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1. Protection of Plant-Related Innovations: Evolution and Current Discussion

2. Intellectual Property Rights, Patents, Plant Variety Protection and Contracts: A Perspective from the Private Sector

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Contents

Editors' Introduction:
PVP and Agricultural Productivity

This volume of *IP Strategy Today* is the first in a series of papers that consider the role of intellectual property (IP) protection in stimulating plant breeding. The first in this series contains two papers: one by Bernard Le Buanec of the International Seed Federation, who provides a comprehensive, global and balanced summary of the evolution of plant variety protection (PVP) and utility patents on plants regulations, and analyses the current situation with specific reference to the patenting of plants. He also highlights a series of unresolved issues, specifically those relating to farm saved seed provisions under UPOV, the need for better protection of hybrid parental lines, and a call for enhanced cooperation among the plant protection offices across the world.

The second paper by a group at Pioneer Hi-Bred International/DuPont Agriculture and Nutrition (Jean Donnenwirth, John Grace and Stephen Smith) provides a private sector point of view with in-dept experience from the USA. They share their experiences in a wide range of aspects and point out the overwhelming need for increased private sector investments in plant breeding as public sector investments have fallen far short of global needs. They discuss eloquently the dual nature of IP protection and how their application can encourage—or hinder—the use of a diverse germplasm, the exchange of and access to improved varieties, the adoption of new technologies, and the increased investments in plant breeding. In that paper, the distinction between protection afforded to plants and to biotechnological inventions *per se* is also discussed together with its ramifications to agricultural productivity. Specifically, they point out the risks of an IP environment that provides strong protection for genes (viz. biotechnological inventions), but weak protection for newly developed varieties *per se*, as "such an environment will tend to encourage the making of relatively small genetic changes on existing varieties while also discouraging the sourcing and introduction of new and useful germplasm".

It might be appropriate to briefly review here the basic rationales for PVP or plant breeders rights (PBR) systems. As in many endeavors, the information value of plant breeding is not decreased if shared with others. What is lost to the breeder, however, is the "market value" if others appropriate the new variety and sell it at the mere cost of seed production. PVP provides the opportunity for breeders to gain a return on the investment made in breeding a new variety. Even though new varieties may be protected, as long as farmers continue to have choices and access to public varieties—or the right to save seed of non-protected varieties (a right that evidently would never be curtailed)—PVP or PBR systems will benefit farmers and agricultural productivity by stimulating private sector investments, increase varietal choices for farmers, and facilitate technology transfer and agricultural development efforts, including the acquisition of biotechnology.

One of the most unique characteristics of seeds is that they are the means of delivering sophisticated technologies in the simplest possible form to any farmer. Thus, advanced technology can be purchased in corner shops in small villages, as long as the improved varieties are being distributed. Companies, however, are deterred from entering markets if varieties—and thus their investment—cannot be protected. As a consequence, farmers are denied the opportunity to access, use or try the new improved varieties. Hence, the cost associated with a delay in developing enforceable PVP systems lies in the delay that farmers will experience in accessing more productive varieties.

These benefits have led many countries around the world to enact PVP and related legislation for decades. As a result of the TRIPS accord under WTO, awareness of the value of PVP world wide has increased significantly and contributed to many countries joining UPOV. Membership now exceeds 50 across the world (Figure 1), some 20 countries formally applied for membership and another group of a dozen or more intend to do so soon. However, there are other mechanisms of *sui generis* systems (Table 1) although the harmonization of regulatory approaches, including those of IP, often yield significant benefits. The following four aspects (discussed in more detail by Krattiger and Potter 2002) are perhaps the most important from the perspective of developing countries:

The Establishment of Enforcement Mechanisms

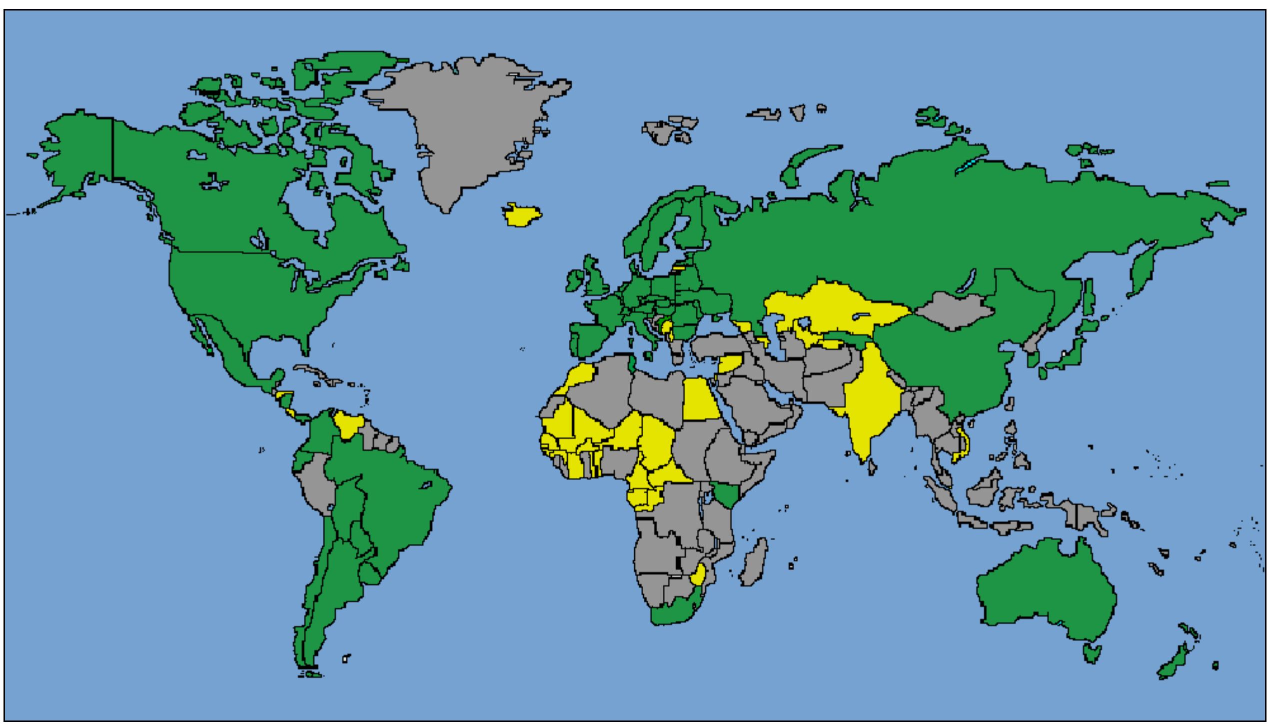
Any law is only as good as its enforcement. This is an area to which countries need to pay particular attention in order not to lose the advantages that an effective PVP system provides. Most legislation incorporates remedies for infringement, but taking advantage of these remedies requires an undertaking that the legal system will recognize the rights of the PVP holder. If a third party is selling a variety, then the holder of the PVP certificate must be able to:

- Take appropriate legal action that is neither very time consuming nor costly;
- Obtain an injunction against the illegal sale of the certified variety; and
- Obtain damages for the illegal action.

Harmonization and Regionalization Leading to Lower Costs and Increased Access to Improved Varieties

A PVP regime—harmonized across different countries of the same region—would significantly lower the costs for users, and hence increase the returns on plant-breeding investments and lead to more varieties and choice for farmers. A costly regime discourages smaller national companies from filing for PVP protection and increases the cost of participating in foreign markets; this favors large multinational companies who have the resources and infrastructure to operate across multiple national regimes.

Figure 1: UPOV Member Countries (54) and States that Applied for UPOV Membership (20)



Areas in green: UPOV member countries. Areas in yellow: Formally applied for membership.

Source: Courtesy UPOV 2004.

Table 1. Comparison of plant variety protection systems

Criteria	**UPOV 78**	**UPOV 91**	**TRIPs Compatible Patent Law**[a]	**Utility Patents** (since 1985; USA)	**Plant Patent Act** (since 1930; USA)	**PVP Act** [b] (since 1970; USA)
Protects	Varieties of selected genera and species as listed	Varieties of all genera and species	All plant species and enabling technologies	Plant genotypes not normally found in nature	Asexually reproduced plants, incl. cultivated, mutants and hybrids	Sexually reproduced plants
Excludes					Uncultivated and tuber-propagated plants	First-generation hybrids, uncultivated plants
Requires	Novelty Distinctness Uniformity Stability	Novelty Distinctness Uniformity Stability	Novelty Inventiveness Enablement	Novelty Utility Non-obviousness Enablement	Novelty Distinctness Stability	Distinctness Uniformity Stability
Disclosure	Full description	Full description	Description of novel characteristics and genealogy Enabling disclosure Deposit of novel material	Enabling disclosure Best mode disclosure Deposit of novel material	As complete as possible Photographs or drawings	Description of novel characteristics and genealogy Seed deposit
Claims			Not determined	Varietal claim, generic claims Claims to plant genes, gene transfer vectors, processes for producing plants, and so on	Single varietal claim	Single varietal claim
Rights	Prevent others from producing for commercial purpose, offering for sale, marketing	Prevent others from producing or reproducing, conditioning for the purpose of propagation, offering for sale, selling or other marketing, importing, exporting, stocking for any purposes detailed above	Making the patented product, using the patented process, or using, offering for sale, selling or importing for those purposes the patented product or the product obtained by the patented process (extends to harvested material)	Prevents others from making, using, selling claimed invention Prevents others from selling a component of the claimed invention	Prevent others from asexually reproducing, selling, or using claimed plant	Prevents others from importing or selling, sexually or asexually reproducing, distributing without proper notice Prevents others from producing a hybrid or new variety using the claimed plant

continued…

Exemptions	Exemptions for breeding and for farmers to save own seed mandatory	Exemptions for breeding except where new variety is essentially derived, optional farmers exemption and only for use on same farm and subject to a license and/or fee, private use and research	Breeders' rights and farmers' rights in principle compatible with TRIPs but not yet tested		Does not protect sexual reproduction of claimed plant Does not protect plant products	Exemptions for developing a new hybrid or variety and for farmers' saving and sale of seed, compulsory license provision
Duration of protection	15 years 20 years for grapevines and trees	20 years 25 for grapevines and trees	20 years from date of filing	20 years from effective filing date (after 8 June 1995) 17 years from issue date (prior to 8 June 1995)	20 years from effective filing date (after 8 June 1995) 17 years from issue date (prior to 8 June 1995)	Protected while application is pending, plus 20 years from issuance date (25 years for vines and trees)
Priority				First to invent in the United States	First to invent in the United States	First to file in the United States or another UPOV member country
Double protection	Protection by both patent and PVP not allowed	Protection allowed by both patents and PVP				

Source: Compiled by Krattiger and Potter (2002).

a Modified from Helfer (2002).

b The initial PVP Act of the United States was not UPOV compliant, but this was rectified, and in 1980 the United States acceded to UPOV 1978 and later to UPOV 1991. A further jump in investment was seen after 1986 when the US Patent and Trademark Office established that plant varieties were patentable subject matter.

This is illustrated by the European situation. Whereas in the past, breeders had to apply separately in each country where they wanted to release their variety, translate the applications into a number of different languages and pay fees in each country, the European Union has created a single Community Plant Variety Office. The procedures to be followed and the conditions required in relation to a variety submitted for community protection is simplified and significantly reduces costs, both for the operations of the PVP system and the applicants.

The need for integrated training and investment programs

In order to reinforce the national policy initiatives in many countries, a comprehensive, in-depth training program is recommended to equip personnel with the information and experience required to solidly establish the long-term health of a PVP system. This can be combined with a drive to regionalize the PVP system by joint training of administrators from a number of countries, which will increase co-operation and harmonization.

The Separation of the Treatment of Modern Varieties from Landraces and Farmers' Rights Issues in National PVP Systems

Many PVP laws that have recently been passed or are being drafted in many countries have their origins in the early 1990s and came amid the excitement of the "Rio" Conference and the drafting of the Convention on Biological Diversity (CBD). An example would be several laws in Asia that combine some of the CBD philosophy with aspects of UPOV. In the years since many of the PVP laws were written, some countries have developed an elaborate committee system, representing various stakeholders charged with advising those drafting the PVP regulations. However, that task in countries wishing to join UPOV has become complicated because many laws (or draft laws) include special treatment for landraces and farmers' rights. In any system, it is important is to keep in mind the essential basis of plant breeding which is access to materials and deposits of materials. For example, to what extent are PVP regimes and utility patents on plants complementary or not? How do these different systems complement each other? And how can a system be devised that encourages the conservation of landraces, both *in situ* and *ex situ*? One option might be to have one law, but then proceed with the implementation of different regulatory mechanisms—one that specifically addresses the landraces and farmers' rights issues, and another one that specifically responds to the objectives of enabling farmers access to the benefits of increased private sector investments. In that way, perhaps, the requirements of UPOV might be met while still respecting the important conservation and equity objectives of the farmers' rights concepts.

Interestingly, countries like India recently initiated the procedure to join UPOV following the parliament's (Lok Sabha) passing of the Indian PVP Bill. As MS Swaminathan noted: "I am happy that at last the Lok Sabha has passed the Protection of Plant Varieties and Farmers Rights Bill. This is a major step in incorporating the ethics and equity of the convention on biological diversity in *a sui* generic system of varietal protection. If implemented in an effective, transparent and speedy manner, the provisions of the bill will improve crops through breeding as well as revitalize the conservation traditions of tribal and rural communities."

Anatole F Krattiger

References

Helfer LR. 2002. Intellectual property rights in plant varieties: an overview with options for national governments. *FAO Legal Papers Online*, No. 31. http://www.fao.org/Legal/Prs-OL/lpo31.pdf

Krattiger AF and RH Potter. 2002. The Status of Plant Variety Protection Issues in the Asia-Pacific Region. APSA Technical Report No 32. APSA: Bangkok. Pp. 1-22.

Swaminathan, MS. 2001. *Down To Earth* 10(8): 48-51. http://www.oneworld.org/cse/html/dte/dte.htm

Protection of Plant-Related Innovations:

Evolution and Current Discussion [1]

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Executive Summary

The protection of plant-related innovations is currently being debated in many international fora with various views expressed on ethical, political and technical grounds. With the exception of the US Plant Patent Act, passed in 1930, the major developments for the protection of plant-related innovations have been achieved during the last 40 years of the 20th Century. These are discussed in detail and include:

- The UPOV Convention and its last 1991 revision.
- The Utility Patent for Plant Varieties
- The TRIPS Agreement
- The European Regulation on the Protection of Plant Varieties
- The European Directive on the Protection of Biotechnological Inventions.

Some of the above have been shaped by milestone court cases which are analyzed, namely a case before the Technical Boards of Appeal at the European Patent Office and before the Enlarged Boards of Appeal of the European Patent Convention (Novartis *vs* Plant Genetic Systems), and the J.E.M. Ag Supply Inc. *vs*. Pioneer Hi-Bred International Case in the USA.

Today there is a coherent set of international and regional treaties as well as national laws and regulations allowing for the effective protection of plant-related inventions. However, many issues often surface to the top of the agenda for debate:

- From a political point of view there is some evidence that adequate protection of plant-related inventions is an incentive for research with a positive impact on horticulture and agriculture industries and on foreign investment and trade.
- Technically several question are reviewed:
    - The patenting of gene sequences
    - The view by many that broad patent claims in utility patents
    - The implementation of the concept of essential derivation and dependence
    - Access to plant varieties protected by utility patents
    - Access to plant varieties protected by PBR and containing patented elements.

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[1] Le Buanec, B. 2004. Protection of Plant-Related Innovations: Evolution and Current Discussion. *IP Strategy Today* No. 9-2004. Pp. 1-18.

Except if explicitly expressed, the opinion given in this paper is that of the author and not of the International Seed Federation, ISF.

Several weaknesses of the present system are analyzed and some suggestions are proposed for improvement:

- The strict application of the UPOV farm saved seed provision by UPOV member countries
- The utilization of the possible protection of products made directly from harvested material of the protected variety
- A better protection of hybrid parental lines
- A better cooperation of Plant Protection Offices across the world.

It is concluded that the present legislative arsenal for the protection of plant-related innovations, if fully implemented, should give effective protection to biotechnology inventors and plant breeders. However, to be fully satisfactory, some improvements in the UPOV Convention should be made as regards the protection of hybrid parental lines, the management of farm saved seed, and the protection of the product obtained directly form the harvested material of the variety. The challenge of assessing distinctness with an increasing number of species and of varieties within each species will have to be faced with caution but also with new ideas.

1. Evolution of the Protection of Plant-Related Innovations

1.1 The Legal Framework

The evolution of the protection of plant varieties is well documented until 1978 (Heitz 1978). The two major milestones are the Plant Patent Act in the United States in 1930 and the establishment of the UPOV Convention in 1961. Both will be briefly reviewed below, followed by a detailed review of more recent developments.

1.1.1 The Plant Patent Act in the USA

The Plant Patent Act was due to the intense lobbying of Luther Burbank, a famous horticulturist at the end of the nineteenth and beginning of the twentieth centuries. It opened the patent route to vegetatively propagated varieties but excluded tuber crops. This important step, however, was not followed widely by other countries.

1.1.2 The UPOV Convention

The UPOV Convention, adopted in 1961, was the second significant step taken to protect plant varieties. A true *sui generis* system at the international level, it is the outcome of several decades of action by plant breeders and the establishment, in 1938, of ASSINSEL,[2] the international Association of Plant Breeders for the Protection of New Plant Varieties (*Association Internationale des Sélectionneurs pour la Protection des Obtentions Végétales*). It was understood at its 1954 congress in Semmering, Austria, that patenting plants at that time was a blind alley, and so ASSINSEL passed a resolution calling for the organization of an international conference to consider officially the question of protecting new plant varieties and, if possible, to lay down principles to govern that protection. With the support of France, this opened the way for the first session of a Diplomatic Conference in 1957. At its second session in

[2] ASSINSEL was merged in 2002 with FIS, the International Seed Trade Federation (established in 1924), to form ISF. See www.worldseed.org

1961 UPOV (*Union pour la Protection des Obtentions Végétales; see www.upov.int*) was created. It entered into force in 1968.

The main features of the 1961 Act of the UPOV Convention are (UPOV 1985):

- Scope of protection:
  Authorization of the breeder is required for the:
  - production for the purposes of commercial marketing;
  - offering for sale; and
  - marketing

  of the reproductive or vegetative propagating material, as such, of the variety.

  Note that the breeder's authorization is not required either for the use of the variety as an initial source of variation for the purpose of creating other varieties or for the marketing of such varieties. This is the "breeder's exception," a central feature of the UPOV Convention.

- Conditions required for protection:

  Whatever may be the origin, artificial or natural, of the initial variation from which it has resulted, the variety must be:
  - clearly distinguishable from any other variety of common knowledge;
  - novel, in terms of commercialization;
  - sufficiently homogeneous; and
  - stable.

A list of 15 species that had to be protected by Members of the Union after 8 years of ratification of the Convention was annexed. It was also stated that the Convention might be applied to all botanical genera and species.

The Convention was revised in 1972 and 1978 with very few changes in the substantive provisions. It provided for a larger grace period of marketing abroad without affecting novelty and obligated the protection of at least 24 genera and species 8 years after having ratified the Convention, without any species listed in the Convention. In 1986, 17 countries were members of the 1978 Union.

1.1.3 Utility Patents for Plant Varieties

The US Utility Patent law designates four broad categories of patentable subject matter: composition, machines, articles of manufacture, and processes. Plants and biological subject matter are not explicitly included. However, in 1980, the Supreme Court decision in *Diamond v. Chakrabarty*, construed section 101 to encompass genetically modified organisms. This case undoubtedly helped to open the gates for the ensuing patents for genetic engineered biological material and plant/plant varieties. In April 1986, based on the US Patent and Trademark Office (USPTO) Board of Appeals and Interferences (the *ex parte* Hibberd decision), the first utility patent for a plant was granted (a high tryptophan corn). Since that date, hundreds of utility patents for plant and plant varieties have been granted. The three main reasons why some seed companies in the US[3] were turning to utility patents are, by order of importance in the opinion of the author:

- The development of biotechnology and transgenic varieties. The possibility of patenting biotechnological inventions and "appropriating" plant varieties protected by PVP thanks to the "Breeder's exception" was considered too unbalanced and minimized the importance of "classical" breeding research.

[3] Utility patents may also be granted for plant varieties in other countries such as Japan and Australia, but that possibility is not used frequently by seed companies.

- The ban of farm saved seed, allowed without restriction in the US plant variety protection act.
- The elimination of the breeder's exception (experimental use)[4].

1.1.4 The 1991 Revision of the UPOV Convention

After 25 years of experience in implementing the Convention, it became obvious that some improvements could be made. In addition, the development of genetic engineering was raising important, new issues that had to be considered.[5] In the spring of 1987 the UPOV Council took the decision to start the preliminary work for revising the Convention. After 4 years of work, the 1991 Diplomatic Conference was convened and a new Act was adopted.

The detailed comparison between the 1978 and the 1991 Acts was presented during a Seminar in Punta del Este in 2000 (Rolf Jördens, 2000). The most relevant changes are:

- The deletion of the ban of the "double" protection (viz., utility patents and plant variety protection) provided for in Article 2 of the 1978 Act, which stated that "A member state of the Union whose national law admits of protection under [both a special title of protection or a patent] may provide only one of them for one and the same botanical genus or species"[6]. This deletion opened the gates to double protection globally.
- Changes in the scope are outlined below (Table 1):

Table 1: Changes in the scope of protection between UPOV 1978 and UPOV 1991

1978 Act (Article 5(i))	1991 Act (Article 14(i))
Production for the purposes of commercial marketing	Production or reproduction (multiplication)
	Conditioning for the purpose of propagation
Offering for sale	Offering for sale
Marketing	Selling or other marketing activities
	Exporting
	Importing
	Stocking for any of the above purposes

A substantial change was made in relation to production. Under the 1978 Act, the breeder's authorization is required only for "production for the purpose of commercial marketing," implicitly allowing for farm saved seed. In order to take into account regular practices, the 1991 Act provides for an optional

4 In December 1995, during the ASTA Corn and Sorghum Research Conference, the representative of a large seed company presenting the new policy of protection of intellectual property clearly indicated that "selfing" patented hybrids would continue to be allowed. The same comment, but less convincing based on experience, was made in 2003 during a meeting in Austin.

5 The breeder's exception, due to the difficulty to define precisely the minimum distance for assessing distinctness, had led to some abuses. Indeed, sometimes "cosmetic modifications" were enough for protecting a new variety. As early as 1961, CIOPORA, the International Community of Plant Breeders of Ornamental Plants, raised that issue. In 1980, ASSINSEL requested UPOV "to take all the necessary measures to prevent converted lines from infringing and pirating breeder's genetic material". In November 1984, UPOV Administrative and Legal Committee recognized that the revision would be raised in the future, when genetic engineering would allow the introduction of a particular gene into an existing variety which was, in fact, already possible since 1983.

6 A derogation to that article was already included in the 1978 Act (Art. 37) for countries having the double protection in place prior to notifying the UPOV Convention. In fact, that derogation was made to allow the US to join.

derogation allowing countries "[…] within reasonable limits and subject to the safeguarding of the legitimate interest of the breeder[7], [to] restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposed, on their own holdings, the products of the harvest which they have obtained by planting, on their own holdings, the protected variety […]".

Another important change in the scope of protection is the concept of essential derivation and dependence, which aims to prevent plagiarism and to provide a better balance between Plant Breeders' Rights and the protection by patents of biotechnological inventions. A variety is deemed to be essentially derived from an initial variety when:

- It is predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.
- It is clearly distinguishable from the initial variety.
- Except for the differences that result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety. Essentially derived varieties may be obtained, for example, by the selection of a natural mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering.

Finally, the protection of the harvested material of the protected variety, which was optional in the 1978 Act, was made compulsory, unless the breeder had had reasonable opportunity to exercise his or her right in relation to the propagating material. An optional provision was made regarding the products made directly from the harvested material which are also subject to certain conditions**.**

The 1991 Act requires the grant of protection for the varieties of all genera and species. Existing member states are given 5 years to achieve this position; new member states have 10 years.

1.1.5 TRIPS—The Agreement on Trade-Related Aspects of Intellectual Property Rights including Trade in Counterfeit Goods

Desiring to reduce distortions and impediments to international trade, the parties to the GATT Agreement agreed to introduce the Intellectual Properties Issues in the Uruguay Round's discussion. This ended with the adoption, in the final act of the Uruguay Round in Marrakech on May 15, 1994, of a specific agreement on Trade-Related aspects of Intellectual Property Rights, known as the TRIPS Agreement. A difficult issue was the patentable subject matter, and in the end a compromise was reached between the US and the European positions.

According to TRIPS, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step, and are capable of industrial application (Art. 27.1).

Parties may exclude inventions from patentability and prevent commercialization within their territory in order to protect human, animal, and plant life or health, to avoid serious prejudice to the environment, and to preserve *ordre public* or morality (Art. 27.2)[8].

In the field of interest of this paper, parties may also exclude plants and animals other than microorganisms, as well as essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, parties shall provide for the protection of plant

[7] Emphasis added by the author.

[8] It is interesting to note here the reference to prejudice to the environment two years after the adoption of Convention on Biological Diversity (CBD) was adopted in 1992. This is the beginning of an endless discussion on the compatibility of TRIPIS and CBD.

varieties either by patents or by an effective *sui generis* system or by any combination thereof. This provision shall be reviewed four years after the entry into force of the agreement (Art. 27.3(b)).

One of the primary effects of the adoption of the TRIPS Agreement is the strong increase in the number of countries becoming members of UPOV, from 24 in 1994 to 54 in January 2004.

1.1.6 The European Regulation on the Protection of Plant Varieties

Adopted in 1994, this milestone regulation is based on the 1991 Act of the UPOV Convention:

- It is, to the author's knowledge, the first piece of legislation to propose practical implementations for the optional farm saved seed exception (Article 14): "… Farmers are authorized to use for propagating purposes in the field, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, propagating material of a variety other than an hybrid or synthetic variety, which is covered by a Community plant variety".
- This is followed by a provision that the exception applies only to a limited list of agricultural plant species.
- Then the regulation states that, except for small farmers[9], farmers shall be required to pay a remuneration to the holder, one sensibly lower than the amount charged for a "normal" license fee. An implementing rule, adopted in December 1998, fixed the level of that remuneration at 50% of the "normal" license fee, unless agreed upon otherwise by all the parties at stake.
- This provision is clearly consistent with the spirit of the 1991 Act of the UPOV Convention, which refers to "reasonable limits and safeguarding of the legitimate interest of the breeder."
- It is also the first regional agreement that allows for a title of protection enforceable in several countries and that formalizes cooperation among countries for the examination of the varieties submitted for protection.

1.1.7 The European Directive on the Protection of Biotechnological Inventions

The European Patent Treaty excludes from patentability plant varieties, animal races, and essentially biological processes for the production of plants and animals (Article 53.b), and so the development of biotechnology in the 1980s raised the issue of the protection of biotechnological inventions.

In addition, since most of the biotechnological inventions are subject to possible self-replication, the impact of the concept of exhaustion of the right after the first sale (see Box 1) had to be clarified.

In order to avoid discrepancies among European Member States, it was proposed in 1988 to have a directive on that important subject. After 10 years of discussion, which reveals just how sensitive the issue was, the European Directive on the Protection of Biotechnological Inventions was adopted in July 1998. Its main provisions relevant to this paper are:

- Biological material isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature. That invention shall be patentable provided it is new, involves an inventive step, and is susceptible of industrial application (Art. 6.3).
- The protection conferred by a patent on a biological material shall extend to any biological material derived from that biological material through propagation or multiplication in an identical or divergent form and possessing those same characteristics (Art. 8).

[9] Farmers who do not grow plants on an area bigger than the area which would be needed to produce 92 tons of cereals or, for other crops, farmers who meet comparable appropriate criteria.

Box 1: Patentability of plant varieties and biological inventions

"Are plant varieties and biological inventions patentable subject matters?" is a question that has been intensively discussed in the past on ethical and technical grounds and is still under discussion.

The ethical aspect is beyond the scope of this paper. The main technical arguments against patentability were/are:

- the lack of inventive step (the non-obviousness criteria), and
- the lack of enabling disclosure.

The second argument has become pointless given the possibility of depositing a sample in an agreed bank, in particular in agreement with the Budapest Treaty.

The first one could merit further discussion but obviously the final decision is not based on technical but on political grounds. Patenting biological inventions in many countries and plant varieties in some countries is now common usage. It is probably useless to continue this debate. It is better to discuss the consequences (see also McManis 2002).

But there is another important question: is a patent an efficient protection for living material capable of self-reproduction? The problem is well presented in Janis and Kesan (2002).

"When a purchaser buys a patented item from an authorized seller, the purchaser is deemed to receive a license under the relevant patent unless the seller and purchaser make an agreement to the contrary. In the usual context, this "implied" license would be construed to allow the purchaser to use and resell the patented item, but not to make a new, patented item. It is sometimes said that the patent owner's rights are "exhausted" in the sold item.

The implied-license doctrine is not easy to apply to biological subject matter, such as patented seed. When the patented seed grows and produces new seed, is the new seed a new "making" of the patented seed, and hence outside the implied license? Or is it simply an aspect of the original "using", and hence within the scope of the implied license?

Courts have not resolved the question, and are not likely to do so in the immediate future because sellers can limit the scope of an implied license by employing express license restrictions as a condition on the sale of the patented item. Seed companies ordinarily prohibit growers from saving patented seed through express agreements entered into in connection with the seed sale."

The jurisprudence shows that these express license restrictions are enforceable.

It is to clarify the situation and lift that uncertainty that Article 8, stating that the protection inferred by patent on a biological material extends to any material derived from that biological material through propagation or multiplication… has been included in the European Directive on the protection of biotechnological inventions.

- The protection conferred by a patent on a product containing or consisting of genetic information shall extend[10] to all material (except the human body) in which the product is incorporated and in which the genetic information is contained and performs its function (Art. 9).
- The protection shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market by the holder of the patent or with his consent, where the multiplication or propagation necessarily results from the application for which the biological material was marketed, provided that the material is not subsequently used for other propagation or multiplication (Art. 10).
- The farm saved seed provision, as articulated in the Regulation on Community Plant Variety Rights, is extended to patented biological inventions (Art. 11.1).

[10] When discussing the draft of the directive, the author was of the opinion that the wording "remains protected" in all material in which the product is incorporated would have been more appropriate, but he was told at that time by a group of lawyers that the meaning was similar. The present discussion on access to genetic resources (see *infra*) shows that it is not the case. That wording "remains protected" was the wording used by ASSINSEL and GIBiP (The Green Industry Biotechnology Platform) in their first position papers.

This directive answers directly questions about the patentability of biological inventions, the status of the patented invention when introduced in a non patent product (e.g., a variety protected by Plant Breeders' Rights), and the exhaustion of the right.

The last three events to be considered do not deal with substantive treaties and laws but with implementing rules.

1.2 Some Judicial Precedents

1.2.1 The "Novartis Case" in Europe[11]

In 1993, the Technical Boards of Appeal at the European Patent Office (EPO) decided that a broad claim in a patent application by Plant Genetic Systems (PGS) to a transgenic plant applied to plant varieties and was excluded from patentability. In line with the PGS decision, the EPO Technical Board of Appeal refused the application made by Novartis (now Syngenta) claiming patents for transgenic plants transformed by recombinant DNA techniques to introduce pathogen resistance and also methods for preparing such plants. By the time the case was examined by the Enlarged Boards of Appeal, the European Patent Convention had been amended for harmonization with the European Directive on the protection of biotechnological inventions. The Enlarged Boards of Appeal reversed the decision of the Technical Board of Appeal and held that the claims were allowable because they did not relate to a single plant variety: the method of the invention was applicable to an infinite number of plant varieties. This decision was a milestone. Genetically modified (GM) plants may be protected in Europe if the invention is not limited to a single variety. Single GM varieties can be protected under the Plant Breeders' Right legislation.

1.2.2 The J.E.M. Ag Supply Inc. vs. Pioneer Hi-Bred International Case in the USA[12]

An Iowa seed dealer, doing business as J.E.M. Ag Supply Inc., argued that the Pioneer Hi-Bred patents were invalid on the ground that the Utility Patent statute's provision restricting paten-eligible subject matter should be interpreted to exclude plants because the US Congress had created other IP regimes, including the Plant Variety Protection Act aimed specifically at protecting plants. J.E.M. Ag Supply lost on this argument in the trial court and again at the Court of Appeals for the Federal Circuit, but persuaded the Supreme Court to review the case. In its 6 to 2 decision (one abstention), the Supreme Court upheld the lower court's rulings.

Two principal rationales were given to support the conclusion. First, the language of the relevant statutory provision of the US Code was extremely broad, as confirmed by the former decision of *Diamond vs. Chakrabarty*. Second, nothing in the plant-specific IP statutes (the 1930 PPA and the 1970 PVPA) indicated a Congressional intent to preclude utility patent protection for plants. This 2001 decision confirmed the possibility to grant patents for plant varieties in the United States. However, the Supreme Court review put the patenting of plant varieties under the spotlight and probably led to a significant change in the USPTO policy regarding acceptable claims. In fact, while confirming the patentability of plant varieties, the Court stated that this patentability should be established according to the same criteria and with the same stringency as for any other invention, in particular as regards enabling disclosure. Contrary to what was done in the past, when broad claims regarding progenies were accepted, the new policy of the USPTO is to grant protection only to the deposited material and its direct use (e.g., for hybrid production in the case of parental lines), limiting the strength of the patent protection.[13]

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[11] See also Fleck and Baldock (2003).

[12] Janis and Kesan (2002).

[13] It must be noted that some applicants are opposing this new policy and we will have to wait some time before knowing the final result.

1.3 Section 1 Conclusions

There is now an extensive set of international and regional treaties, as well as laws and regulations allowing for the effective protection of plant-related development in the world, with some important differences between countries. However, these issues are often at the top of the agenda for debate.

2. The Current Debate

2.1 The Ethical Issues

An in-depth discussion of the ethics of protecting life forms is certainly beyond the scope of this paper. However, it is not possible to ignore opponents to the protection of plant-related development who consider it unethical to protect life forms because of a move they call "appropriation of life." This is particularly true for patenting. Activists very often present these arguments during international meetings.

2.2 The Political Issues

As indicated by Helfer (2002), two broad philosophical approaches underlie the decision to grant IPRs to the products of human intellectual effort and ingenuity.

The first approach takes the position that the products of the human mind are stamped with the personality of their creator, inventor, or author, thus endowing him or her with a moral as well as an economic claim to exploit those products to the exclusion of third parties. This "moral approach" is reflected in the wording of Article 27 of the Universal Declaration of Human Rights, which guarantees to everyone "the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author."

The second approach to IPR protection takes as its starting premise an instrumental view of intellectual property. Legal protection for the products of human intellectual effort and ingenuity is granted not because of a moral commitment to compensating creators or innovators, but rather because the products they create enrich a society's culture and knowledge and thus its welfare.

The policy goals of granting IPRs to plant-related developments are grounded on those two approaches. This is particularly illustrated by the preamble of the 1961 Act of the UPOV Convention: "The Contracting States, convinced of the importance attaching to the protection of new varieties of plants not only for the development of agriculture in their territory but also for safeguarding the interests of breeders…"

The "instrumentalist" part of the approach opens the door to lively debates on the interest or not of IPRs. As indicated by Lesser (2002), virtually all developing countries are asking about the economic implications of compliance to the Article 27.3(b) of the TRIPS Agreement, even as this article is under review. As Lesser (2002) states, answering this question is an important and urgent task because we need better insights into the results of enhanced IPR for developing countries. This would allow governments to take a prior informed decision and possibly counter the voices, such as those heard in Seattle in 1999, condemning the globalization taking place under the WTO process. IPRs are a particular target of that rhetoric.

Jaffé and van Wijk (1995) consider that there are few evidences of the positive impact of Plant Breeders' Rights in developing countries. Lesser, in contrast, shows a clear positive impact on foreign direct investment and trade[14].

[14] The Canadian Government has recently issued a "10-Year Review of Canada Plant Breeders' Rights Act (www.inspection.gc.ca/english/plaveg/pbrpov/10yrenglish.pdf). In summary, the report states "A decade after the Plant Breeders' Rights Act was enacted, it is generally accepted by industry, researchers and government,

Another broad issue under discussion on the occasion of the review of the TRIPS Article 27.3(b) is the compatibility of TRIPS and the Convention on Biological Diversity (CBD) as discussed recently by the Crucible II Group (2000). Article 16 of the CBD refers to protection of IPRs in a somewhat ambiguous manner in particular Article 15.5: "The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives." Some organizations and some governments consider TRIPS to be in conflict with CBD. Some on the contrary consider that they are mutually supportive and that one of the three main objectives of the CBD—benefit sharing—needs a strong protection of IP.

The opinion of the International Seed Federation (ISF) is that Article 27.3(b) is the best compromise that can be achieved at the moment and that it should not be modified. The only concern is the interpretation of the term "effective" qualifying the *sui generis* system (ASSINSEL 1999 and Leskien and Flitner 1997). While some argue that the term "effective" refers to a certain minimum level of protection, others argue that the *sui generis* system is effective if it provides for an enforcement procedure so as to permit effective legal action against any act of infringement of the *sui generis* right. For ISF, an effective system is one that gives protection to breeders of plant varieties against commercial competition by abuse or plagiarism, thus encouraging innovation by ensuring that innovators can recover their development costs. This is provided for by the 1991 Act of the UPOV Convention, which should be considered as the minimum standard for compliance with TRIPS.

2.3 The Technical Issues

2.3.1 The Implementation of Laws and Treaties

Several topics deserve consideration.

The patenting of genetic sequences

Patent laws generally accept the protection of biological material that is isolated from its natural environment (e.g., genetic sequences) provided that they fulfill the patentability criteria. A strong debate took place in the 1990s about the possible "appropriation of nature" when patenting genetic sequences. The situation now seems clarified, in particular since the adoption by the USPTO of the revised interim utility guidelines in the year 2000. These guidelines, in line with the European Directive on the protection of biotechnological inventions, insist on the assessment of the utility that has to be credible, specific, and substantial. This is consistent with the ASSINSEL position adopted as early as 1988: "Only genetic components which directly serve to cause expression of a useful characteristic in crops should be eligible for protection" (ASSINSEL 1988). This is confirmed in the ISF View on Intellectual Property (ISF 2003): "a mere DNA sequence or nucleotide without indication of a function does not contain any technical information and is not a patentable invention."

More recently, a new debate has arisen: should the protection given to a genetic sequence for a given application extend to other applications if discovered after the grant of the patent? Some argue that genetic sequences have to be treated as any chemical compounds and that the answer is yes. Some argue that the specificity of living matter should be taken into account and that the answer should be

that the scientific and economic well-being of the horticulture and agriculture industries has improved. There have been improvements in the yields and quality of many crops and an expansion of the area under production. Farmers and nurserymen have greater access to more and better varieties. In addition, some sectors of the horticulture and agriculture industries have enhanced their export capability, or have become net exporters of products. This includes the floriculture, nursery, potatoes, and pulse sectors. The PBR Act is felt to have had a direct impact on many of these changes".

no. It is the opinion of the author that the extension should not be granted unless there is a demonstrated link between the first application/characteristic and the new one(s).

Broad patent claims

Some broad patent claims have been accepted by the USPTO and, less frequently, by the European Patent Office (EPO).

The Agracetus case[15]

In April 1991, Agracetus was granted a US patent (No. 5 004 863) covering a genetic engineering technology for transforming cotton plants using *Agrobacterium tumefaciens.* Also in April 1991, they received a US patent (No. 5 015 580) covering a method for genetically engineering soybean plants using the gene technology. In addition, Agracetus claimed, in other applications, all genetically engineered cotton plants (US patent granted No. 5 159 135 in October 1992) and all transgenic soybeans (European patent 0 301 749 B1 in March 1994). Those last two patents have met criticism and were opposed. After re-examination several claims were cancelled and some re-examination procedures are still open. Obviously the examiners were accepting too broad claims when granting protection not only to the products obtained by the protected process, but to all products having the same characteristics. As early as 1988, ASSINSEL opposed such broad claims (ASSINSEL 1988), stating that "only direct products of a process should be included within the scope of a process patent."

The Basmati and the Enola Cases

Two other cases have been broadly talked about, very emotionally, feeding rumors of biopiracy against the seed industry (see also Crucible II Group 2000).

In September 1997, RiceTec Inc. was issued US patent No. 5 663 484, claiming all "Basmati rice lines and grains" on the ground that they had developed and claimed a method allowing to screen, in the progeny of a cross, the lines having a certain quality of starch (Crucible II Group 2000)).

In 1999, US patent No. 5 894 079 was granted to John Procter (Enola bean), covering all yellow beans on the ground that he had selected in a segregating population of yellow beans bought in Mexico a line with uniform and stable color (see also www.law.duke.edu/journals/dltr/articles).

Both patents have been re-examined and several claims have been refused or are still under scrutiny. Obviously several claims were too broad, as stated by ASSINSEL several years ago (ASSINSEL 1988): "Characteristics of crops should not be patented unless their direct causative agents are identified and themselves qualify to be patented. Alternative genetic approaches to achieve the same characteristics or trait in crops shall not infringe a prior patent."[16]

The initial acceptance of such broad claims, which show the lack of experience of patent examiners in that rather new domain, has been solved by legislation, examination guidelines, decisions by courts, and opposition Boards. They have launched, however, a firestorm of controversy, giving ammunition to the opponents of the protection of plant related inventions.

The implementation of the concept of essential derivation and dependence

The objective of this concept, introduced in the 1991 Act of the UPOV Convention, was to discourage the plagiarism and easy breeding made possible due to the difficulty of defining the necessary "minimum distance" for declaring a new variety as distinct from other varieties of common knowledge. If the

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[15] See also Bijman 1994.

[16] The author considers that the *ex parte* Hibberd patent (see section 1.3 above), claiming all maize varieties with a tryptophan content higher than a given level, is also in that category of non-acceptable broad claims.

concept seems simple, its implementation is complex, and as early as 1992 ASSINSEL developed implementation guidelines (ASSINSEL 1992). The present position of ISF is stated in the document "ISF View on Intellectual Property" (ISF 2003).

Technically, for a variety to be considered as essentially derived, it must fulfill together three requirements in relation to the initial variety:

- Clear distinctness in the sense of the UPOV Convention.
- Conformity to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.
- Predominant derivation from the initial variety.

Legally speaking, concerning dependency:

- The initial variety must be a protected one.
- Dependency can only exist from one variety alone.
- An essentially derived variety can be directly derived from the initial variety or from a variety that is itself essentially derived from the initial variety. It is possible to have a "cascade" of derivation. However, each essentially derived variety shall only be dependent on one, the initial protected variety.
- According to the general rule of burden of proof, the owner of the initial variety must prove essential derivation and then claim dependency. However, if the owner of the initial variety can give reasonable evidence of essential derivation (*prima facie* proof), ISF is in favor of the reversal of the burden of proof. The use of genetic similarity coefficients, which would be a trigger point for the reversal of the burden of proof, is an interesting approach. That threshold would divide the scale of genetic distance into two parts: below the threshold there would be no presumption of essential derivation; above the threshold there would be presumption, and the burden of proof of non-predominant derivation would fall on the breeder of the putative essentially derived variety.

The ISF Sections have worked on such a scheme, and a code of conduct was adopted for Ryegrass in 2001 (ISF 2001). Results for Lettuce should be adopted in May 2004, on the occasion of the ISF Congress (Le Buanec 2003). The study for Oilseed Rape is also nearly completed.

There is no jurisprudence on essential derivation.[17] However, there are several cases the author is aware of that have been solved amicably using the *prima facie* proof. It must also be noted that the introduction of the concept of essential derivation has changed breeding schemes and that "close" breeding is becoming rare—much to the benefit of breeders and the diversity at the disposal of farmers.

[17] The Australian situation is worth noting. It is the only country where the decision on essential derivation is taken by the Plant Variety Protection Office, contrary to the guidance given by UPOV and to the opinion of the Seed industry. In addition, the interpretation made by the Australian PVPO regarding transgenic variety (www.anbg.gov.au/breeders/plant-breeders-rights-act-report.pdf) seems totally incorrect when they are considering that a variety modified by the insertion of a Transgene is not an essentially derived variety, contrary to the examples given in the 1991 Act of the UPOV Convention. We must remember that the trigger point to introduce the concept in the UPOV Convention was genetic engineering (ASSINSEL 1999). In the opinion of the author, there is a confusion between the protection of non trivial trait, the transgene and the protection of the essential characteristics of an already protected variety.

2.3.2 The Access to Genetic Resources and the Research Exemption[18]

Plant breeding progress is generally considered as incremental, and breeders have built on existing varieties to develop improved ones. Indeed, to make progress, contrary to the situation in mechanics or chemistry, the description of the invention is not enough, as it is not (yet?) possible to rebuild a whole genome starting from nucleotides. This is why the "fathers" of the UPOV Convention had included an exception to breeders' rights: "The utilisation [by others] of the [protected] new variety as an initial source of variation for the purpose of creating other new varieties and the marketing of such varieties" (Art. 5.3 of the 1961 Act). This exception, widely known as the breeder's exception, has been one of the engines of the breeding industry during the past 40 years.[19]

Until recently, the position of the seed industry was unanimous on the importance and need of the breeder's exception, as indicated in the position adopted on the occasion of the ASSINSEL Congress in June 1999 in Melbourne (ASSINSEL 1999). That paper stated, "When a commercially available plant variety protected by PVP contains patented traits, it should remain freely available for further breeding, according to the breeder's exception provided for in the UPOV or UPOV-like systems."

Since that date, internal seed industry discussion[20] has taken place on three main aspects of this important matter:

- Access to plant varieties protected by patent
- Access to plant varieties protected by PBR
- Access to plant varieties protected by PBR and containing patented elements.

Access to plant varieties protected by patent

This is a case mainly occurring in the USA and, in fact, little formal discussion has officially taken place. However, a few companies consider that the research exemption is too narrow and that some flexibility should be given for breeding purposes. This is also debated in academic circles (e.g., Janis 2001 or McManis 2002). Janis (2001) is in favor of having discussions in the USA over the scope of allowable experimental use in the plant breeding area, without certainty to get a result. McManis (2002) considers that a WTO member could choose to amend its patent statute to provide a plant-specific experimental use exception patterned on the breeder's exception provision of the UPOV Convention, on the grounds that Article 27.3(b) states that WTO members are to provide for the protection of plant varieties "either by patents or by an effective *sui generis* system or <u>by any combination thereof</u>" (emphasis by McManis).

Access to plant varieties protected by PBR

During the past twenty years breeding methods have evolved drastically, allowing faster results due in particular to the following four factors: the development of greenhouses facilities, the generalization of counter-seasons nurseries facilitated by new transportation capabilities, haplo-diploidisation, and the more recent development of so-called molecular breeding, which uses molecular markers to trace genes and QTL. While not refusing the breeder's exception principle, some companies, mainly based in the

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[18] The broad issue of access to genetic resources is presently in the spotlight in international discussions, in particular at the Convention on Biological Diversity and the FAO International Treaty on Genetic Resources for Food and Agriculture levels. We will focus here on access to protected genetic resources by patent or Plant Breeders' Rights.

[19] The concerns of the breeders regarding possible plagiarism due to that exception have been taken care of by the new concept of essential derivation (cf. *1.4 and 2.3.1*).

[20] That discussion is not internal only to the seed industry, but also exists in many other fora. The recent PIPRA initiative in the USA (Public Intellectual Property Resource for Agriculture) is a good illustration of the debate (www.pipra.org).

USA at the moment, are considering a possible limitation during a certain period to give a minimum time to the breeder to benefit from his innovation.[21]

Access to plant genetic resources protected by PBR and containing patented elements

This is probably the most controversial issue on intellectual property within the seed industry and also probably the one with the most uncertain outcome legally speaking, at least outside the USA. In June 2003, ISF (2003) adopted a position on that subject that reads as follows: "…further clarification is needed as regards the use of transgenic varieties containing patented elements and protected by Breeder's Right for further breeding. ISF is strongly attached to the breeder's exception provided for in the UPOV Convention and is concerned that the extension of the protection of a gene sequence to the relevant plant variety itself could extinguish this exception.

Therefore ISF considers that a commercially available variety protected only by Breeder's Rights and containing patented elements should remain freely available for further breeding. If a new plant variety, not an essentially derived variety resulting from that further breeding, is outside the scope of the patent's claims, it may be freely exploitable by its developer. On the contrary, if the new developed variety is an essentially derived variety or if it is inside the scope of the patent's claims, a consent from the owner of the initial variety or of the patent must be obtained."

However it must be noted that for the first time since 1988,[22] an ASSINSEL/ISF position paper on Intellectual Property did not reach unanimity, some members from the USA voting against (6.4%), some national associations from developing countries and one European company abstaining (7.3%). The majority of 86% was, however, overwhelming supportive.[23]

In the light of those results, and in order to have in-depth discussions on that important matter, ISF has decided to hold an international seminar on Protection of Intellectual Property and Access to Genetic Resources on May 27-28, 2004, just after its annual congress, in Berlin, Germany.

2.3.3 The Deficiencies of the Legislation

The patent system for plant varieties

If the new policy of the USPTO to refuse claims on the progeny hold, the protection by patent will become partly ill-suited. In addition, the possible consequence of a very narrow research exemption is under debate (see *2.3.2*).

The UPOV Convention

The 1978 Act of the UPOV Convention has several weaknesses that have been corrected in the 1991 Act. However, some problems remain either due to the Act itself or to its implementation at the national level.

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[21] In addition, it must be noted that since the adoption of the CBD and of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture, access to plant genetic resources either in situ or ex situ gene banks is restricted, with prior informed consent and material transfer agreements. In fact the only genetic resources that remain available for research and breeding are the plant varieties protected under UPOV and one can dispute the logic of that situation.

[22] Except in Chicago in 2002 on exactly the same subject.

[23] In fact the rationale of the two minority groups were opposed, the companies voting against being of the opinion that the breeder's exception was too broad, the members abstaining thinking that the wording was not clear enough to allow a clear breeder's exception. This shows the complexity of the debate.

At the national level

The most frequent loophole in national implementation relates to the farm-saved seed clause. While Article 15.2 of the 1991 Act says that farm-saved seed is allowed "within reasonable limits and subject to safeguarding of the legitimate interests of the breeder," several national laws do not set any reasonable limits and do not take into account the legitimate interest of the breeder. ISF considers that such laws are inconsistent with the 1991 Act of the UPOV Convention and should not be considered in line with the 1991 Act by the UPOV Council. They are also inconsistent with Art. 27.3(b) of the TRIPS Agreement. During its meeting of October 20-21, 2003, the UPOV Administrative and Legal Committee considered a document on possible guidance for explaining the scope and implementation of "Acts done Privately and of Non-Commercial Purposes and the Farmers Privilege" (UPOV Document CAJ 48.3). It was agreed to continue the discussion in Autumn 2004.

ISF members interpret the words "within reasonable limits" in terms of acreage, quantity of seed, species concerned, and "subject to the safeguarding of the legitimate interest of the breeders" in terms of payment of a remuneration and information. The recommendation adopted by the Diplomatic Conference of 1991, indicating that the optional exception "should not be read so as to be intended to open the possibility of extending the practice commonly called "farmer's privilege" to sectors of agricultural or horticultural production in which such a privilege is not a common practice on the territory of the contracted party concerned" must also be taken into account.

The definition given in the Kinghize law "on legal protection of breeding achievement" (Art. 24) for personal and non-commercial purposes, that is "the use of new plant variety to re-produce in private gardens to be further consumed as food products" seems appropriate (Law of the Kyrgyz Republic, 1998).

Another weakness at the national level is the difference in the implementation of Article 12, the examination of the variety to test distinctness and uniformity. According to the article, "the authority may grow the variety or carry out other necessary tests, or take into account the results or other trials which have already been carried out." This flexibility results in important differences, and in some countries the value of the description and of the assessment of distinctness may be disputable.[24]

At the level of the Convention

If fully and correctly implemented, the 1991 Act of the UPOV Convention provides an efficient intellectual property protection for new plant varieties. But three major improvements regarding the content itself and one regarding the implementation are still necessary to make it completely satisfactory.

The protection of products made directly from harvested material of the protected variety

Article 14(3) of the 1991 Act gives an option to the Contracting Parties to the Convention to extend the scope of the Breeder's Right to the products made directly from harvested material of the protected variety through the unauthorized use of the said harvested material, unless the breeder has had reasonable opportunity to exercise his right in relation to the said harvested material. Instead of being optional, that clause should be made compulsory.

The protection of the parental lines of hybrids

The UPOV Convention has been written mainly for varieties that are put on the market for exploitation, but it is not well adapted for the parental lines of the hybrids. The only implicit reference to those parental lines is found in Article 5(a)(iii) of the 1991 Act referring to the "repeated use of the protected variety" for producing a new one.

[24] ISF has recently decided to make a survey among its members to have a better appreciation of that subject.

In particular, the parental lines are generally not sold or otherwise disposed of to others, by or with consent of the breeder, for purposes of exploitation of the variety.[25] They are exploited indirectly through the hybrids they are parents of. This means that, as there is no "legal" access to these lines, except by direct contract with the owner, they should not be used for further breeding by third parties as an implementation of the Breeder's Privilege."[26] As the genetic variations of the parents are available for further breeding *via* the hybrid, this is not contradictory to the spirit of the Convention.

However, it is not possible to prevent the accidental presence of seeds of the parents in a bag of hybrid seed, and some people are practicing what is known as "line fishing" to extract those parent seeds from the seed purchased and then using those seeds for further breeding. There are uncertainties in the present wording of the UPOV Convention on the legality of such behavior and a clarification is needed. In order to avoid the risk, breeders are now using bag tags and shrink-wrap agreements forbidding that usage. ISF is considering the generalization of such agreements until UPOV is clarified.

DUS testing

It was indicated earlier in this paper that DUS testing varies from country to country and harmonization is needed.

DUS testing is raising a more general issue about the management of the so-called "reference collections." According to UPOV, a candidate variety for plant breeder's right must be compared with "any other variety whose existence is a matter of common knowledge at the time of filing the application." This is becoming increasingly difficult for two main reasons:

- The increasing number of varieties due to the breeding efforts and the steady extension of UPOV;
- The protection of all genera and species.

There is no easy solution and drastic changes will certainly be necessary in the future. UPOV and Industry members are involved in that important discussion. An analysis of all the existing systems is necessary so that the best of each of them can be used to design the next one. The utilization of new description tools could also be envisaged. However, the approach has to be very cautious to avoid undermining the whole system.

Meanwhile short- to medium-term improvements should be envisaged.

- In-depth collaboration, both among PVP offices and between PVP offices and breeders should be encouraged.
- The examination reports belong to the breeder who has paid for the examination procedure. On the request of the breeder the examination reports should be sent free of charge, but for a reasonable handling fee, to other PVP offices.[27]

UPOV and other relevant bodies should investigate as soon as possible the feasibility of a worldwide database of phenotypic descriptions of varieties of common knowledge, at least including but not necessarily limited to varieties protected under the UPOV system. This would facilitate distinctness testing. In particular, in countries where applicable, the database will be used for grouping comparable varieties and the candidate variety for testing. It would also be useful to plant breeders prior to the application for Breeder's Right. The database should only contain the phenotypic characteristics indicated in the

[25] Emphasis added by the Author.

[26] The only conditions for UPOV Protection are Novelty, Distinctness, Uniformity, Stability and an acceptable Denomination. The grant of breeder's right shall not be subject to any further or different conditions (UPOV 1991, Art. 6(2)). The owner of the variety cannot be required to put the propagating material of the variety at the disposal of any third party.

[27] PVP offices mean Plant Variety Protection authorities in charge of granting Breeder's Right.

UPOV Guidelines. Those characteristics are not confidential business information and must be publicly available.[28]

The preliminary examination on the data submitted by the breeder should also contribute, to a large extent, to facilitate the application of the UPOV Convention to all species.

Farm Saved Seed

Breeder's Right has been introduced progressively and cautiously over the second part of the 20th century, taking into account the evolution of plant breeding, the agricultural socio-economic situations of farmers, and the requirement for food security. The Farm Saved Seed issue is very sensitive and has political implications. However, as for any other property right, the only exemptions should relate to acts done privately and for non-commercial purposes and acts done for experimental purposes, including the breeder's exception with possible adaptation. The ultimate goal should be to take out the Farm Saved Seed exception, in a step-by-step and country-by-country approach.

3. Conclusions

The present legislative arsenal for the protection of plant-related innovations, if fully implemented, should give effective protection to biotechnology inventors and plant breeders.

However, to be fully satisfactory, some improvements in the UPOV Convention should be made as regards the protection of hybrid parental lines, the management of farm saved seed, and the protection of the product obtained directly form the harvested material of the variety. The challenge of assessing distinctness with an increasing number of species and of varieties within each species will have to be faced with caution but also with new ideas.

The debate on the research exemption and the breeder's exception is far from finalized and an acceptable balance will have to be found between the various pieces of law and the stakeholders.

References

ASSINSEL. 1988. Position of regarding the Protection of Biotechnological Inventions, Brighton, June 10, 1988.

ASSINSEL. 1992. Statement regarding the implementation of the new principle of essentially derived varieties in the UPOV Convention. Toronto, June 5, 1992.

ASSINSEL. 1999. Development of New Plant Varieties and Protection of Intellectual Property, Doc. ASSINSEL No. A.99.47.

ASSINSEL. 1999. Fostering Plant Innovation. ASSINSEL Brief on Review of TRIPS 27.3(b). ASSINSEL: Nyon.

Bijman J. 1994. Agracetus: Patenting all transgenic cotton. Biotechnology and Development Monitor, No. 21, December 1994.

Clarification of Plant Breeding Issues under the Plant Breeders' Rights Act 1994. Report of the Expert Panel on Breeding, December 2002, Plant Breeders' Rights Office, Australia. www.anbg.gov.au/breeders/plant-breeders-rights-act-report.pdf

Crucible II Group. 2000. Seeding Solutions. Policy options for genetic resources: People, Plants and Patents revisited. Co-published by the International Development Research Centre, the International Plant Genetic Resources Institute and the Dag Hammarskjöld Foundation, pp. 49-52 and p 23.

Fleck B and C Baldock. 2003. Intellectual property protection for plant-related inventions in Europe. *Nature Biotechnology* 4:834-838.

[28] A limitation to such a database is the variation of the phenotype according to the various locations. Common check varieties in those locations would facilitate the comparisons.

Heitz A. 1987. The history of plant variety protection, *in* the First Twenty-Five Years of the International Convention for the Protection of New Varieties of Plants, UPOV publication No. 879 (E), Geneva.

Helfer LR. 2002. Intellectual Property Rights in Plant Varieties: an overview with options for National Governments, *FAO Legal Paper Online* No. 31. www.fao.org/legal/pub-e.htm

ISF 2001. Principles of a Code of Conduct in Essentially Derived Varieties of Perennial Ryegrass. Document 02.162. www.worldseed.org. ISF 2003. View on Intellectual Property, Bangalore, June 2003. www.worldseed.org

Jaffé W and J van Wijk. 1995. The impact of plant breeders' rights in developing countries. Univ. Amsterdam: Amsterdam and Inter-Am. Institute for Cooperation on Agriculture (IICA): San Jose.

Janis MD and JP Kesan. 2002. Intellectual property protection for plant innovation: unresolved issues after J.E.M. v. Pioneer. *Nature Biotechnology* 20:1161-1164.

Janis MD. 2001. Sustainable Agriculture, Patent Rights and Plant Innovation. *Journal of Global Legal Studies* 9:91-117.

Jördens R. 2000. The 1978 and 1991 Acts of the UPOV Convention, Seminar on the UPOV Convention, Punta del Este (Uruguay), 23-24 November.

Law of the Kyrgyz Republic on Legal Protection of Breeding Achievement, Russian Kyrgyz patent, June 13, 1998, No. 79.

Le Buanec B, Bruins M, de Ponti O, Kramer T, Lor D, Moquet F, Reinink K, van Eeuwijk F, van Grinsven M, 2003.Essential Derivation in Lettuce, UPOV BMT/8/18..

Leskien D and M Flitner. 1997. Intellectual Property Rights and Plant Genetic Resources: Options for a *Sui Generis* System. IPGRI *Issues in Genetic Resources* 6**,** pp 26 and sq.

Lesser W. 2002. The Effects of Intellectual Property Rights on Foreign Direct Investments and Import into Developing Countries in the Post-TRIPS Era. *IP Strategy Today* No. 5-2002, pp 1-16. www.biodevelopments.org

McManis CR. 2002. Are there TRIPIS-compliant measures for a balanced coexistence of patents and plant breeders' rights? Some lessons from the United States of America's experience to date. WIPO-UPOV Symposium on the coexistence of patents and plant breeders' rights in the promotion of biotechnological developments, Geneva, October 24, 2002.

UPOV Document CAJ/48/3. Acts done Privately and for Non-Commercial Purposes and Provisions on Farm-Saved Seed under the 1991 Act of the UPOV Convention.

UPOV. 1985. International Convention for the Protection of New Varieties of Plants of December 2, 1961, Art. 5 and Art. 6, UPOV, Geneva. www.upov.int

Intellectual Property Rights, Patents, Plant Variety Protection and Contracts:

A Perspective from the Private Sector[1][29]

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"This slushy farmyard, so humble, so lacking in all props and the appointment of power, was yet the foundation of society. Upon this fabric rested, upon this was erected all that glittered and all that shone. I gazed into the farmyard, aware that here, only in this place could I find the roots of grandeur and the keys of life"

From: "The worm forgives the plough"
John Stewart Collis

Executive Summary

How agriculture is conducted determines the quality and sustainability of food production, health, and the environment. Food production cannot be conducted sustainably by continuing to take more land into cultivation; besides, increasing urbanization is removing land from production. Consequently, it is imperative to increase agricultural productivity to help meet increasing demands for food, fiber, and feed. Increased agricultural productivity and environmental quality goals can, and indeed, must be in alignment. More productive agriculture helps the environment by reducing pressures to farm fragile and natural habitats.

The development and use of improved varieties that comprise new combinations of genetics can also reduce other input needs. For example, nitrogen use in Iowa has declined since 1975 as yields of maize hybrids increased 20%. Many activities that can provide environmental benefits are also core activities that commercial breeding organizations are already pursuing. Such "environmental" traits, after all, are fundamental to improving agricultural productivity. The private sector's efforts to develop new varieties, however, are heavily influenced by intellectual property regimes, which determine the levels of risk-taking and the time-lines, thus delimiting the kinds of research that can be profitably pursued.

Public investment in the development of genetically improved varieties that can increase agricultural productivity has been and continues to be a prerequisite for helping to lift millions out of poverty and banishing hunger and malnourishment. Public investments in agricultural research, however, have not kept pace with acknowledged needs. Global food security, therefore, increasingly depends upon research and product development by the private sector.

A more productive and environmentally harmonious agriculture requires innovative, research-driven solutions that collectively use both genetic diversity and appropriate methods of crop husbandry to the greatest possible effectiveness. Achieving these solutions depends upon research investments by both

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1 Donnenwirth J, J Grace and S Smith. 2004. Intellectual Property Rights, Patents, Plant Variety Protection and Contracts: A Perspective from the Private Sector. *IP Strategy Today* No. 9-2004. Pp. 19-34.

the public and private sectors. Private investments, moreover, require an intellectual property regime that will encourage those needed investments. Indeed, new genetic diversity on farms will not be deployed successively unless breeders can invest at least some resources into prebreeding or germplasm enhancement programs that incorporate germplasm initially unadapted or exotic to the region for which they are developing improved cultivars. If risks outweigh research and business opportunities, then breeders will instead choose to make relatively lower-risk investments, working with a small cadre of well- characterized and well-adapted varieties that are already widely used on farms, thereby reducing the genetic base and actually putting food and feed security at risk. Affordable intellectual property systems that include contracts, patents, trade secrets and more effective UPOV style protection must be created so that developers of new and improved crop varieties in all countries can choose the most suitable form of protection.

In short, both Intellectual Property Protection (IPP) and technologies impact research and product development strategies. New genetic technologies and breeding approaches can facilitate the use of genetic resources that otherwise would not be used in breeding, and so they should be encouraged by intellectual property regimes. Indeed, the past decade has witnessed a very rapid development of new technologies that can speed and facilitate access to germplasm. New technological capabilities not only facilitate existing pathways to genetic resources but also create new and critically significant pathways for breeders to access these resources, allowing them to more effectively use a broader array of germplasm diversity than had hitherto been possible—or even been contemplated.

However, it does not automatically follow that plant breeders will take advantage of available technologies and a more diverse and readily usable germplasm base to increase the breadth of genetics that they use in their breeding program. Whether breeders employ these technological developments in the private sector to increase access to a broader germplasm base and thus to sustain and improve agricultural productivity through plant breeding—and thereby provide associated health and environmental benefits—depends fundamentally upon the IP regimes in place.

Technology can be a two-edged sword with respect to the effective level of IPP and the utilization of genetic resources. While technology can facilitate the use of genetic resources, it can also be used in a fashion that threatens to undermine existing levels of IPP.

Two extreme positions for the use of new technologies in plant breeding can be postulated. On the one hand, new technologies can be used to facilitate access to genetic resources that were hitherto practically unavailable to breeders due to their presence in wild species or in exotic or unadapted varieties, or simply because the range of exotic germplasm is simply too large to screen using conventional field approaches. Or, those same technologies could be used to facilitate access, and even to attempt to evade existing forms of protection, in varieties that are already deployed on farms. The former, more innovative approach contributes to making more effective use of a broader genetic base in agriculture. The latter approach contributes to reduced levels of innovation, a narrowing of diversity in breeding populations, and lower agricultural production. Ultimately, in this latter scenario, the food supply would be jeopardized, incentives to conserve genetic resources would be compromised, and health and environmental security would be put at risk.

The IP environment will clearly influence investment decisions regarding the use of a broader repertoire of genetic resource diversity, and the effectiveness of IPP is impacted by the state of technology. Without effective IP, technology and breeding practices will tend to follow the path of least resistance in respect to the risks and resources employed. This would not be an environment for sustainable development. New diversity would not enter into breeding programs. Existing diversity would diminish, fail to support continued genetic gain, and be vulnerable to loss.

An IP regime that only encourages access to varieties that are already well-adapted and high-performing will lead to less use of a broader base of germplasm; reduce the diversity of germplasm used in breeding; reduce long-term on-farm performance gains; increase vulnerabilities to pests, diseases, and climate across a growing region; and increase reliance on single-gene biotechnological solutions practiced upon a relatively narrow genetic base.

In contrast, biotechnological inventions are usually eligible for stronger IPP via patent protection than are plant varieties. But increases in agricultural productivity have been and will remain dependent upon the development of improved germplasm in concert with the application of biotechnology. It is therefore very important that activities in all fields of endeavor that contribute to increasing agricultural productivity be encouraged to attract investments and innovations. An environment that provides strong protection for genes, but with increasingly weak protection for newly developed varieties per se, is potentially dangerous with regard to sustaining increases in agricultural productivity. This is because such an environment will tend to encourage the making of relatively small genetic changes on existing varieties while also discouraging the sourcing and introduction of new and useful germplasm which is, as yet, incompletely characterized according to gene sequences.

The general concept of a PVP-type system is appropriate and important to provide affordable IP for plant breeders whilst retaining the availability of germplasm as an initial source of variation in breeding. PVP remains especially important for providing IP for successful breeders who, either because of the incredible and still largely incomprehensible complex biology of their crop species or through lack of expensive technology cannot describe an individual gene and its agronomic impact, but who, nonetheless, develop improved varieties that are needed in agriculture, horticulture, or forestry. It is time to update the provisions of UPOV once again to accommodate advances in technology that have occurred since 1991, in order to encourage continued infusions of new germplasm into breeding pools. Detailed updates for UPOV are presented and discussed.

Knowledge intensive solutions are required for the complex biological problems of food, health, and environmental quality faced by the world today. New varieties developed from a broad germplasm base can help meet both agricultural production goals and improve environmental quality. Technologies and analytical methods are now available that allow a broad base of varieties, including exotic land-race varieties and wild relatives, to be characterized for genetic resource diversity. However, it will always remain far easier to incorporate useful diversity from existing well-adapted varieties than to identify, evaluate, adapt, and incorporate useful genetic diversity from varieties or landraces that are themselves less well adapted to the target region. Nonetheless, it is clear that continued genetic gain will depend upon infusions of diversity that is both useful and new to the target region. However, public investments in agricultural research have declined in most industrially developed countries and are stagnant or increasing only marginally in developing countries. Therefore, the private sector has an increasingly important role that it can, indeed must, assume in characterizing and deploying improved varieties utilizing new germplasm sourced from a broader base of genetics. But the deployment of a broader base of germplasm by private sector organizations will only take place provided the appropriate incentives to invest, take risks, and to innovate are in place. No private sector organization can afford to make investments that, immediately upon commercialization, become free donations to competitors. IPP as applied to plant breeding must be improved on a global basis to attract research investments and to encourage the use of a broader base of genetic resources. More effective IP can encourage access to germplasm and can ensure that benefits flow to providers of germplasm. Material Transfer Agreements can clearly state mutually agreed obligations by accessors of genetic resources to return benefits to germplasm providers. At the end of the day, consumers ultimately benefit from the use of germplasm. These changes in UPOV are required on a worldwide basis to achieve the twin goals of increased, more sustainable, and reliable food production and improved environmental quality.

1. Introduction

1.1 The key role of agriculture in providing food, health, and environmental security; important roles for the public and private sectors

How agriculture is conducted determines the quality and sustainability of food production, health, and the environment (Thrupp 1998). Food production cannot be conducted sustainably by continuing to take more land into cultivation. While there are significant acres of agriculturally productive ground left in the world, for example in parts of Brazil, these areas are limited. At the same time, increasing urbanization removes agricultural ground from production. Consequently, it is imperative to increase agricultural productivity to help accommodate the increasing demands for food, fiber, and feed.

Governments are also increasingly including direct environmental benefits as goals to be achieved through agricultural policy. For example, the USDA strategic plan for 1997-2002 includes goals to "Enhance the quality of the environment…" and to achieve "Greater harmony between agriculture and the environment." The U.K. Department of Environment, Food and Rural Affairs (DEFRA) states that "DEFRA supports crop genetic improvement research to improve the sustainability of agricultural production by reducing the intensity of the use of external inputs and reducing adverse impacts on the environment whilst maintaining profitability", (DEFRA 2002). The environment commissioner of the European Union, Margot Wallstrom recently (2004) stated that "the EU should continue to shift agricultural policies towards habitat protection."[2]

Increased agricultural productivity and environmental quality goals can, and indeed, must be in alignment. A more productive agriculture helps the environment by reducing pressures to farm fragile and natural habitats. "Improved yields have allowed the global area harvested for grain to remain stable at 600 million hectares, sparing another 800 million hectares that would otherwise be cultivated if productivity had plateaued at 1960 levels, the land saved is the size of the Amazonian river basin" (Ausubel 1996). Collectively, if the US were still using 1930's genetics for its major field crops then an additional land area at least the size of the state of Texas would need to be cultivated. The development and use of improved varieties that comprise new combinations of genetics can also reduce other input needs. For example, nitrogen use in Iowa has declined since 1975, while yields of maize hybrids have increased 20%. Other genetic changes in crop varieties can reduce use of pesticides and allow the use of herbicides with safer chemistries. Huang *et al.*, (2002) have noted that Chinese cotton farmers have reduced pesticide use by an average of 13 sprayings per year. This figure translates into 49.9 kg less pesticide use with a seasonal cost saving of $762 per hectare. Huang *et al.*, (2002) estimate that the financial savings in China for use of Bt cotton, compared to non-Bt cotton, was $197 million in 1997 alone.

DEFRA (2002) notes that " economic incentives to enhance food production are large compared to incentives for environmental benefits, whereas the considerable potential for genetic research and plant breeding to meet DEFRA's objectives will depend on maintaining germplasm collections, characterizing collections and linking genes to traits…, [and] researching complex traits…, [which] should enable breeders to produce varieties which need reduced fungicide and pesticide inputs,…reduced herbicide inputs,… reduced fertilizer use,… and which demonstrate more efficient water use…" . Yet many of these activities (linking genes to traits, researching complex traits, breeding for reduced inputs and greater stress resistance, and characterization of adapted germplasm) are core activities with which several commercial breeding organizations are already engaged because these "environmental" traits are fundamental to also improving agricultural productivity. Goals to increase agricultural productivity and improve environmental benefits therefore will frequently also depend upon private sector strategies in the

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2 The entire speech is available at http://www.environmentdaily.com/docs/40120a.doc

development of new crop varieties. The private sector, therefore, has important roles to play both in the increase of food production and in improving the environmental "footprint" of agriculture. The private sector's efforts to develop new varieties, however, are heavily influenced by intellectual property regimes, which determine the levels of risk-taking and the time-lines, thus delimiting the kinds of research that can be profitably pursued.

Public investment in the development of varieties with improved genetic potential for increased agricultural productivity has been and continues to be a prerequisite to help lift millions out of poverty and to banish hunger and malnourishment. However, public investments in agricultural research have not kept pace with acknowledged needs. While significant investments by national governments and foundations contributed to the Green Revolution of the 1960's and 1970's, public investments in crop improvement in the US have declined from a high of about $650m per year during 1993-1994 to $600m per year in 1997 (Heisey *et al.* 2001). In developed countries, the annual growth rate of real public investment in all agricultural research fell from 2.7% during 1971-1981 to 1.7% for 1981-1991. Similarly, in developing countries, the growth rate of public investment in agricultural research fell from 6.4% in the 1970s to 3.9% in the late 1980s. Of greater concern, variety development has been a decreasing percentage of all agricultural research. Real funding for the International Agricultural Research Centres has increased, but by less than 1% per year between 1985 and 1996 (Pardey *et al.* 1997). And serious shortfalls in public funding for the conservation and evaluation of genetic resources in the United States and globally (Imperial College 2003) threaten continued abilities to improve crop varieties.

On the other hand, private sector investment in agricultural research has generally increased, tempered by the IPP available. The first U.S. seed companies were established based upon the IPP provided through the biology of hybrid maize (ca. 1940, as hybrids cannot be replicated on the farm and inbred lines can be maintained as trade secrets). Private sector investments in U.S. agricultural research increased from $50m per year in the 1960s to $500m per year in the late 1990's (Heisey *et al.* 2001). This mirrors the IPP available: UPOV since the 1960s, and patent protection available in the 1990s. The resulting yearly yield increases and the stability of yield under extreme weather conditions is a matter of public record (USDA annual reports). United States maize production has been increasingly dominated by farmers' use of privately bred varieties. However, neither public nor privately funded development of improved crop varieties can continue effectively into the future unless the conservation and evaluation of a broad base of genetic diversity that is applicable to food and agriculture is secured. And sufficient public sector investments into improving agriculture for crops and regions of the world that cannot attract privately funded commercial activities are needed to improve health and economies, both of which would make a vital contribution to global political security.

1.2 The conservation, improvement, and deployment of genetic resource diversity

In the United States and in most of Europe, new crop varieties have replaced traditional landrace varieties; effectively landraces no longer exist as populations on the farm. As performance advantages are proven, this same trend can be seen in many other countries (Smale *et al.* 2002). Farmers cease the conservation of crop diversity, which they had unconsciously practiced for thousands of years, as they instead specialize in producing higher yielding and more reliable crops using seed that has been developed by professional plant breeders. No longer is all available crop genetic resource diversity annually arrayed in cultivation on farms.

Increasingly, current and future abilities to improve agricultural productivity are completely dependent upon conscious human acts to conserve genetic resource diversity and to develop improved varieties using that genetic diversity. Ex situ genebanks and breeding nurseries have become new sites for the sequestration of genetic resource diversity. Genebanks allow genetic resources to be stored for future use and breeders' nurseries are sites in which new diversity is developed. New varieties then deploy genetic resources successively in time and in space on farms (Donini *et al.* 2000; Manifesto *et al.* 2001; Christiansen *et al.* 2002; Parker *et al.* 2002; Smale *et al.* 2002; Duvick *et al.* 2003; Srinivasan *et al.* 2003).

The ability of professional plant breeders to provide a succession of new and improved genetic diversity onto farms ultimately depends upon the sourcing of new diversity and the maintenance of different or contrasting pools of genetic diversity between different breeding programs. To achieve these goals requires a broad base of germplasm that is not only conserved but is also technically accessible through programs of evaluation and adaptation. Conserving plant genetic resources is such a long-term endeavor that public funding is mandatory. Indeed, it is preferable so as to avoid private ownership of the essential genetic resource base. The capabilities of the private sector to contribute to genetic diversity on farms ultimately depends upon the extent to which commercially funded breeding organizations source exotic germplasm and are able to offer to farmers different genetics from different proprietary breeding programs. Sourcing and deploying exotic germplasm are longer-term and more high-risk activities than breeding from already well-established and well-adapted high yielding varieties. Consequently, intellectual property regimes that encourage the high-risk activities required to source and deploy exotic germplasm have a key role to play in encouraging more genetic diversity in production agriculture. IP regimes are also critically important in determining genetic diversity among different proprietary breeding programs. For example, IP regimes that allow competitors immediate and free access to newly developed varieties will both undermine the willingness of any single program to undertake high-risk activities and they will lead to different breeding programs using ever more similar germplasm pools. Breakdowns in IP through misappropriation of protected germplasm will have similar negative impacts on genetic diversity in breeding and in production agriculture.

2. Intellectual Property Protection

2.1 Incentives to invest in research and development

More productive and environmentally harmonious agriculture requires innovative, research-driven solutions that collectively make the most effective use of genetic diversity and appropriate methods of crop husbandry. Achieving these solutions is dependent upon research investments by both the public and private sectors. In particular, private investments are dependent upon an intellectual property regime that will encourage the needed investments. The successive deployment of new genetic diversity on farms will not occur unless breeders are able to invest at least some resources into prebreeding or germplasm enhancement programs, efforts that should incorporate germplasm that is initially unadapted or exotic to the region for which they are developing improved cultivars. If risks outweigh research and business opportunities, then breeders will instead choose to make relatively lower-risk investments, working with a small cadre of well- characterized and well-adapted varieties that are already widely used on farms, thereby reducing the genetic base and putting food and feed security at risk. It is therefore important to create affordable intellectual property systems that include contracts, patents, trade secrets and more effective PVP/PBR (UPOV style protection), so that developers of new and improved crop varieties in all countries can choose the most suitable form of protection.

2.2 Path-dependence

The endeavor of plant breeding exhibits “path-dependence” (McGuire 1997). Progress along a new path (e.g., using exotic germplasm) places initial costs and risks on the breeder, though all entities eventually benefit. The issue of access to germplasm therefore becomes of paramount importance in this light.

Path-dependence prevents the private sector from introducing new germplasm diversity and increasing agricultural productivity through breeding when:

- publicly funded germplasm conservation programs are not in place

  and/or

- pre-breeding or germplasm enhancement programs are not in place

  and/or

- there is a lack of available technologies to assist in the identification and incorporation of potentially useful new germplasm

  or

- the level of IP is insufficient to support commercial organizations taking the relatively long-term and high risks associated with introducing exotic germplasm

  or worse,

- the level of IP is so low that it begins to penalize would be innovators who have no alternative but to release newly bred varieties into an environment that provides immediate access for use in product development by other breeding programs.

The continued deployment of new crop varieties with improved performance due to the use of new combinations of genetics is essential for a stable and increasing supply of food and feed. It is therefore axiomatic that the type of investment environment that is available to commercially funded plant breeders will directly impact the sustainability of plant breeding and of agriculture overall, at least for those regions and crops where the private sector provides farmers with their seed supply. If the level of IP is insufficient to warrant the exploration and utilization by breeders of a broader genetic resource base, then new, diverse genetics will not be created by the private sector for use by farmers, consumers, and other breeders.

2.3 Types of IP

An economic study of intellectual property regimes as they relate to plant breeding was conducted by Lence *et al.*, (2004). This study showed that the optimum level of IPR in terms of providing benefits to society from the development of plant varieties with improved on-farm performance is greater than the level that existed in the North American maize seed market in 1996 and 1997 when contract licenses, PVP, and utility patent protection on varieties were used. A recent study on soybean diversity in the US (Sneller 2003) lends support to the argument that an effective IP regime can promote investments into developing a broader germplasm base. Sneller (2003) found that increased opportunities to obtain IPP for new soybean varieties have led to different germplasm being developed by different commercial companies. Thus, a greater breadth of genetic diversity is utilized than would be the case if there had been fewer investments, which would have resulted in the use of a shared but narrower genetic base among companies. Sneller (2003) cited a concern that restricting the exchange of germplasm among companies could leave individual companies with a narrow genetic base that could inhibit progress by breeding. However, companies exchange germplasm through cross-licensing, and patented germplasm is provided in the public domain for free exchange once protection has expired. Increased IP therefore can attract more investments and consequent use of more diversity, which ultimately adds to the stock of well-adapted and well-characterized germplasm that belongs to the public domain. Germplasm access under conditions of prior informed consent (PIC), which include terms for benefit sharing, is not unique to strong IP regimes such as patents. For example, obtaining PIC and including terms for access and benefit sharing are fundamental precepts of the Convention on Biological Diversity (CBD). And Linares (2002) has documented that individual, west African women rice farmers in Jola do not make their rice varieties freely available to other farmers; they instead obtain access to new germplasm through the exchange of varieties that have a perceived new and potentially advantageous use by each recipient.

In contrast, an environment of free and immediate access as, for example, has been proposed by Troyer and Rocheford (2002), will not encourage investments into broadening the germplasm base. In such an environment, the most successful, innovative and risk-taking plant breeders will be penalized because of "path-dependence". The competition will make use of the improved germplasm before the breeder of the initial variety can recover the research investment. Yet increased risk (and investment) is required to introduce more diverse germplasm. Consequently, an IP environment that features free and immediate access to newly developed varieties will ultimately both reduce access to new genetic diversity and focus increased breeding activities upon a small cadre of existing varieties that are already well-adapted to a particular region. The overall impact of such a weak IP regime will be a further narrowing of the elite germplasm base. The women rice farmers of sub-Saharan Africa (Linares 2002) have already determined from practical experience that mutually agreed exchange of germplasm, and not free access, is the acceptable norm to encourage progress through breeding. Similar respect for intellectual property is evidenced and enshrined in the CBD.

The breakdown of IPP through misappropriation also contributes to a narrowing of genetic resource diversity in breeding and in agriculture. When misappropriation occurs, breeding programs that were once developing new varieties from different genetic resources then converge, working with similar, and sometimes even identical, germplasm. Consequently, the breadth of diversity in the genetic resource base narrows both in breeding and ultimately in production agriculture. The genetic resource base across the growing region then becomes increasingly vulnerable to stresses imposed by inclement weather, pests, and diseases. Breeders are less able to respond to biotic and abiotic challenges because the available repertoire of useful genetic diversity has been eroded and they have fewer incentives to take risks to evaluate and utilize more diverse, but initially less well-adapted germplasm. Effective IP regimes, therefore, not only encourage private sector investments to improve the productivity of crop varieties, they also promote benefit sharing. These practices collectively contribute to the more effective and equitable use and responsible stewardship of the genetic resource base.

3. Interactions between IP and technology

3.1 The technology aspect

IPP and technologies both impact research and product development strategies. The ability to maintain inbred lines as trade secrets and annual purchases of hybrids by farmers attracted private investments in research and product development very early in the history of hybrid maize. New genetic technologies and breeding approaches also can facilitate the use of genetic resources that otherwise would not have been used in breeding (Tanksley and McCouch 1997). The past decade has witnessed a very rapid development of new technologies that can speed and facilitate access to germplasm. And companies are increasing their investments into high-throughput molecular marker screening laboratory facilities. For example, Syngenta recently announced that the company will invest 2 million Euros to double its present capacity at a facility in France (Economie, issue no. 135, January 2004). The new facility will be able to process millions of DNA sequences daily.

New technologies include:

- high-throughput semi-automated molecular marker profiling
- off-season winter nurseries giving multiple generations per year

- high-throughput gene expression assays using DNA on silicon chips
- high-throughput proteomics assays
- high-throughput DNA sequencing facilities
- ability to DNA profile both the female and male parents of hybrids without accessing either parent per se via use of maternally inherited tissue (e.g., use of pericarp tissue)
- ability to create homozygous progeny very rapidly using di-haploid genetic stocks
- ability to conduct genome-wide gene-trait association studies involving hundreds or thousands of genotypes, including landraces
- ability to conduct genome-wide scans comparing domesticated varieties or landraces and to compare them with wild relatives to identify potentially useful loci and new genetic diversity

Particularly when used in combination, these technologies can provide formidable new abilities to more rapidly develop new genotypes. However, it is important to recognize that these technologies will not only allow plant breeders to conduct their current breeding strategies more quickly. Of potentially far greater importance are the fundamentally new capabilities that these technologies could allow. Plant breeders have historically been bound to the phenotype as the sole informative agent and selection tool for creating new, improved varieties. But molecular marker studies (Tanksley and McCouch 1997) show that breeders can now begin to identify agronomically useful genetics in germplasm that would have been ignored and previously over-looked when phenotypes alone were considered. And epistatic gene interactions that were hitherto practically impossible to grasp can now begin to be identified and used to advantage in breeding programs (Rafalski *et al.* 2004). Whole genome scans are now possible using a dense array of DNA markers. When coupled with surveys of hundreds or thousands of genotypes, then powerful new methods exist to identify useful new genetics, including in exotic landrace collections (Remington *et al.* 2001; Sela-Buurlage *et al.* 2001; Buckler and Thornsberry 2002; Yu *et al.* 2003; Gebhardt *et al.* 2004; Rafalski *et al.* 2004; Simko *et al.* 2004). Molecular scans of wild relatives of domesticated crop plants also provide new means to identify loci that can be further modified to improve the agronomic performance of existing varieties (Vigoroux *et al.* 2002; Kikuchi *et al.* 2003; Jantasuriyarat *et al.* 2004).

New technological capabilities can be used not only to facilitate existing pathways to genetic resources but also to create new and critically significant pathways for breeders to access and more effectively use a broader array of germplasm diversity than hitherto had been possible, or even contemplated (Tanksley and McCouch 1997). Field programs that characterize, evaluate, adapt, and re-evaluate exotic germplasm diversity can also facilitate existing pathways and add new pathways or options that plant breeders can choose to adopt in sourcing germplasm into breeding programs. Using new technologies and having more ready access to a broader base of better adapted germplasm that is at least preliminarily evaluated for utility in plant breeding can collectively reduce the historic dependence of plant breeders upon sourcing breeding parents from the commercial products developed by other public or privately funded plant breeding programs, which may also supply varieties to farms situated in the same localities or agro-ecological environments.

However, it does not automatically follow that plant breeders will take advantage of available technologies and a more diverse and readily usable germplasm base to increase the breadth of genetics that they choose to incorporate into their breeding program.

Whether technological developments will be employed by breeders in the private sector to increase access to a broader germplasm base and thus to sustain and improve agricultural productivity—as well as to provide associated health and environmental benefits—fundamentally depends upon the IP regimes in place.

3.2 Technology-IP interactions

Technology can be a two-edged sword with respect to the effective level of IPP and the utilization of genetic resources. While technology can facilitate the use of genetic resources, it can also be used in a fashion that threatens to undermine existing levels of IPP. For example:

- Molecular marker technologies can be used to attack trade secrets by rapid identification of female parent inbred line contaminants in bags of hybrid seed. These inbred lines might then be used directly as parents of hybrids or as parents for further breeding.
- Molecular marker technology can be used to identify segregating molecular characteristics in an otherwise uniform variety and thus to select a distinct "new" variety from the segregating source without any breeding effort being expended.
- An existing variety could be transformed by genetic engineering and thus achieve varietal status by virtue of its distinctness but without any effort expended to change the genetic base of the variety.
- An existing variety could be changed just sufficiently and even only cosmetically using marker assisted breeding so that it retains the important agronomic attributes of the initial variety but would evade the dependency resulting from its status as an Essentially Derived Variety (EDV) through selection for a molecular marker profile that is "sufficiently different" from the initial variety.
- An existing variety could be changed dramatically in its overall DNA marker profile yet contain some or all of the key genetics impacting important agronomic traits due to targeted selection of its genetics using molecular marker or genomics data.
- An inbred containing the key genetics of the female parent of a hybrid can be rapidly recreated using one or a suite of technologies including di-haploidy, molecular markers, genomics, winter nurseries, and high-throughput laboratory genetic profiling and screening. The inbred can then either be used as a parent of a hybrid or as a parent for further breeding.
- An inbred containing the key genetics of the male parent of a hybrid (hitherto essentially impossible to access via a hybrid) can similarly be recreated and used.

Two extreme positions for the use of new technologies in plant breeding can be postulated. On the one hand, new technologies can be used to facilitate access to genetic resources that were hitherto practically unavailable to breeders due to their presence in wild species or in exotic or unadapted varieties, or simply because the range of exotic germplasm is simply too large to screen using conventional field approaches. Or, those same technologies could be used to facilitate access, and even to attempt to evade existing forms of protection, in varieties that are already deployed on farms. The former, more innovative approach contributes to making more effective use of a broader genetic base in agriculture. The latter approach contributes to reduced levels of innovation and to a narrowing of diversity in breeding populations and in production agriculture. Ultimately, in this latter scenario, the food supply would be jeopardized, incentives to conserve genetic resources would be compromised, and health and environmental security would be put at risk.

The IP environment can clearly influence investment decisions regarding the use of a broader repertoire of genetic resource diversity, and the effectiveness of IPP is impacted by the state of technology. Without effective IP, technology and breeding practice will tend to be applied along the path of least resistance in respect to risks and the resources employed. And although new advances in technology and learning facilitate capabilities to incorporate new exotic genetic diversity it will likely always remain a far easier proposition, and a far speedier option, to source diversity from varieties that are already well adapted to the target region. If an IP environment that effectively promotes the use of well-adapted varieties, and which therefore essentially provides disincentives to sources more exotic germplasm, were to predominate then the initial source of variation that is used by breeders will increasingly be a smaller cadre of existing, well-adapted varieties. This is not an environment for sustainable development. New diversity would not enter into breeding programs. Existing diversity would diminish, fail to support continued genetic gain, and would be vulnerable to loss.

4. The Future

4.1 Setting the Scene

It has been recognized that IP regimes do not always remain static in respect to the incentives they initially were able to provide. For example, UPOV was revised in 1991, introducing the concept of the "Essentially Derived Variety" to address the potential of genetic engineering to "pirate" existing varieties. The introduction of the EDV concept was a positive and significant step. Breeders in national and international seed associations are developing procedures to define and implement the EDV concept. However, it remains unclear how effective the EDV concept can be in regard to sustaining research investments in germplasm development, including encouraging access to a broader germplasm base. This concern increases as we look into the future, a future that is rapidly evolving in terms of demands made upon breeders to help meet growing needs for food, health, and environmental security and in terms of technological advances. The current forms of UPOV allow immediate and free access by other breeders to commercial varieties for further breeding. In such a circumstance, the breeder of the initial variety has no redress to withhold consent or to negotiate a royalty from the breeder of the derivative unless that derivative is declared an EDV—and it is only UPOV 1991 that provides for EDVs. Even then, the EDV system could prove not be an effective remedy for combating plagiarism. First, EDV is not formally defined. Breeders are developing criteria for implementing the EDV concept. Further refinements will probably be necessary to take account and advantage of new technologies and an increased understanding of the genetic basis of phenotype. However, final determination of the effectiveness of the EDV concept might depend upon future decisions made by courts. These outcomes cannot be predicted and might conceivably set precedent that ultimately undermines the ability of PVP to encourage innovation and investment. Second, the use of new technologies could undermine the intent of the EDV provision. The EDV system, as currently envisioned, examines overall genetic similarity among varieties. Thus, the envisioned EDV system could conceivably be used to hide cosmetic breeding by the targeted extraction of key essential elements from a protected variety while obscuring that origin by retaining a high proportion of the other parent's germplasm. And finally, any unlicensed use in product development by a competitor during, at least, the initial period of commercial life of a newly developed variety, will undermine the willingness of the breeder of the initial variety to invest in relatively high-risk or more innovative research and product development.

Consequently, investment incentives to conduct innovative and high-risk research and to develop new and improved germplasm will decline under the current UPOV system, if that form of protection is the only IPP available to the breeder. Allowing free and immediate access to commercial varieties actually provides perverse incentives for breeders not to invest in high-risk innovative research and product development because the results of their research and product development are immediately placed in the public domain for others, including those who might make less risky or significant investments, to use as breeding parents. Consequently, under the research environment provided for by the current UPOV scheme, the economic incentive is for breeders to make relatively low risk investments in product development by utilizing already adapted starting materials (their own germplasm or that of other breeders, with or without Prior Informed Consent). An IP regime that only encourages access to varieties that are already well-adapted and high-performing will lead to less use of a broader base of germplasm; reduce the diversity of germplasm used in breeding; reduce long-term on-farm performance gains; increase vulnerabilities to pests, diseases, and climate across a growing region; and increase reliance on single-gene biotechnological solutions practiced upon a relatively narrow genetic base.

In contrast, biotechnological inventions are usually eligible for stronger IP via patent protection than are plant varieties. This disparity in levels of available IP is the case in all countries that have patent systems; that is, apart from the United States, Australia and Japan, which allow plant varieties to be eligible for patent protection. But increases in agricultural productivity have and will remain dependent upon the development of improved germplasm in concert with the application of biotechnology. It is therefore very important that activities in all fields of endeavour that contribute to increasing agricultural productivity be encouraged to attract investments and innovations. However, there is currently a growing global disparity in the levels of IP that are available to biotechnological innovations compared to those that are available for germplasm development. Most countries do not allow plant varieties to be eligible for patent protection. Yet the effective level of protection that is available under UPOV is declining due to an accelerated growth of technological capacities and capabilities to characterize, modify, and select genes and germplasm. At the same time, countries that do provide patent protection include gene sequences as patentable subject matter. An environment that provides strong protection for genes, but with increasingly weak protection for newly developed varieties per se, is potentially dangerous with regard to sustaining increases in agricultural productivity. This is because such an environment will tend to encourage the making of relatively small genetic changes on existing varieties with less encouragements, and even to discourage the sourcing and introduction of new and useful germplasm which is, as yet, incompletely characterized according to gene sequences.

4.2 A future IP scenario

The general concept of a PVP-type system is appropriate and important to provide affordable IP for plant breeders whilst retaining the availability of germplasm as an initial source of variation in breeding. PVP remains especially important to provide IP for successful breeders who, either because of the incredible and still largely incomprehensible complex biology of their crop species or through lack of expensive technology cannot describe an individual gene and its agronomic impact, but who, nonetheless, develop improved varieties that are needed in agriculture, horticulture, or forestry. Other forms of IP (trade secrets, contracts, patents) are also important.

UPOV was updated once due to changes in technology. It is time to update the provisions once again to accommodate advances in technology that have occurred since 1991, in order to encourage continued infusions of new germplasm into breeding pools. These UPOV updates should include:

i. Providing compensation for and/or limits on saved seed in all countries.

ii. Making the EDV system more effectively further definition to avoid technological loopholes

iii. Revising the breeders' exemption to include a period of "x" years from the date of a PVP application during which the breeders exemption would not be available for UPOV-protected material including commercialized varieties.

iv. Require a seed deposit for all UPOV-related applications.

v. Requiring the disclosure of all material deposited with PVP applications at the end of "x" years and making all material deposited available for research under the breeders exemption at the end of "x" years unless the disclosure and availability would be in conflict with a utility patent on the same material.

vi. Place all UPOV-related deposits (excepting parents and synthetics) into the public domain following expiration of UPOV protection

vii. Create a PCT-like system to facilitate filing of PVP applications on an international basis.

viii. Provide for and facilitate under UPOV global benefit sharing consistent with the International Treaty on Plant Genetic Resources for Food and Agriculture.

Patent law and UPOV provide different kinds of protection. While plant patents are not allowed worldwide, patent protection on germplasm may effectively become available in Europe and elsewhere in the world with the issuance of utility patents on genes with claims that that extend to the plant. Patent claims that extend to the plant provide an opportunity for increased IPP on the germplasm of the variety within which the patented gene resides. Immediate reactions to these changing circumstances have caused several (mainly Europe based) breeders to argue for: a) an exemption under patent law to access the germplasm of a variety that contains a patented element with claims extending to the plant, and b) further exemptions under the claims of the patented element. Such exemptions would allow breeders to carry out the additional work needed to remove the patented elements inherited from the respective breeding parent so that those elements would then (presumably) be absent from the newly developed variety.

However, there are a number of reasons why such change is undesirable, why it would not be effective, and why it may be impossible to achieve:

- Inventors in the area of plant breeding and development should not be penalized, but in fact should be rewarded to at least the same level and extent as inventors in other fields. Markets or countries that provide weak or inadequate protection simply will not attract substantial investments for research and development.
- US statutory law does not provide for a research exception under patents, nor does US case law support a research exception,
- A research exception would be a drastic change to the US patent system and must be passed by Congress and signed into law by the President before such an exception could be enacted. Making such an exception unique to agricultural germplasm would be difficult or impossible to accomplish.
- A research exception under patents is not required by the TRIPS agreement.
- Any support for a research exception may have an overreaching affect of appearing to support research exceptions in general as well as other exemptions (e.g., farm saved seed).
- The breeder who seeks to develop a variety from a variety that carries a patented transgene would commit new resources to removing patented elements from derivatives. A compulsory license under patent law would therefore create perverse incentives to invest less in research because new resources would be directed toward removing patented elements from derivatives. Under such a scenario increased resources would be directed toward activities that provide no improvement in agronomic performance. The end results would be less investment in innovation and a narrower germplasm base in breeding and in agriculture. Crop productivity could be jeopardized and the germplasm base could be vulnerable to erosion.
- By removing patented elements, the breeder would face potential regulatory issues (e.g., Is the patented element still in the variety, but not expressing? Does a fragment of the patented element remain?) Going through the transgenic regulatory process in order to clear a variety that is expected not to contain the patented element is a significant economic burden.

A revised UPOV would contribute to an improved solution. All plant breeders working under such a revised UPOV would have increased IP for the germplasm in the varieties they have created. Stronger IP on varieties provides more opportunities to negotiate access to germplasm developed by another breeder, including access to germplasm prior to the addition of patented elements.

5. Conclusions

Knowledge intensive solutions are required for the complex biological problems of food, health, and environmental quality faced by the world today. New varieties developed from a broad germplasm base can help meet both agricultural production goals and improve environmental quality. Technologies and analytical methods are now available that allow a broad base of varieties, including exotic land-race varieties and wild relatives to be characterized for genetic resource diversity. However, it will always remain far easier to incorporate useful diversity from existing well-adapted varieties than to identify, evaluate, adapt, and incorporate useful genetic diversity from varieties or landraces that are themselves less well adapted to the target region. Nonetheless, it is clear that continued genetic gain will depend upon infusions of diversity that is both useful and new to the target region. However, public investments in agricultural research have declined in most industrially developed countries and are stagnant or increasing only marginally in developing countries. Therefore, the private sector has an increasingly important role that it can, indeed must, assume in characterizing and deploying improved varieties utilizing new germplasm sourced from a broader base of genetics. But, the deployment of a broader base of germplasm by private sector organizations will only take place provided the appropriate incentives to invest, take risks, and to innovate are in place. No private sector organization can afford to make investments that, immediately upon commercialization, become free donations to competitors. IPP as applied to plant breeding must be improved on a global basis to attract research investments and to encourage use of a broader base of genetic resources. A key reason to increase IP globally is because exotic genetics have a proven track record of materially increasing productivity in regions far removed from their original site of origin or widespread use. For example, Argentinean Maize Amargo germplasm has had an important impact on U.S. maize agriculture and Iodent maize germplasm developed in the United States has had huge impacts upon maize agriculture in France. Also, U.S. soybean varieties are being included in breeding programs in China, even though China is the site where soybean was first domesticated. There are numerous dependencies upon crop germplasm that cut across country and continental boundaries. Therefore, increasing incentives to invest in breeding on a global basis are required to encourage both access and benefits. More effective IP can encourage access to germplasm and they can ensure benefits flow to providers of germplasm. Material Transfer Agreements can clearly state mutually agreed obligations by accessors of genetic resources to return benefits to germplasm providers. At the end of the day it is consumers who ultimately benefit from the use of germplasm. These changes in UPOV are required on a worldwide basis to achieve the goals of increased, more sustainable, and reliable food production and improved environmental quality.

Terms regarding access to genetic resources and benefit sharing have been discussed at length in the international community. Incentives and equity are two fundamental elements that must be satisfactorily dealt with in order to encourage conservation and use of plant genetic resources. A crucial component in allowing the more effective use in agriculture of a broader germplasm base is a revised UPOV system that provides greater incentives to invest in germplasm development by changing the breeder exemption clause. Such a revised UPOV system and an effective utility patent system would facilitate achievement of the goals of the IT and CBD by providing increased opportunities for benefit sharing to germplasm providers and increased incentives to holders of germplasm to conserve and to evaluate those resources. Adequate public funding is required both to conserve and evaluate plant genetic resources for food and agriculture and to breed improved varieties for use by farmers in regions that cannot attract private investments in plant breeding and seed production.

Those who endeavour to make advances through research in the area of plant breeding and varietal development should not be penalized, but, in fact, must be encouraged to take risks and invest resources to at least the same level and extent as inventors in other fields of endeavour. Food, health and environmental security are dependent upon the creation of new, improved varieties and genetic solutions to complex problems. Markets or countries that provide weak or inadequate IPP will not attract substantial investments for the research and development of more productive crop varieties, and may not reap the benefits of agricultural innovation generated in countries that provide adequate IPP. A lack of plant breeding investments would jeopardize both the near-term and future genetic resource base by narrowing diversity in agriculture and undermining programs to conserve and more effectively utilize a broader genetic resource base.

References

Ausubel JH. 1996. Can technology spare the earth? Amer. Scientist 84: 166-178.

Buckler, ES and JM Thornsberry. 2002. Plant molecular diversity and applications to genomics. Current Opinion in Plant Biology 5: 107-111.

Christiansen MJ, SB Andersen and R Ortiz. 2002. Diversity changes in an intensively bred wheat germplasm during the 20th century. Molecular Breeding 9: 1-11.

Collis JS. 1973. The Worm Forgives the Plough. Penguin Books, London, UK. 360pp.

DEFRA 2002. The role of future public research investment in the genetic improvement of UK grown crops. Final report September 2002, Department of Environment, Food and Rural Affairs, UK Government, London, UK, 222pp.

Diamond J. 1997. Guns, germs and steel: The fates of human societies. Norton, New York.

Donini P, JR Law, RMD Koebner, JC Reeves and RJ Cooke. 2000. Temporal trends in the diversity of U.K. wheat. Theor. Appl. Genet. 100: 912-917.

Duvick DN, JSC Smith and M Cooper. 2003. Long-term selection in a commercial hybrid maize breeding program. Pp 109-152 (part 2) IN J. Janick (ed.) Plant Breeding Reviews. John Wiley and Sons Inc., Hoboken, New Jersey, 290pp.

Gebhardt C, A Ballvora, B Walkemeier, P Oberhagemann and K Schuler. 2004. Assessing genetic potential in germplasm collections of crop plants by marker-trait association: a case study for potatoes with quantitative variation of resistance to late blight and maturity type. Mol. Breeding 13: 93-102.

Heisey PW, CS Srinivasan and C Thirtle. 2001. Public sector plant breeding in a privatizing world. Econ. Res. Service, U.S. Department of Agriculture, Agriculture Information Bull. No. 772, Washington, DC, 19pp.

Huang J, R Hu, C Fan, CE Pray and S Rozelle. 2003. Bt cotton benefits, costs, and impacts in China. AgBioForum 5: 1-14.

Huang J, R Hu, S Rozelle, F Qiao and C Pray. 2002. Transgenic varieties and productivity of smallholder cotton farmers in China. Australian Jour. Ag. Res.Econ. 46: 367-387.

Huang J, S Rozelle, C Pray, and Q Wang. 2002. Plant biotechnology in China. Science. 295: 674-677.

Imperial College 2003. Crop Diversity at Risk: The case for sustaining crop collections. Imperial College Wye, Wye, UK 32pp.

Jantasuriyarat C, MI Vales, CJW. Watson and O Riera-Lizarazu. 2004. Identification and mapping of the free-threshing habit and spike compactness in wheat (Triticum aestivum L.). Theor. Appl. Genet. 108: 261-273.

Kikuchi S, S Taketa, M Ichii and S Kawasaki. 2003. Efficient fine mapping of the naked caryopsis gene (nud) by HEGS (High Efficiency Genome Scanning)/AFLP in barley. Theor. Appl. Genet. 107: 73-78.

Lence SH, DJ Hayes, A McCunn, S Smith and W Niebur. 2004. Welfare impacts of property rights in the seed industry. Amer. Jour. Ag. Econ. (in review).

Linares OF. 2002. African rice (Oryza glaberrima): History and future potential. Proc. Natl. Acad. Sci., 99: 16360-16365.

Manifesto, MM, AR Schlatter, EE Hopp, EY Suarez and J Dubcovsky. 2001. Quantitative evaluation of genetic diversity in wheat germplasm using molecular markers. Crop Sci., 41: 682-690.

McGuire 1997. The effects of privatization on winter-wheat breeding in the UK. Biotechnology and Development Monitor 33: 8-11.

Pardey PG, JM Alston and VH Smith. 1997. Financing science for global food security. 1997 IFPRI Ann. Rep. (www.ifpri.org/pubs/books/ar1997-1.htm) International Food Policy Research Institute, Washington, DC.

Parker GD, PN Fox, P Langridge, K Chalmers, B Whan and PF Ganter. 2002. Genetic diversity within Australian wheat breeding programs based on molecular and pedigree data. Euphytica 124: 293-306.

Rafalski A, M Junh, S Luck, K Palaisa and S Tingey 2004. Genetic association mapping for marker assisted selection. Proc. 4th International Crop Science Congress.

Simko I, KG Hayes and RW Jones. 2004. Mining data from potato pedigrees: tracking the origin of the susceptibility and resistance to Verticillium dahliae in North American cultivares through molecular marker analyses. Theor. Appl. Genet. 108: 225-230.

Smale M, MP Reynolds, M Warburton, B Skovmand, R Trethowan, RP Singh, I Ortiz-Monasterio, and J, Crossa. 2002. Dimensions of diversity in modern spring wheat in developing countries from 1965. Crop Sci., 42: 1766-1779.

Sneller C. 2003. Impact of transgenic genotypes and subdivision on diversity within elite North American soybean germplasm. Crop Sci., 43: 409-414.

Srinivasan CS, C Thirtle and P Palladino. 2003. Winter wheat in England and Wales, 1923-1995: what do indices of genetic diversity reveal? Plant Genetic Resources 1: 43-57.

Tanksley SD and S McCouch. 1997. Seed banks and molecular maps: Unlocking genetic potential from the wild. Science 277: 1063-1066.

Thrupp LA. 1998. Cultivating diversity: Agrobiodiversity and food security. World Resources Institute, Washington, DC, 80pp.

Troyer AF and TR Rocheford. 2002. Germplasm ownership: Related corn inbreds. Crop Sci., 42: 3-11.

Yu W, J Xu, C H M Vijayakumar, J Ali, B Y Fu, J L Xu, Y Z Jiang, R Marghirang, C Aquino, S S Virmani and Z K Li. 2003. Molecular diversity and multilocus organization of the parental lines used in the International Rice Molecular Breeding Program. Theor. Appl. Genet. 107: 131-140.

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