for Cultivated Plants was first adopted in 1953 and last revised in 1995 (6th edition), and is subordinate to the International Code of Botanical Nomenclature, devised in the mid-19th century. The rule is that the first validly published name for a particular plant is the one designating this plant. However, in some instances, an earlier validly published name may be retrieved much later after it had been forgotten and replaced with another subsequently published name. In other situations, the name of a plant may be modified in the ICNCP as a result of thorough investigations and corrections of errors in identification. For details, see Chris Brickell and Piers Trehane *The Royal Horticultural Society Advisory Panel on Nomenclature and Taxonomy* in *The New Plantsman* 4(2): 115-119, 1997, available at http://www.rhs.org.uk/research/APONAT1.asp, visited January 7, 2005.

According to Leskien and Flitner (1997), the UPOV Test Guidelines, by insisting on visible characteristics, have some inherent tendency towards cosmetic breeding; the positive aspect is that Guidelines can be modified in a much more straightforward way than a Convention Act.

The 1991 version strengthens the rights of breeders vis-à-vis farmers (Leskien and Flitner 1997), by extending the protection granted to a variety to varieties essentially derived thereof, and by transforming the farmers' right to use, only on their own holdings, the product of their harvest, into a facultative exception to the breeder's right. The States that have ratified the 1991 version are thus not obliged to grant this right, so far implicitly recognised to farmers. The Crucible II Group (2001) explains that UPOV 1978 conferred an implicit authorisation of propagation for non-commercial purposes. On this ground, the US Supreme Court held in 1995, in *Asgrow Seed Co. v. Winterboer*,[31] that under the farmers' privilege provided by the PVPA, a farmer may sell for reproductive purposes only that amount that he or she has saved for replanting on his or her own acreage. This decision thus made clear that the practice called "brown-bagging" was authorised under certain conditions.[32] The International Seed Federation, FIS/ASSINSEL, declared likewise that the "farmer's privilege" should not go "beyond the provision of the 1991 Act of the UPOV Convention, i.e., within the reasonable limits in terms of acreage, quantity of seed and species concerned and subject to the safeguarding of the legitimate interests of the breeders in terms of payment of a remuneration and information."[33] The Crucible II Group (2001) contrasts the situation prevailing in the US to that in Europe, as breeders are not entitled to any equitable remuneration in this respect. As recalled by Rangnekar (2002), the Committee on Transactions in Seeds, i.e. the consultative body that recommended the introduction of plant breeders' rights in the UK in the 1960s, considered that a charge on farm-saved seeds would force farmers to pay a second charge on something they already possess. In any case, as reminded by Leskien and Flitner (1997), the "Farmers' privilege" under the UPOV Convention is utterly different in nature and far more limited in scope than the "Farmers' rights" enunciated in Resolution 5/89, annexed to the FAO International Undertaking.[34] Leskien and Flitner (1997) consider that the restriction imposed on Farmers' rights by UPOV 1991 may conflict with Art. 10 (c) of the Convention on Biological Diversity.[35]

Conversely, breeder's rights have been broadened and now consist not only of the production, the sale or offering for sale of the propagating material of the variety, but also the conditioning for the purpose of propagation of said material, its stocking for

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[31] 513 U.S. 179, 1995

[32] In 1994, the Plant Variety Protection Act was amended to prevent the unauthorized sale of seed of varieties whose protection certificate was issued from 4 April of that year. So the Asgrow decision applied only to varieties granted protection under the Act prior to that date, after which brown-bagging was not allowed at all.

[33] Cf. *Position Paper on Farm Saved Seed* adopted May 31, 2001, quoted in Biswajit Dhar 2002, p.15.

[34] According to Resolution 5/89, Farmers' rights mean "rights arising from the past, present and future contributions of farmers in conserving, improving, and making available plant genetic resources, particularly those in the centres of origin/diversity". They aim to "ensure that the need for conservation is globally recognized and that sufficient funds for these purposes will be available", and to allow farmers to benefit from the improved use of plant genetic resources.

[35] "Each contracting party shall (…) protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements."

any of the purposes aforementioned, its importing or exporting (Art. 14 of the 1991 version). As stressed by Helfer (2002), members of UPOV 1991 are even permitted – although not compelled – to provide additional rights to breeders, including rights in products made directly from harvested material.

Moreover, under the 1978 Act, varieties derived from a protected variety could more easily give rise to protection or, at least, they were deemed not to infringe the breeder's rights on the protected variety as long as their commercial production did not require the repeated use of the protected variety (Art. 5(3) of the 1978 version).

Pursuant to the 1991 version, the acts of derivation might more often fall within the scope of protection of the variety, which also covers "essentially derived varieties". Basically, the breeder of protected variety A has the right to demand that the breeder of variety B secure his or her authorization to commercialise B if it was essentially derived from A.

To be an essentially derived variety (EDV), the variety must be derived from an earlier variety and, while being clearly distinguishable from it, must nonetheless retain the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.

The main idea here is that breeders should not be able to acquire protection too easily for minor modifications of extant varieties or free-ride without doing any breeding of their own, problems that the increased application of biotechnology in this field appeared likely to exacerbate.

Beyond resolving these particular issues, but related to them, the provision was also intended to ensure that patent rights and PBRs operate in a harmonious fashion in jurisdictions where plants and their parts, seeds and genes are patentable and access to these could be blocked by patent holders. Such a practice would undermine one of the main justifications for PBR protection, which is that breeders should be able to secure returns on their investments but without preventing competitors from being able freely to access breeding material. An example here might be useful. Let us consider the case of a PBR-protected variety called A and a patented genetic element owned by a separate company (see Jördens 2002:6). The owner of a patent on this genetic element is free to use A to produce his or her variety B and, absent of the essential derivation provision, place B on the market with no obligations to the owner of A despite the fact that B differs from A only in the addition of the patented genetic element. However, the owner of A would need a license from the producer of B to use the patented genetic element in the breeding of further varieties. In such a situation, then, patents can have the effect of blocking the breeders' exemption that PBR rights normally provide.[36] It should be noted here that the PBR-issuing office will not itself determine whether a variety is essentially derived from an earlier one. This will be left to the courts.

[36] The EC Directive on the Legal Protection of Biotechnological Inventions seeks to make PBRs and patents operate more harmoniously by providing that where the acquisition or exploitation of a PBR is impossible without infringing a patent, or vice versa, a compulsory license may be applied for. If issued, the licensor party will be entitled to cross-license the licensee's patent or PBR.

Srinivasan (2003) shows that the notion of EDV, i.e. distinctness based on genetic composition, shakes the very foundations of conventional plant variety protection systems, based on morphological differences.

As explained by Helfer (2002), and in more details by the International Seed Foundation[37], the genetic distance between two varieties is appreciated on a case-by-case basis. As expected, this notion has already started to give rise to some litigation. It might be worth mentioning here a first, and so far, provisional judgment on essentially derived varieties, rendered by the Civil Court of The Hague in the Netherlands in October 2002. The court had to assess whether the variety "Blancanieves" of the species Gypsophila was a mutant of the variety "Dangypmini", as claimed by the holder of a Community plant certificate on the latter against the Netherlands-based holder of another Community plant certificate on the former. The court considered that the phenotype of "Blancanieves" differs from that of "Dangypmini" in several characteristics, held to be essential characteristics resulting from the genetic material of "Blancanieves", and not present in "Dangypmini".[38] Hence, it seems that at this stage, the court deems that "Blancanieves" is not an EDV, as the Plaintiff has not convinced the court that these differences are related to the act of derivation. The final decision is still pending, and it will be interesting to see new cases arise.

Such situations may lead to cross-licences between plant varieties and essentially derived varieties. The need for compulsory licences was already contemplated in UPOV 1978, whose Article 9 deals with compulsory licences in the public interest that give rise to an equitable remuneration for the breeder. A similar provision can be found under Art. 17 of UPOV 1991, although the phrase "in order to ensure the widespread distribution of the variety" has disappeared compared to the 1978 version.

Further, within the European Community, a specific scheme was set up in order to organise relations between patentees and breeders. Article 12 of the Directive 98/44/EC on the legal protection of biotechnological inventions designed a cross-licensing scheme between patents and plant breeders' rights. The conditions set forth for such licenses are the following ones:

- They must be compulsory licences,
- For a non-exclusive use,
- Giving rise to appropriate royalties.

This provision draws on the conditions listed in Art. 31 of the TRIPS (which is concerned only with compulsory licences on patents). In particular, the applicant must give evidence of his/her unsuccessful attempt to obtain a contractual license; and the plant variety or the invention concerned must represent a significant technical progress of considerable economic interest. The Regulation 2100/94 on Community plant variety rights had to be amended accordingly, which was achieved by the Council Regulation (EC) 873/2004 that modifies Art. 29 of Regulation 2100/94.

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[37] ISF Position Paper *Essential Derivation and Dependence – Practical Information*, 1999; available at http://www.worldseed.org/positions.htm, last visited August 9, 2005.

[38] See the summary of the decision provided by Mr. Krieno Fikkert, Secretary, Board for Plant Breeders' Rights, Netherlands, in *UPOV Gazette* no 94, December 2002, p. 7.

The assessment of the impact of UPOV on genetic variability (in terms of recombination of genes) is poorly documented and not conclusive. The Crucible II Group (2001) considers that there has been no evidence of any decrease in genetic diversity measured by coefficients of co-ancestry and molecular markers in a given crop since the development of the DUS (distinctness-uniformity-stability) test. Leskien and Flitner (1997) quote Jaffe and van Wijk (1995), who estimate that plant breeders' rights may have prevented a reduction in R&D expenditure rather than having stimulated additional private investment in domestic plant breeding. In any case, the value of plant variety certificates appropriated by right holders constitutes a relatively small portion of the overall returns from agricultural R&D (Srinivasan 2003).

The description of the reach of patents on plant-related innovations and of plant breeders' rights, accompanied by a reminder of the criticisms they receive, is a prelude to a review of the suggested traits that a *sui generis* system adapted to the needs of farmers in differing developing countries could show.

5/ The economic welfare impacts of patents and plant breeders rights

What is the impact of patent protection on plant-related innovation? As shown by Watal (2001), patents are resorted to in order to recoup allegedly huge R&D investments of up to US$ 300 million made over ten years or so to commercialise such plant varieties. However, some flexibility can be introduced into patent regimes, and in this respect Watal (2001) gives the example of Singapore, whose patent law of 1994 removed any bar to the patentability of living organism; however, Sec. 13(5) of the Patent Act permits the minister to vary the new provisions 'for the purposes of maintaining them in conformity with developments in science and technology'.

The UPOV system has found itself under attack from a number of quarters. Legal experts and practitioners schooled in patent law are sometimes unsympathetic towards the Convention and its basic principles. Some of them find it difficult to understand why it should be possible for protected varieties to be used as source material by breeders, and have called for limiting the research exemption. In 1988, for example, AIPPI (1988:222) recommended in a resolution on biotechnology that Article 5(3) of UPOV 1978, 'which permits the free utilisation of a protected variety as an initial source for breeding new varieties should be amended to provide, at least, for a royalty in the case of commercial exploitation of that new variety'. Implicit in some of these criticisms seems to be a perception that advances in biotechnology will tend to diminish the need for traditional plant breeding and the freedom of access to germplasm which most breeders feel strongly about maintaining.

Unlike many patent lawyers, though, plant breeders continue to stress the importance of access to genetic material including that which is IP-right protected. Barry Greengrass, former vice secretary-general of UPOV, pointedly mentioned (at an AIPPI congress as it happens) this 'perennial complaint' about the research exemption as one that was 'primarily … on the part of patent specialists rather than plant breeders' (Greengrass 1989:631). According to Lange, plant variety protection and patents differ in quite fundamental ways, not just in terms of criteria for protection, but also of how the rights and obligations of producers and users are balanced. He argues that 'breeding (including genetic engineering) is always based on what already exists, requires a broad range of variability and demands the free use of material' (Lange 1997:27). Moreover:

> Since the purpose of plant variety protection is not to protect an invention, for instance a specific property in plant material, but the creation (including the discovery) of a new plant variety (that is to say a unique new 'shuffled' genotype with a corresponding phenotypical expression) (...), there must be the continuing possibility of using the protected material of competitors to develop new varieties with a new and unique genotype (for example, by crossing – that is to say a new 'reshuffle'), without there being dependency [on the authorisation of plant variety right holders] (ibid.).

Studies on the economic impacts of PBRs are few in number, and those which exist vary in their conclusions from the positive to the highly sceptical. Lesser and Masson's (1983) study on the US Plant Variety Protection Act sponsored by the American Seed Trade Association was highly favourable. But several other studies have suggested that while research investment and the number of research programmes tend to increase, such research tends to focus mostly on those crops likely to offer the highest profits, which in the US are soya and wheat (Butler and Marion 1985; Janis and Kesan 2002:775-6; Rangnekar 2002).

As for developing countries and the issue of neglected crops and others of primary interest to small farmers, critics have claimed that even if breeders did turn to neglected crops, many of the small farmers that grow them would not be better off if their freedom to dispose of saved seed were diminished. In most developing countries a very large proportion of the farming population consists of small-holders, and for these people 'seed saving from their harvest for further propagation, selling and exchanging of seeds is a common practice' which contributes to food security (Verma 1995:286). In India, for example, farmers produce two-thirds of the country's annual seed requirement.[39]

But however positive or critical the findings are, it is not always easy to separate the incentive effect of PBRs from other factors that influence decisions on where a company should direct its research, such as increased industrial or consumer demand for certain crops and reduced demand for others. It is generally agreed that, because of PBRs, the number of varieties introduced into European and Northern markets is greater than it would otherwise have been. However, Dwijen Rangnekar (2000:1) has suggested that while this is probably true, PBRs encourage breeders to adopt strategies of planned obsolescence 'to reduce the durability of plant varieties so as to induce regular replacement purchases by farmers'. He claims some empirical evidence that UK wheat breeders do adopt such strategies. If this is correct, farmers may well benefit far less from PBRs than their proponents claim. Existing seed companies have almost certainly gained from the existence of PBRs, at least in the USA and Europe. To sum up, PBRs are likely to have been beneficial on balance. But, if Rangnekar is right, we need to reflect on whether the right incentives are

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[39] 'Only about 7% of wheat seed and 13% of rice seed planted in India is from the formal sector' (Turner 1994, cited in Tripp 1997).

necessarily being created, and if they are not, how the system can be modified to encourage breeders to shift their research in more farmer-friendly directions.

6/ Environmental effects of IPRs

Until the 1980s, few if any people considered IPRs to have anything whatsoever to do with genetic erosion. This is not the case now. Critics maintain that IPRs provide perverse incentives which encourage activities that are prejudicial to biodiversity. Are they right? One way to investigate this issue is to frame it in the form of three sets of questions, which will be discussed in this chapter. These are as follows:

1. Do intellectual property rights encourage the spread of monocultural agriculture? And if so, does this cause erosion of biodiversity?
2. Do plant variety rights encourage the breeding of genetically uniform varieties and the use of a relatively small pool of genetic material? And if either of these is the case, is it prejudicial to biodiversity?
3. Is the increasing production and sale of seed-agrochemical 'packages' (such as transgenic crops sold with pesticides and/or herbicides for which they have built-in resistance) harmful to biodiversity? And if so, are IPRs an inducement for companies to produce these kinds of 'package'? In other words, is this an IPR issue?

IPRs and monocultures

With respect to the first set of questions, one of the most plausible critiques of IPRs is by Reid (1992), who identifies a strong connection between IPRs and a bias towards centralised research, and believes that this has an impact on agro-biodiversity. He finds that the prevailing policy framework for the use of genetic resources for food and agriculture favours 'centralised crop breeding and the creation of uniform environmental conditions, and discourages agro-ecological research or local breeding tailored to local conditions.' IPRs enhance incentives to develop seeds that will have a large potential demand. To ensure maximum demand for their products, the seed companies will tend to focus their research on commonly utilised high-value crops and develop varieties that can be cultivated as widely as possible. To do so means either breeding through selection of genes for maximum adaptability, or introducing the new seeds while also promoting farming practices that reduce environmental heterogeneity. The biodiversity-erosive effects of this IPR-supported bias towards centralised crop breeding programmes are: (i) decreased crop diversity; (ii) decreased spatial genetic diversity; (iii) increased temporal genetic diversity due to the need to replace cultivars with new ones every few years; and (iv) increased use of external inputs.

It is important to point out that monocultural agricultural systems are not inherently biodiversity-erosive. It is true that they may cause biodiversity loss if they replace more biologically-diverse ecosystems. But *if* a monocultural system produces higher yields per harvest and/or more harvests per year compared to a more polycultural agro-ecosystem it replaced, pressure to open up biologically-diverse ecosystems to cultivation *may* be reduced as a consequence.

Kothari and Anuradha (1997) conclude that IPRs alone cannot be held responsible for the loss of agro-biodiversity, but that IPRs are bound to encourage the displacement of a wide diversity of traditional local varieties in favour of a small number of widely adapted hybrids and homogeneous modern varieties (ibid.). Moreover, they point out that one of the lessons of the Green Revolution is that the development of new varieties by the seed industry is unlikely to match the loss of traditional varieties after these new varieties are introduced.

However, the erosion of biodiversity will not necessarily result from the spread of monocultural systems. If a monocultural system produces higher yields per harvest and/or more harvests per year compared to a more polycultural agro-ecosystem it replaced, pressure to open up biodiverse ecosystems to cultivation *may* be reduced as a consequence (though the opposite result is also possible). It is important also to point out though that this trend in crop breeding dates back to when the Green Revolution began, and earlier still in some countries. The varieties most commonly associated with the Green Revolution were developed by public crop breeding institutions, not corporations. On the face of it, this suggests that this may not be an IPR-related problem at all.

According to a preliminary study produced for the Secretariat of the CBD for consideration of the 3rd meeting of the COP (CBD Secretariat 1996a), other policies that might encourage the use of new crop varieties and the loss of landraces include: (a) government farm credits and subsidies, and extension services; (b) the policies and programmes of international agencies and donor institutions; (c) the marketing and research and development policies and programmes of transnational corporations; and (d) the increasingly concentrated corporate control of pesticide and agro-biotechnology research and distribution.

IPRs and genetic uniformity

Rangnekar (2003), quoting Allard (1960: 50-51), insists that it is well established that breeders do not create variation but recombine existing variation. Accordingly, the patenting of genetic resources might result in less genetic variability. As Donald Duvick of Pioneer Hi-Bred, quoted by Rangnekar (2002),[40] explains, "(…) USA farmers have many more soybean varieties available to them today (…) Unfortunately, many of these commercial soybean varieties are very close relatives, if not essentially identical (…)".

As for PBRs, Rangnekar has suggested that they encourage plant breeding based upon existing material already in scientific use, while providing 'juridical legitimization to the breeding of genetically uniform varieties' (2000a:1). On what basis may such claims be credible?

Let us consider first the point that PBRs encourage the use of a narrow pool of germplasm by crop breeders. What makes such a claim plausible is the breeders' exemption, which, since it permits free use of plant genetic resources already in circulation, does little to encourage the discovery and input of resources that may exist in the fields of traditional cultivators and other types of ecosystem characterised

[40] From a quotation from Pray and Knudson (1994).

by relatively high levels of biodiversity. Defenders of PBRs may counter that the number of varieties introduced into European and Northern markets is probably greater than it would have been without the incentive of a PBR system. On the other hand, an increased quantity of plant varieties being cultivated does not necessarily mean that agro-biodiversity is greater than would otherwise exist in farmers' fields. This is because new varieties tend to be based on the recombination of genes acquired from a fairly limited gene pool shared by plant breeders, who generally do not claim exclusionary rights over discovered genes or plants into which they are inserted. Furthermore, Rangnekar claims that PBRs encourage breeders to adopt strategies of planned obsolescence 'to reduce the durability of plant varieties so as to induce regular replacement purchases by farmers' (2000b:1; 2002b). He claims some empirical evidence that UK wheat breeders do adopt such strategies.

If we turn to the point about juridical legitimization, this relates to the fact that the UPOV PBR rules require individual plant varieties to be genetically uniform.[41] Consequently, the genetic variability of each protected variety is quite limited as compared to folk varieties. In defence of UPOV, though, the trend towards cultivation of genetically uniform varieties is due also to the seed certification requirements of many countries. Often these apply more stringent uniformity standards than UPOV (Louwaars 1999).

IPRs and crop-agrochemical linkages

With respect to the second set of questions, it is true that seed companies often develop hybrids and other modern varieties that depend upon applications of agrochemicals (such as fertilisers, herbicides and insecticides) to achieve high yields. A common accusation is that excessive use of these chemicals is encouraged and other plants growing nearby are killed as a result. However, IPRs are unlikely to be directly responsible for this trend in crop breeding, which dates back to the time when the Green Revolution began, and earlier still in some countries. The Green Revolution is frequently blamed for the development and spread during the 1950s and 1960s of high-yielding wheat and rice varieties requiring heavy applications of agrochemicals, but the varieties most commonly associated with the Green Revolution were developed by public crop breeding institutions and were not IPR protected.

However, the IPR link appears stronger in the case of genetically modified crops. In recent years, life-science corporations (often originally chemical companies that have bought seed companies) have increasingly been creating transgenic plants with built-in resistance either to herbicides marketed by the same company (see Bell 1996; Kloppenburg 1988) or to insect pests. In the former case, both the herbicide and the seed for which it is designed are likely to be patent-protected. For example, Monsanto had made enormous profits from one of its patented agrochemicals, a glyphosate-based herbicide marketed under the name of Roundup, and was concerned to ensure that once the patent expired, it would not face too drastic a shortfall in revenues as

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[41] This is also a food security issue. The mass-cultivation of uniform varieties based on a narrow range of breeding material can result in outbreaks of devastating diseases. This happened with the potato crop in Ireland in the 1840s, and the United States in the 1960s and 1970s with wheat and maize respectively. Of course, many such disease outbreaks predated the introduction of PBRs to the affected countries. Despite this, critics argue that PBRs encourage the genetic uniformity that can potentially increase the dangers of such outbreaks occurring.

competing producers of the same herbicide entered the market. Monsanto turned to biotechnology for a solution. The company developed and patented transgenic soybeans, canola, cotton and corn containing a gene providing resistance to its Roundup. Monsanto's patents protect the gene for Roundup resistance and all plants containing it, and these have several more years to run. As farmers who buy these 'Roundup Ready' seeds are contractually obliged to purchase Monsanto's patented herbicides, sales of the seeds are good for sales of the herbicides and vice versa. It is unclear, however, that this strategy will work in the long term. Roundup Ultra went off patent in 2000 and farmers may well turn to cheaper versions sold by competitors.

An example of a crop with built-in resistance to a pest (rather than a herbicide or pesticide) is Monsanto's NewLeaf potato, which claims to provide *total* protection against the Colorado beetle (Magretta 1997). Another is Novartis' patented Bt corn, which is designed to resist the European corn borer pest.

The position of the large life-science corporations such as Monsanto and Novartis is that genetic engineering can reduce or even obviate pesticide use. Monsanto's claim is that when they produce packages of herbicides and plants resistant to these herbicides, their aim is not to ensure that farmers will need to increase herbicide use. Their main interest is to ensure that farmers use *their* herbicides. If these are more effective than alternative products, overall herbicide use may decrease. According to the company, 'Roundup herbicide can reduce the number of weed treatments and can also help reduce tillage to conserve soil moisture and reduce erosion of valuable topsoil'.[42]

Environmentalists and some scientists counter that genetically-engineered herbicide resistance has negative environmental effects.[43] Among the claims commonly made are that use of herbicide-resistant transgenic plants may: (a) encourage excessive use of herbicides which may kill other plant varieties and species (Bell 1996); (b) accelerate the development of resistance among pests (Jenkins 1998); and (c) create the possibility of herbicide resistant genes crossing over to other plants including the weeds being targeted. This could create 'superweeds' which would render the herbicide ineffective in the long term, and cause ecological impacts that cannot easily be predicted. It may also be possible that transgenic plants themselves could become 'weeds' if the added characteristic gives them a competitive advantage over neighbouring wild species (de Kathen 1996), though this is unlikely in the case of the most highly domesticated crop species. Some critics also allege that herbicides are far more toxic than the manufacturer companies are willing to admit, and that the health of both farmers and consumers could be affected (McNally and Wheale 1996; Tappeser and von Weizsäcker 1996).

Concerns are also expressed that increased use of hybrids and other modern varieties specifically designed for use with other proprietary agricultural inputs such as fertilisers and pesticides may have serious social impacts, especially in developing countries. These crop-herbicide-pesticide linkages can be considered to represent a shift towards capital intensive agriculture that increases the costs of farming and may therefore be detrimental to small farmers. Consequently, critics maintain that farmers

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[42] Monsanto World Wide Web site (http://www.monsanto.com).
[43] For excellent assessments of the environmental impacts of agricultural biotechnology see Lappé and Bailey (1999) and Krimsky and Wrubel (1996).

must have the right to choose whether or not to accept these packages and should not be subjected to aggressive sales promotion campaigns.

Even if we accept that these concerns are well-founded, are IPRs implicated just because plants (where transgenic or not), herbicides and pesticides can be patented? Corporations in these technological fields tend to claim that without IPR protection they would have no incentive to invent or to innovate. This suggests that these products would not exist without IPRs. But this does not mean that the national patent office is the appropriate place to deal with marketing approval for such products. Most countries have an agency with jurisdiction over such matters, and such a body is probably much better placed than the patent office to decide whether plant-herbicide-pesticide packages are in the public interest or not.

In conclusion, there is a dearth of reliable empirical evidence on the IPR-genetic erosion connection. What can be presumed with some certainty is that the loss of agro-biodiversity cannot be attributed to a single cause.

7/ Plant breeders rights and developing countries: food security and agricultural development

The term 'food security' applies to more than just ensuring that an adequate amount of food is cultivated or available through the market. It also embraces the question of whether people can afford to buy or cultivate enough food to satisfy their basic nutritional requirements. If not, as is frequently the case throughout the developing world, one can argue that food security is lacking.

What is the connection with IPRs? In the developed world, while plant biotechnologists tend to use the patent system, plant breeders have generally sought IPR protection for new plants, including new foodstuffs, through PBRs.[44] The main point at issue is whether the international acceptance of common standards of PBRs through the UPOV Convention, initially developed to meet the conditions in the advanced industrialized countries, and of patents on plants, are inappropriate for developing countries in ways that may have the effect of undermining food security.

Concern has been raised that the UPOV system was drawn up mainly by European countries, and is designed to accommodate the specific characteristics of the capital-intensive large-scale commercial agricultural systems that generally prevail in that continent. As a result, it is often argued, the system is unsuitable for most developing countries (see Gaia Foundation and GRAIN 1998). Among such critics, the current system of IPR protection for plants has raised concerns over their impact on food security in three areas: (i) PBRs and research priorities; (ii) the interests of poor farmers; and (iii) the availability of genetic resources for further breeding.

PBRs and research priorities

[44] However, a small number of countries allow plant varieties to be patented. These include the USA, Japan, Australia and Hungary.

Many resource-poor farmers cultivate minor food crops that enable them to meet the nutritional needs of rural communities much better than if major crops such as wheat, rice and maize alone are cultivated. In the hills and valleys of Nepal, for example, villages may grow more than 150 crop species and cultivated varieties (Riley 1996). However, PBRs generally do not encourage breeding related to minor crops with small markets. This is because the returns on breeders' research investment will be quite small. Rather, they encourage breeding targeted at major crops with significant commercial potential. Moreover, protected varieties of plants may not even be food crops. In Kenya, for example, until very recently, about half the protected new varieties were foreign-bred roses cultivated for export.

It is conceivable, then, that PBRs may contribute to a trend whereby traditional diverse agro-ecosystems, containing a wide range of traditional crop varieties, are replaced with monocultures of single agrochemical-dependent varieties, with the result that the range of nutritious foods available in local markets becomes narrower. Admittedly this trend is a global phenomenon whose beginning predates the introduction of PBR systems. Nevertheless it is one that the existence and increasingly widespread use of PBRs may indirectly encourage. On the other hand, there is nothing to stop developing countries from encouraging research on such minor crops that are important for local communities, either by providing strengthened IPR protection for such species, or through non-IPR-related measures such as public subsidies.

PBRs and the interests of poor farmers

The second issue is that in most developing countries, a large proportion of the population depends on agriculture for employment and income. Many of these farmers are small-holders for whom seed saving, across-the-fence exchange and replanting are common practices. This is especially in countries where neither the public nor private sectors play a significant role in producing or distributing seed. Although the UPOV system allows on-farm replanting, its rules restrict farmers' freedom to buy seed from sources other than the original breeders or their licensees.

Seed companies argue in response that farmers do not have to purchase PBR-protected seed just because it is available. They point out that the farmers are free to continue cultivating non plant variety-protected seed, including traditional local varieties, if they so wish. Therefore their basic freedoms are unaffected by PBRs. While this is likely to be true, folk varieties are often disparaged and may be excluded from government-approved seed lists that some countries maintain. Moreover, in many developing countries, government support for farmers including credit is sometimes conditioned on the sowing of particular crops and types of seed, such as hybrids (Sperling pers. comm. 1999). Also seed aid is often used by providers as a way to promote the use of particular crops and seeds.

It should be noted here that seed saving is not always a cost-effective option for farmers. According to van Wijk (1996:4), 'the cost advantage of saving seed is eroded by the deterioration of saved seed, causing yield losses over time. Deterioration is especially rapid with hybrids, but even here, the wide gap between new seed prices and the cost of seed-saving has encouraged some farmers in Latin America to save hybrid maize for a second generation'. It must be borne in mind, though, that the purchase of seed is one among several agricultural inputs that must be paid for, and even poor farmers may decide to pay a higher price for better quality seed if they expect a bigger harvest to result.

Wherever the exact truth lies, the ‘sui generis’ clause in TRIPS does give governments a certain amount of freedom to tailor their PBR systems to address such concerns. Thus, while an increasing number of developing countries are joining UPOV, some countries are devising alternative PBR systems that aim in part to strengthen food security. They do this, for example, by allowing farmers to acquire protected seed from any source and/or requiring protected varieties to display qualities that are genuinely superior to existing varieties.

The Indian parliament has passed legislation that would maintain farmers’ freedom to save, sell and exchange all produce of a protected variety, and the African Union (formerly the Organization of African Unity) has developed a model law for the consideration of member governments, known as the African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources. In both cases, as much importance is attached to the interests of farmers as to those of breeders.

IPRs and the availability of genetic resources for breeding

Plant breeders and other supporters of UPOV tend to stress the necessity of being able to freely access genetic material including that which is IPR protected. This is why the UPOV Convention contains such a broad breeders’ exemption. Patent law tends to have a much narrower research exemption which is often limited to non-commercial scientific or experimental use. Moreover, while a protected plant variety is covered by a single title, plant-related biotechnological inventions are likely to be protected by a patent and in some cases several patents. The patents may cover not just plants, but also seeds, genes and DNA sequences. The effect of patents is to restrict access to the patented ‘products’. It has been argued that ‘locking up’ genetic resources with patents is a bad thing because innovation in plant breeding is cumulative and depends on being able to use as wide a stock of material as possible. It was to deal with this concern that the FAO International Treaty introduced a number of provisions as were laid out above.

However, apart from patents, the restrictions on access to breeding material may have other causes than IPRs. For one thing, some countries have chosen to except certain categories of plant genetic resources they consider to be strategically important from the multilateral system to be set up under the International Treaty. Also, some developing countries have been exercising their rights under the CBD to regulate access to their genetic resources and in doing so have restricted their free flow. This may well be detrimental to long-term food security even in their own countries (Fowler 2002).

But beyond these issues about how specific intellectual property rights privatise genetic material needed for breeding is the association of IPRs with the privatisation of agricultural research, the shrinkage of non-proprietarian public sector research, and the increased concentration of ownership of breeding material, research tools and technologies in the hands of a small number of giant corporations (see Herdt 1999). Not only does this trend reduce the free circulation of breeding material, but it can also make public policy making aimed at enhancing food security harder to put into practice. This is because it is much more difficult for governments to influence companies than the public institutions they partly or wholly fund.[45]

Empirical evidence

This discussion on how PBRs affects food security and nutrition in developing countries leads one to consider in more general terms the applicability of such an IPR to these countries. Unfortunately, we have very few empirical studies to go on. One of the few was a joint project of the Anti-American Institute for Cooperation in Agriculture and the University of Amsterdam carried out in 1994, which examined 'the (expected) impact of plant breeders' rights (PBR) on developing countries with respect to: private investment in plant breeding, breeding policies of public institutes, transfer of foreign germplasm, and diffusion of seed among farmers' (Jaffé and van Wijk 1995:7).

Five countries were used as case studies of which three (Argentina, Chile and Uruguay) had PBR systems already in place, and two (Colombia and Mexico) were about to introduce them. These countries are similar in the sense that there are basically two seed markets. The hybrid seed market is controlled by transnational corporations, whereas the seed market for self-pollinating varieties is dominated by domestic firms.

However, Argentina differs from the others in that it is the only country in which PBR owners have successfully enforced their rights to the extent that their control over seed supply for wheat and soya is comparable to that of their counterparts in the United States. This leads the authors of the study report to conclude that in all probability, PBRs in that country have 'prevented the local wheat companies from reducing or even terminating their breeding activities and triggered the reactivation of some soya bean breeding programmes' (ibid.:8).

With respect to exotic germplasm, there is little evidence to show that PBRs have led to any significantly improved access for domestic seed companies to modern cultivars, special genetic stocks and genomic material from abroad (ibid.:61-8). Moreover, companies with licences from overseas breeders to use proprietary varieties may sometimes have to contend with restrictions on where they can export to. For example, in 1994 Argentinean strawberry plant growers were prevented from exporting their plantlets to Europe because the United States breeder and the European licensees did not want these plantlets to compete with those that were already produced in Europe.

In Argentina and Chile public agricultural research centres are using PBRs to secure income and collaborate with companies. According to the report, this is shifting the orientation of public research and reduces the public availability of their germplasm.

How are farmers affected? First, Argentinean seed dealers must now pay royalties and taxes on the seed they trade. So far these costs have not been passed on to the farmers. Second, PBR legislation in the three countries where it is well established has not

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[45] It is true though that cash-strapped governments have to reduce their research expenditures out of necessity and the private sector can play a useful role in taking up the slack.

prevented the replanting of farm-saved seed. Third, as the report indicates, 'since many modern plant varieties are not appropriate for resource-poor farmers, PBR predominantly favour plant breeding for those farmers who operate under relatively prosperous conditions' (ibid.:9).

8/ **Alternative proposals for a *sui generis* system**

TRIPS allows WTO members to provide a sui generis alternative to patents for the protection of plant varieties. Frequently such an alternative (to patents) is assumed to be a system based upon the UPOV Convention, either in its 1978 version or the 1991 revision. But Article 27.3 (b) makes no mention of UPOV and permits countries to design their own plant variety protection system as long as it is considered to be effective.

The sui generis system may be defined and provided in various legal forms. For example, the system could be a stand-alone plant variety law, or it could be provided by, say, a modified patent law, as is, for example, with the United States Plant Patent Act, which protects asexually reproduced plants through a modified patent system. Alternatively, the sui generis system could be embedded within non-IPR legislation, such as a biodiversity conservation or access and benefit sharing law, as in Costa Rica.

Realistic proposals for non-UPOV plant variety protection systems have been few and far between. This is probably one of the reasons why more developing countries are joining UPOV. Nonetheless, it is important to consider alternatives to UPOV so that informed decisions can be made.

In order to help countries devise an appropriate sui generis system, the International Plant Genetic Resources Institute (IPGRI) came up with a list of key questions that decision makers should take into account (1999). These are as follows:

- 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 involves will other countries be?

The fact that the answers to these questions will vary widely from one country to another suggests that, as with patents, one size is unlikely to fit all.

Four main types of solutions have been contemplated in the relevant literature. They revolve around the following:

1. A modification of existing UPOV criteria
2. The introduction of the notion of "Value in Cultivation and Use" (VCU)
3. The setting up of a seal system
4. The verification of certificates of origin and of prior informed consent in the course of patent or plant breeders' rights (PBR) examination.

A modification of existing UPOV criteria

How could a sui generis system be devised to resolve the alleged difficulties concerning UPOV's protection requirements? Leskien and Flitner, in their report for IPGRI on options for a sui generis system (1997), suggest a number of alternative requirements.

Relaxing uniformity and stability

The first is to apply a less strict interpretation of 'uniformity' and 'stability' requirements. In theory this might provide an incentive for breeders to rely less on elite germplasm and to seek out less researched and more genetically diverse resources. This could in turn result in more seed varieties appearing on the market and those available differing more widely from the others. More choice for farmers is likely to enhance the viability of agricultural systems everywhere. However, lower standards of uniformity/stability could lead to situations of overlapping between protected varieties as the subject matter evolves through the period of protection (Louwaars 1998, Rangnekar 2002). In particular, who would be the owner of rights over evolved varieties (The Crucible II Group, 2001)? Correa (2000), quoting IPGRI (1999), recommends defining minimum genetic distances between two varieties covered by overlapping claims.

Substituting uniformity for identifiability

The third possibility is to replace the criterion of uniformity with that of identifiability (see also Louwaars 1998, Correa 2000, Rangnekar 2002). Identifiability would "emphasise the legal need to identify the protected subject matter instead of the specific physical properties a plant has to have" (Leskien and Flitner). Accordingly less genetically uniform new (or hitherto not widely used) varieties could become eligible for protection. Presumably this might provide an incentive for breeders to rely less on elite germplasm and to seek out less researched and more genetically diverse germplasm. Rangnekar (2002) also questions the distinctness requirement and quotes IPGRI recommendation[46] that distinctness be based on truly important characteristics, i.e. traits of agronomic or nutritional value. It seems more indicated to insist on agronomic rather than nutritional value, as the former is wider than the latter, and could apply to ornamental plants, of importance to some developing countries such as India.[47] The French Law on plant variety protection certificates of 1970 and the Czech

[46] IPGRI, 1999

[47] An interrogation of the USPTO pre-grant patent database (more than twenty relevant patent applications as of July 1st, 2005) and the USPTO issued patents database shows that the Council for Scientific and Industrial Research of India applies for many patents on plant-related innovations (herbal

Law of 1989 add the notion of "important characteristic". According to the Crucible II Group (2001), more genetic heterogeneity could be recognised simply by altering UPOV examination guidelines.

Leskien and Flitner (1997) discuss the uniformity criterion and suggest that some open-pollinated varieties that have been protected in Europe for decades are hardly less heterogenous than many of today's landraces in many developing countries. Moreover, the Swiss experience shows that the UPOV system can coexist with a "second register" for highly heterogenous groupings of cereals (landraces).

The Crucible Group II (2001) additionally suggests a right for farmers to sell saved seeds in their customary market. This would lead to a case-by-case definition of the relevant market (as is the case in European competition law).

Tripp (2003) proposes the establishment of regional common variety catalogues, and, further, regional harmonised variety registration systems. This could also extend to regional or sub-regional seal systems. Harmonisation would be relevant as long as the cultural systems of the countries participating in the scheme are similar.

Providing protection for folk varieties (landraces)

The second is to allow both homogeneous/uniform varieties and heterogeneous folk varieties to be protected. However, if more fuzzily defined rights are provided so as to protect local/traditional varieties, rights should be limited in nature (Leskien and Flitner 1997, Rangnekar 2002). One possible danger of allowing broader claims in this way is that corporate bioprospectors rather than local communities would take advantage of this and 'jump the queue' by promptly submitting applications for discovered landraces (or those they already hold in their collections).

The Plant Variety Protection Act, B.E. 2542 (1999) of Thailand establishes a distinction between a "new plant variety", defined as *per* the UPOV Convention, and a "local domestic plant variety", i.e. "a plant variety which exists only in a particular locality within the Kingdom and has never been registered as a new plant variety and which is registered as a local domestic plant variety under this Act". A new plant variety shall not constitute a "wild plant variety", i.e. "a plant variety which currently exists or used to exist in the natural habitat and has not been commonly cultivated."[48]

The introduction of a requirement to describe the breeding method

Louwaars (1999) considers that UPOV-type laws could require that the applicant disclose the method through which he develop the variety, the materials used and evidence showing that he was duly authorised to make such use of these materials (Material Transfer Agreements, other contracts, etc…) Art. 3 of The Plant Variety Protection Act, B.E. 2542 (1999) of Thailand states that "details showing the origin of the new plant variety or the genetic material used in the breeding of the variety or in the development of the new plant variety, including its breeding process, provided

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compositions, novel compounds, novel uses of known compounds), including plant patents on ornamental or pharmaceutical varieties (see for instance PP 14,287, PP 12,030).

[48] See Articles 3 and 11 of the Plant Variety Protection Act, B.E. 2542 (1999) of Thailand.

that details enabling clear comprehension of such process shall also be included." Art. 44 of this Act requires likewise that the application for a local domestic variety contain "at least (…) the plant variety jointly conserved or developed and the method of its conservation or development." The Portuguese Decree-Law no 118/2002 described below includes a similar provision under Art. 3 (2)(b): "the description [of traditional knowledge associated with the commercial or industrial utilization of local varieties and other autochthonous material developed in a non-systematic manner by local populations, either collectively or individually] shall be so phrased that third parties may reproduce or utilize the traditional knowledge and obtain results identical to those obtained by the owner of the knowledge."

The introduction of the notion of "Value in Cultivation and Use" (VCU)

The value in cultivation and use (VCU) used to be a criterion for PBR protection in Germany. The rationale for reinstating this criterion is that a variety may offer significant advantages in some parts of a country and not in others, or that it may have lower yields than other varieties but prove resistant to specific pathogens. Leskien and Flitner (1997) argue that the VCU of protected varieties would have to be reassessed periodically. This is particularly true as pathogens themselves evolve, spurring new adaptations in plants or conversely, rendering the VCU of a given variety higher to what it used to be, or lower. This discussion is not far from that on distinctness and the notion of important characteristic.

The verification of certificates of origin and of prior informed consent in the course of patent or plant breeders' rights (PBR) examination.

The creation of certificates of origin and of prior informed consent, which should be issued by source countries prior to the granting of patents or PBRs in the same or third countries, would raise a series of questions. First and foremost, an international coordination would be required for species that can be found in several countries, or even continents (Leskien and Flitner, 1997; The Crucible II Group, 2001). As wondered by the Crucible II Group (2001), what could applicants do if the relevant authority in the source country does not answer their request? A way to answer this situation would be for patent offices to accept evidence of filing of such a request. The rationale behind certificates of origin lies in the implementation of benefit-sharing schemes in source countries and the documentation of prior art in patent examination. If the source country faces difficulties concerning the first objective, the second one should not be impeded, in order to ensure that traditional knowledge is not described in a patent application, in the interest of custodians of traditional knowledge and of a good administration of patent offices[49]. In this respect, Mangeni (2000) and Mgbeoji (2001) indicate that there would be a need for a uniform standard of novelty and prior art. The Crucible II Group (2001) questions how far back should the ancestry of a plant be traced for the purpose of obtaining a PIC certificate. Srinivasan (2003) signals that transaction costs for obtaining protection will increase as breeders will be asked to establish that their parental lines – which may be numerous – have

[49] The argument concerning the good administration of patent granting is two-fold: firstly, the novelty requirement has to be fulfilled; secondly, disclosure of origin may facilitate the working of the invention where the biological material used in the invention is endemic to a specific location – cf. WIPO/IP/GR/05/3 at 106.

been legally obtained. Currently, parental lines are accessed at nominal costs of about US$ 5-20 (ten Kate & Laird 1999, quoted by Rangnekar 2002).

Trying to reconcile the FAO International Treaty, in particular its benefit sharing scheme envisioned under Art. 13.2 (d) (ii), and the TRIPS Agreement, Helfer (2002) argues that TRIPS nowhere prohibits members from imposing fees or levies associated with the holding of patent rights, which is indeed the common practices of patent offices. Additionally, as noted by Correa (2000), collective entities for the collection and administration of authors' rights are common in the field of copyright and related rights. For their part, Leskien and Flitner (1997) consider that benefit-sharing schemes, which were already called upon by Chapter 14 of Agenda 21 (1992) and the FAO Code of Conduct for Plant Germplasm Collecting and Transfer (1993), should be implemented in a context broader than intellectual property rights, as not all uses of plant genetic resources are covered by IPR applications; accordingly, exclusive marketing rights should give rise to benefit-sharing as well. These authors show nonetheless the limit of a model of concurrent implementation of both FAO ITPGR and TRIPS that would exclude altogether IPR-like rights and be confined to marketing rights. In such a case, the distribution of revenues obtained from a seed tax levied by the government would not fit the concept of civil and administrative procedures and remedies, as there is no remedy for the right holder against tax evasion.

Indeed, it seems that the very idea of a multilateral fund for benefit-sharing purposes each time that plants incorporating material accessed from the FAO Treaty multilateral system are commercialised was inspired by existing copyright collecting societies (collecting levies on photocopy machines, blank tapes, public radio or cable broadcasts…). It must be hoped however that the multilateral system will not be prone to similar criticism as collecting societies, which are reproached with being tempted by a monopolistic behaviour, as well as by a bureaucratic drift, and having inherent conflicts of interests (between authors/artists and publishers/phonogram producers)[50]. Another type of criticism that could be addressed to such a multilateral system is that, in most instances, it will not be straightforward to reconstruct the parentage of plant genetic resources and to locate the place where they originate from, in order to allocate benefit shares. Thus, it can be argued, in reference to the FAO Resolution 5/89, that the multilateral system will not aim so much at rewarding past contributions but rather at encouraging future ones and conservation of plant genetic resources by local communities.[51] The FAO multilateral system is based on liability rules rather than on a property paradigm,[52] as an answer to a situation of market failure – due to difficulties in appropriating a rent on traditional agricultural knowledge – and to high transaction costs (presence of too many potential licensors).

The Plant Variety Protection Act, B.E. 2542 (1999) of Thailand, as well as the Decree-Law no 118/2002 of Portugal, institute a benefit-sharing scheme. In Thailand, "[w]hen a plant variety only exists in a particular locality and has been conserved or developed exclusively by a particular community, that community shall have the right to submit, to the local government organisation in whose jurisdiction such community

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[50] See Roger Wallis, Charles Baden-Fuller, Martin Kretschmer and George Michael Klimis 1999, and Martin Kretschmer 2002.
[51] See Stephen Brush 2003; see also Correa (2000) at 12.
[52] See Calabresi, Guido and A. Douglas Melamed, 1972.

falls, a request for initiating an application for registration of the local domestic plant variety in the name of such community."[53] This local government organisation, or the farmers' group or co-operative to which the certificate of registration of the local domestic plant variety is granted, shall make a profit-sharing agreement in the name of the community with a "person who collects, procures or gathers a local domestic plant variety or any part thereof for the purposes of variety development, education, experiment or research for commercial interest."[54] The Thai law sets up a Plant Varieties Protection Fund that shall receive income accruing from benefit-sharing agreements for the collection or use of domestic plant varieties or wild plant varieties.[55] Interestingly, the Thai law provides an exemption for farmers: a farmer may cultivate the propagating material that he obtained and saved from a protected local domestic plant variety, so long as the quantity obtained by further propagation does not exceed three times the quantity initially obtained.[56] A final remark concerning the Thai scheme relates to the co-ordination between this law and trademark protection. Art. 67 states that "[a]ny person who forges or imitates a mark or does any act for the purpose of misleading other persons that a given plant variety is a protected plant variety under this Act shall be liable for imprisonment for a term of six months to five years and to a fine of twenty thousand to two hundred thousand Baht."

The Portuguese Decree-Law dated April 20, 2002 for the registration, conservation, legal safeguarding and transfer of autochthonous plant material and associated traditional knowledge takes a broader stance by creating a link between a *sui generis* scheme for the protection of traditional knowledge and unfair competition law, including the registration of geographical indications (specifically referred to in the sixth preambular paragraph, as mentioned by Bhatti, 2004, and in Art. 6). The subject matter of the Portuguese scheme is any "autochthonous plant material of current or potential interest to agrarian, agroforest and landscape activity, including the local varieties and spontaneously occurring material (…) as well as associated knowledge", "regardless of their genotypical composition, with the exception of varieties protected by intellectual property rights (…)"[57] Plant material that falls within the scope of the Decree "may be registered" in the Register of Plant Genetic Resources (RRGV).[58] Associated "traditional knowledge shall be identified, described and registered in the register of Plant Genetic Resources (RRGV)".[59] However, the owners of the traditional knowledge may choose to keep it confidential; the registration is then limited to the disclosure of the existence of the knowledge and identification of the varieties to which it relates. In any case, in order to be registered, the knowledge is required to not have been used in industrial activities and not be publicly known outside the population or local community in which it originated. Registration confers the right to object to the direct or indirect reproduction, imitation or unauthorised use of the knowledge, and to assign, transfer (including by succession) or license the

[53] Art. 45
[54] Art. 48. Article 49 describes how the percentages of benefits accruing from the commercial use of a local domestic plant variety are broken down between the different stakeholders, namely the persons who conserve or develop the plant variety, the community and the local government organisation, the farmers' group or the co-operative.
[55] See Art. 54
[56] See Art. 47(3)
[57] Cf. Art. 1(1) and 2(1).
[58] Art. 4(1)
[59] Art. 3(2)(a)

rights in the traditional knowledge. The registration of traditional knowledge is effective for a period of 50 years from the application, and may be renewed for an identical period. In contrast, the registration of plant material is valid for a period of 10 years, renewable for subsequent periods of the same duration. "The use, for industrial or biotechnological purposes, of plants or parts thereof included in the [protected] plant material (…), either directly or through application of the active ingredients contained in them, shall also be subject to prior authorization by the Technical Council of the Ministry of Agriculture, Rural Development and fisheries on Agrarian Genetic Resources, Fisheries and Aquaculture (CoTeRGAPA) (…)".[60] Such "access (…) requires a fair allocation of the benefits resulting from such use, by prior agreement with the owner of the registration."[61] The owner of a registration may be any entity, whether public or private, individual or corporate, that represents the interests of the geographical area in which the local variety is most widely found.[62]

As rightly highlighted by Carvalho (2003), it is still early at this stage to evaluate the impact of these statutes. Nonetheless, Carvalho (2003) observes that the Portuguese system grants a protection *erga omnes* of private property rights (even collectively held), while ensuring dissemination of useful knowledge, and empowering people rather than their government.

The plant variety protection seal model[63]

According to Leskien and Flitner (1997), this model would grant the right holder an exclusive right to a seal or certificate for a variety that has fulfilled the requirements laid down in the *sui generis* system (e.g. distinctness and identifiability). The difference between such a seal and a trademark is that the seal would not only constitute the variety's denomination but would also certify full compliance of the variety with the protection requirements. Only the use of the seal in combination with the registered denomination and the material of the variety would be the exclusive right of the holder and those having the holder's authorisation.

Once seed has been sold by the seal owner or others authorised by the owner, there will be no further restrictions on use and sale of the variety. Thus farmers would be allowed to save and sell seed. Leskien and Flitner argue that in spite of this, the seal holders could still enjoy a competitive advantage especially if the protection requirements of the *sui generis* system were adapted to the needs of farmers. Given that the rights are not as strong as those provided by the UPOV Convention or patents, Leskien and Flitner suggest that the duration of the right could be made longer than the minimum protection terms required by UPOV or the TRIPS patent provisions.

In Helfer (2002)'s view, following Tewolde (1996), under a seal system, the protected material would remain absolutely free; only the use of the seal in combination with the registered denomination and reproductive material of the variety would be the exclusive right of the holder and authorised persons. Rangnekar (2003) has a slightly

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[60] Art. 7 (2)
[61] Art. 7 (4)
[62] Art. 9
[63] According to Heitz (pers. comm. 1998), this model is based on an abandoned IPR system devised in Czechoslovakia in the 1920s.

differing perception of this system, insofar as this author considers that it confers a competitive advantage to the breeder, without defining infringing acts. It seems that Tewolde describes rather the exclusive marketing rights mentioned by the Crucible II Group.

It seems very doubtful that seal holders really could sustain a comparative advantage for any length of time when other breeders (or farmers) can so easily produce and sell the same variety. Therefore, the system would almost certainly be highly unpopular with plant breeders, who, if the system came into existence, would very likely respond by focusing more of their research on developing genetically-uniform hybrids and crops that lend themselves to hybridisation. Helfer (2002) warns that it would be ill-advised where consumers do not put a premium on the quality and source of the seeds they purchase.

In practice, many national seed certification laws are based on the UPOV "DUS test" and make varietal registration and certification compulsory for seed commercialisation. However, as underlined by Louwaars (2005 b), in most of these laws the term "commercialised" is not defined. Where it is, like in South Africa and Malawi, it may cover exchange and barter. In the case of Malawi, this situation is mitigated by the fact that certification rules only apply to a certain number of crops or varieties, like in Zambia, India, Bangladesh or Indonesia. The latter country has additionally defined a specific exemption for farm-produced seed marketed within the village. As to Zambia, followed by Sri Lanka and Thailand, the certification procedures have been relaxed and interpreted more flexibly. The challenge in designing or modifying seed certification laws consists in combining divergent interests or goals, such as promoting foreign direct investments by foreign breeders, initiatives aimed at reducing on-farm loss of genetic diversity, and consumer protection (Louwaars, 2005 b)

The 'remuneration without ownership/property right' model

This model has been proposed by Butler and Pistorius (1996). Accordingly, it is designed with the following objectives: (i) to remunerate innovative plant breeding and provide incentives to encourage the development of novel plant varieties; (ii) to allow farmers access to varieties available on the commercial market and to save, sell, exchange, and use these varieties for breeding purposes, without violating private property rights; and (iii) to provide incentives to preserve, create and enhance biodiversity. Butler and Pistorius (ibid.) propose that the system should follow the example of a Dutch law in force between 1941 and 1966 by eliminating the concepts of 'ownership' and 'property rights' in plant genetic resources and relaxing the conditions for the registration of new varieties. The model would require all farmers to pay a tax on each crop based on the number of hectares they planted in each crop variety. The funds collected this way would be used to pay plant breeders a remuneration for breeding new varieties with payment based on the proportion of total hectares planted each year for 25 years. The right of farmers to save, sell and use seed for breeding purposes would not be restricted. According to the two authors (ibid.), although breeders are likely to be concerned about these freedoms, in developing countries they may have little to lose from not being able to enforce exclusive rights to their varieties. This is because most of the seed trade in developing countries is in the informal sector, and farmers often cannot afford new commercial varieties.

Butler and Pistorius also acknowledge that estimating the areas of cropland planted in a particular variety could be difficult. One might go further and suggest that the costs of monitoring and enforcement could be so huge as to make the system unworkable, especially in large countries and those that lack an effective seed certification system. Besides, TRIPS states that IPRs are private rights, yet this system does not allow the breeders even to control the level of remuneration due to them. Therefore, it may well be considered unacceptable by the TRIPS Council.

The Convention of Farmers and Breeders (CoFaB)

This model was devised by an Indian NGO called Gene Campaign (1999). In Article 1, the purpose of CoFaB is stated as follows:

> to acknowledge and to ensure that farmers have rights ensuing from their contribution to the identification, maintenance and refinement of germplasm and that breeders of new plant varieties have rights over the varieties that they have bred.

With respect to the requirements for protection, CoFaB is quite similar to UPOV in that the new variety must also be distinguishable, stable and homogeneous. However, while UPOV also requires that varieties must be distinguishable from any other variety "whose existence is a matter of common knowledge", CoFaB seeks to clarify the meaning of "common knowledge" so that no knowledge within local communities relating to a "new" plant variety, whether documented or not, can legally be misappropriated. According to Article 6 (a):

> Common knowledge may be established from oral or documented reference in the formal and informal sector, to various factors such as: cultivation, use and marketing already in progress, entry in a register of varieties already made or in the course of being made, inclusion in a reference collection or precise description in a publication.

Supplementary text in the paragraph dealing with stability states that

> Breeders of new varieties shall try to base the new variety on a broader rather than a narrower base, in order to maintain greater genetic diversity.

This is an interesting requirement though it is difficult to see how it could be turned into a binding obligation. Inclusion of the verb "try to" implicitly acknowledges that it is intended to encourage rather than oblige breeders to breed genetically-diverse varieties.

When applying for protection, the breeder is required to disclose

> the name and source of all varieties used in the breeding of the new variety. Where a landrace or farmer variety has been used, this must be specially mentioned (Article 6.1 (b))

Also, upon receiving the right, the breeder must

> provide the geneology of the variety along with DNA finger printing and other molecular, morphological and physiological characteristics (Article 7.2).

With respect to the rights of farmers, these are monetary in nature and have no time limit. Basically, they are in the form of funds paid from a National Gene Fund. Decisions on distribution of funds, which may go to communities or individuals as appropriate, will be made by a "multi-stakeholder body" (Article 2 (3)). Contributions to the NGF will be in the form of fees levied on breeders "for the privilege of using land races or traditional varieties either directly or through the use of other varieties that have used landraces and traditional varieties, in their breeding program" (Article 2 (1)). In its present form, CoFaB apparently envisages a flat-rate fee for the use of a landrace or traditional variety rather than a weighted sum according to how far a particular landrace/variety contributed to the useful characteristics of the new variety or to its genetic make-up.

Two problems can be identified that ought to be considered in any revision of CoFaB. First, it should be remembered that the final customers of seeds are the farmers. If the seed companies raise their prices to make up for their losses due to the fee payments, the farmers themselves will be the real contributors to the gene fund.[64] Second, new varieties use a very large number of landraces as breeding material and from various countries. For example, the breeding of IR-72, a rice variety developed at the International Rice Research Institute, depended upon landraces that came from India, Vietnam, Philippines, China, Indonesia, Thailand, Malaysia and the United States (see Chrispeels and Sadava 1994). This raises two sets of questions.

First, should only *domestic* landrace providers be compensated? Presumably, this is what would happen, but whatever, this should be made clear in the text. Alternatively, future CoFaB member states could apply the reciprocity principle by recognising and compensating communities and individuals only from other member states whose governments agree to do the same.

Second, should community or individual donors be compensated *only* for their present-day donations of germplasm, or should compensation be paid for -- and fees levied on -- use of germplasm collected in the past, held in *ex situ* collections, and subsequently acquired by breeders? In case of the latter, how far back in time would collected germplasm continue to be subject to fee payment?

9/ Conclusions

Rangnekar (2002) seems to offer the best concluding words when he writes, after Mangenni (2000), that the notion of effective *sui generis* system could be widened by including concerns about national development, in compliance with TRIPS Art. 7 and 8 and with the CBD. As mentioned earlier, this approach was endorsed by the Doha Declaration under paragraph 19. Rangnekar (2002) recommends, as Ghijsen (1998), Louwaars (1999), and IPGRI (1999), a patent-like protection for ornamental and high-value crops, and weaker protection for other species, especially open-pollinated food crops. The Ethiopian proposal during the negotiations of the CBD, quoted by Mgbeoji

[64] Dr Suman Sahai, Gene Campaign's Director is aware that the National Gene Fund would require funds from other sources and has suggested the levying of sales taxes on non-agricultural goods as one possibility (pers. comm. 1999).

(2001), of domestic laws invalidating the domestic efficacy of any patents or other IPRs on plant genetic resources can be contrasted to the Singaporean patent law reform described by Watal (2001) and mentioned earlier. Countries, especially developing ones, may exclude patent protection on plant genetic resources (although not on non-biological processes); they will nevertheless have to protect PGRs at least through exclusive marketing rights, combined or not with a seal system. They may also opt for a differentiated system of protection. In all cases, they will need to adopt where necessary legislations on prior informed consent and certificates of origin, and on benefit-sharing.

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