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

## A Perspective from the Private Sector[1]

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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"*
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> *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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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.

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