Add Monsanto and the amount of time that will be saved by sharing data about rice (Financial Times

Knowledge includes both empirical material and that derived by inference or interpretation
Information is usually construed as narrower in scope and implies a random collection of material rather than orderly synthesis

Professor Thomas Cottier
University of Berne
Hochschulstrasse 4
3012 Berne
Switzerland

William Lesser
Department of Agricultural, Resource and Managerial Economics
405 Warren hall
Cornell University
Ithaca, NY 14853-7801

Rebecca Eisenberg
Law School, University of Michigan
408 Hutchins Hall
625 South State Street
Ann Arbor, MI 48109-1215

Agricultural Biotechnology and the Privatization of Genetic Information: Implications for Innovation and Equity

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Lee Ann Jackson
Department of Applied Economics
University of Minnesota

Abstract

Changes in intellectual property rights systems have lead to the privatization of genetic resources and subsequently to the proliferation of new agricultural biotechnology products. Since these innovations have the potential to increase agricultural production while limiting environmental degradation, the benefits from these technologies could be far-reaching. However, while intellectual property rights are intended to encourage innovation in the private sector, private sector domination of the development of new products may skew the distribution of benefits away from marginally productive agricultural areas where poorer communities live.

The primary purpose of this paper is to explore the tension between the public goals of encouraging innovative use of genetic resources and supporting the equitable access to genetic resources. The paper also discusses overlapping systems of intellectual property rights on genetic resources, and how this complex system of rights for genetic resources influences the relationship of users and producers of genetic knowledge. The paper will include a discussion of private and public good aspects of genetic resources and how various intellectual property systems affect genetic resource use. The paper will also examine the challenge of creating public policies and legal systems that encourage innovation and ensure the equitable distribution of benefits from genetic resources.

Agricultural Biotechnology and the Privatization of Genetic Information: Implications for Innovation and Equity

If nature has made any one thing less susceptible than all others of exclusive property, it is the action of the thinking power called an idea…He who receives an idea from me, receives instruction himself without lessening mine; as he who lights his taper at mine, receives light without darkening me.

Thomas Jefferson as quoted in
The Economist, April 8th, 2000 p. 17

INTRODUCTION

From the early development of cultivated crops to the Green Revolution of the 1960's, agricultural innovation has acted as a catalyst for societal change. While on balance these changes provided benefits, political, social and economic forces often biased the distribution of these benefits towards society's powerful and rich. The current biotechnology revolution, which represents one step along a continuum of agricultural innovation, offers many potentially health and environmental improving products. However, like previous generations of agricultural innovations, without appropriate management, legal systems and institutional support, the benefits of these new technologies may bypass poor and marginalized groups in society, thus shifting the benefits away from those who need them the most.

The current creation of new technologies depends upon highly sophisticated genetic manipulation techniques as well as knowledge accrued over the long history of agricultural development. Two general types of knowledge are used in the production and marketing of new agricultural products: industrial knowledge which focuses on using scientific manipulation of DNA to create new economic products and traditional knowledge which encapsulates understanding of the potential uses of naturally occurring plants. National and international property regimes governing the use and distribution of genetic resources and knowledge have evolved over time. Industrial knowledge is protected through the use of economic policy tools such as patents, while traditional knowledge is supported mostly through arrangements that provide communities the right to negotiate future use of genetic resources found in their local plant species. Although the two types of knowledge require different types of protection based upon their uses and users, currently institutional harmonization of policies is biased towards the industrial type of protection,.

Changing legal intellectual property rights systems have lead to privatization of genetic resources in the industrial sector. This privatization has been promoted as a necessary means to encourage the development of new agricultural biotechnology products. The drive to privatize genetic resources has carried over into areas of traditional plant knowledge. The privatization trend is raising questions about the tradeoffs between promoting equitable access to plant genetic resource knowledge and creating incentives for agricultural innovation. Also concerns have been raised that private sector domination of the development of new products may skew the distribution of private rights to genetic resources benefits away from marginally productive agricultural areas where poorer communities live. The flow of information from developing countries to private industries may lead to long term distortions in the distribution of benefits from agricultural biotechnology innovations.

Thus, Intellectual Property Rights have implications for access to new technologies and agricultural innovations. This analysis explores the tension between the public goal of encouraging innovative use of genetic resources and the public goal of supporting the equitable access to genetic resources and their associated benefits. It argues that complete privatization is not an effective means for promoting innovation and distorts access to genetic resources. The paper describes current international property rights institutions, and how this complex system of rights for genetic resources influences the relationship of users and producers of genetic knowledge. The paper concludes with suggestions about characteristics that would be necessary in a property rights system to encourage agricultural innovation without distorting access to genetic information and new agricultural products.

This paper avoids two topics within the broad area of intellectual property rights (IPR) and genetic resources. First, some of the controversies inherent to the discussion of appropriate protection for knowledge about genetic resources revolve around the ethics of assigning property rights to living organisms. Nevertheless, the following paper is not intended to provide a discussion of the ethics of privatization of genetic resources. Rather it provides an overview of current efforts to assign property rights and a discussion of the benefits and costs associated with various property regimes. Secondly, this paper does not specifically develop themes concerning intellectual property and incentives for conservation although these issues may be included in broader discussions of the impacts of privatization.

GENETIC RESOURCES AND GMOS

Rapid developments in the agricultural biotechnology industry have provided a myriad of products and innovations. The current generation of marketed products includes plants that produce pesticides and plants that are resistant to herbicide. Farmers benefit from directly from these products with enhanced input characteristics, while consumers primarily benefit in the long run from lower food prices. In the United States farmers are growing corn that has been genetically modified to contain genes from a bacterium that provides the plant with the ability to produce its own pesticide. This pesticide in the free-standing form is used throughout the organic farming industry. Another marketed Genetically Modified Organism (GMO) characteristic is the ability to resist a broad base herbicide called Round-Up. Farmers adopt plants with this characteristic because these plants withstand treatment by herbicide and therefore farmers can reduce herbicide application and soil manipulation and thus reduce soil erosion. Some of the next generation of marketed GMO varieties will have improved nutritional or health characteristics providing direct nutritional or health benefits to consumers. For example, Rockefellar Foundation is sponsoring research on to develop rice that contains forms of vitamin A that the body can absorb and rice that contains higher levels of iron to combat anemia. Researchers at Cornell University are working to produce fruits that include vaccines for hepatitis B.

Science and economics of agricultural innovation

To understand the science of genetic engineering and some of the controversies related to IPR of Plant Genetic Resources (PGR) it is useful to have an understanding of the relationship between the genotype (gene structure) of plants and the resulting phenotypic, or physical, characteristics. DNA is composed of a series of base pairs that provide the code for protein creation. Proteins in turn are the building blocks of enzymes that control all cellular activity from breakdown of molecules for energy to the synthesis of cell structural molecules. Each protein's unique three-dimensional shape determines its function. Altering a single base pair in the DNA sequence that encodes a specific protein can lead to a mutation that makes the protein incapable of performing its original function. These single base mutations also occur naturally and may lead to natural variations in species characteristics.

Agricultural innovation has moved through three distinct historical technological periods. In the first phase of innovation farmer breeding and selection efforts provided the catalysts for new product development. In this phase, in order to develop a new improved plant variety farmers or breeders first screened existing plant phenotypes within a species for the desired trait. Next, breeders incorporated this trait into the genetic material through successive breeding trials. Farmers had to wait for an entire growing season to determine the outcome of the crosses. Thus, this type of innovative process included a lot of trial and error and required a long time to produce plants with particularly desirable characteristics.

In the second period of agricultural innovation, scientists used knowledge of plant hybridization to create plants with enhanced growth characteristics. This type of innovation was based on a more sophisticated understanding of the plant genetics and the relationship between plant genotypes and plant phenotypes. Scientists learned how to create pure-bred plant lines that could then be crossed to obtain hybrids with the desired characteristics. Breeding efforts became more systematic and required less time to accurately produce the desired plant phenotype. In the mid-1900s scientists began experimenting with producing hybrid plants, particularly in corn[1]. These hybrid varieties produced more output and required less inputs. Seeds produced by these hybrids produced less than their parent plants. Thus farmers, who had traditionally re-used seed from their harvest in subsequent years, became more dependent upon the seed industry to supply their seed inputs on an annual basis. Many of the Green Revolution varieties had this characteristic (Rausser 1999). This lower productivity of hybrid corn gave seed companies the ability to appropriate gains from breeding without patent protection.

Traditionally public universities conducted most research on agricultural products, while the private sector specialized in the development of manufactured products. Public sector involvement in this type of research was justified by the perceived public benefits associated with agriculture. Private sector had limited incentive to contribute to agricultural research, since the private sector could not capture enough profits from these products to justify their investment in research and development. With the introduction of hybridization techniques private companies like, Pioneer Hybrids,

[1] See Walden, 1966.

began focusing on developing marketable seed products. Product development still required substantial time commitments. For example, Pioneer Hybrid took fifteen years to develop a new line of corn germplasm adapted to tropical conditions. Thus hybridization techniques created a new relationship between farmers and the private sector.

Improvements in molecular biology techniques and computer systems that allow the codification and analysis of huge amounts of genetic data have catalyzed the development of the biotechnology industry and initiated the third phase of agricultural innovation. In genetic innovation, based on biotechnology techniques, the DNA of plants is manipulated directly and genes added into the sequence that carry the desirable traits. Powerful computers provide scientists with the tools necessary to analyze huge volumes of genetic information. With this information they can isolate the genetic code that represents crucial proteins that alter the phenotype of plants in desirable ways. This process eliminates the trail and error step of traditional breeding in which breeders spent years crossing and re-crossing plants to achieve the desirable expression of the trait for which they were selecting. Once a trait has been identified, its gene located, isolated and introduced into a plant the genetic composition of plant is altered and a new type of plant is created. Very small differences in the genetic code may lead to substantial phenotypic variation.

One of the criticisms of biotechnology industry is that because private firms are dominating the development of marketable GMOs, the choice of traits to pursue is based on the potential economic payoff associated with new plant species. This may result in an inequitable distribution of economic benefits from biotechnology, with the needs of poorer small-scale farmers not being addressed. Also, the differences in the cost of searching for desirable traits may lead to strategic choices in which some plant species are systematically ignored (Traxler 1999).

Shifting policies have created new economic environments in which companies perceive increasing value in producing agricultural products. Multi-national firms are conducting much of the current development of marketable products. In 1998, Monsanto marketed GMOs in Argentina, S. Africa, Mexico, China, Australia, US, Brazil, Canada (Falck-Zepeda et al 1998) Multi-nationals often develop the genetic trait in larger countries that have the scientific capacity to produce and analyze the genetic data, then produce the plants in other countries. Small countries represent an attractive market for multinational biotech firms when the firms can capitalize on price premium and smaller costs of R&D. These firms are more likely to choose to pursue the second stage of biotechnology development in a particular country if they have access to adapted germplasm and the acceptance of biotechnology by farmers, regulators and legislators within the country. Firms also seek an environment that provides a transparent science-based regulatory process and the legal systems to claim and enforce IPRs that leads to increased pressure for countries to harmonize their IPR systems.

DEFINING GENETIC PROPERTY RIGHTS

Appropriation of natural resources traditionally occurs as resources gain economic and commercial value. Scientific and technological advances lead to resource scarcity that in turn lead to increased resource value and pressures to allocate rights to these resources. This trend towards resource privatization can be seen through historical examples such as the English enclosure movement in the 1600s and the development of property rights governing the use of marine resources.

This explanation of the catalysts for the development of property rights focuses on the value of resources that economists refer to as private goods. These are goods that are characterized by the fact if one person consumes a unit of the resource, that unit is unavailable to others for consumption. In contrast, public goods are goods where one individual's consumption does not limit the consumption by others. Many resources actually have both private and public good characteristics. For example, a fishery is composed of fish that can be privately appropriated, but at the same time provides regenerative capacity that provides social benefits to user groups. A park is composed of private resources, land, plants, and animals, but one visit to the park does not decrease the availability of the park to other visitors.

Genetic resources provide broad public benefits, such as ecosystem resiliency and providing potential inputs for plant breeding to produce new types of plants. But genetic resources also have the classic characteristics of public goods. The fact that an individual knows the genetic code does not limit the ability of others to know this genetic code and the use of genes to create new crop varieties does not alter its performance in the original plant (Zohrabian and Traxler 1999). In addition, the use of genetic resources by individuals, or groups, for the above benefits does not decrease the ability of others to access these benefits.

The biotechnology revolution is in part based in the de-coupling of the value of genetic resources from the value of the information captured in the genetic code. Information and knowledge has traditionally been considered a pure public good. In addition to non-rival possession, public goods are also characterized by low marginal costs of production and high fixed costs of production[2]. Knowledge has public good properties but differs from other conventional public goods because knowledge is cumulative and interactive (David 1993). The stock of knowledge grows incrementally.

Differentiating Industrial and Traditional Knowledge

As mentioned above, two types of knowledge systems, traditional and industrial, capture the value of genetic information. Traditional knowledge includes knowledge based in communities of the potential uses of plants and plant products. Industrial knowledge includes the explicit map of genetic information and the understanding of how pieces of genetic code can be manipulated to produce new types of products (See Cottier 1998).

The relationship between industrial and traditional knowledge is defined by their speed of evolution and by the direction of the information flow. Industrial knowledge focuses upon creating and distributing new types of knowledge and evolves rapidly in response to competition with other firms for markets in new products. The knowledge embodied in traditional forms represents a more static stock of knowledge that evolves slowly based upon the needs of communities. One way of describing these differences in knowledge is that traditional knowledge represents a stock of knowledge about potential uses of plant products, whereas industrial knowledge produces a flow of new knowledge

[2] According to the American Heritage Dictionary, knowledge includes both empirical material and that derived by inference or interpretation, while information is usually construed as narrower in scope and implies a random collection of material rather than orderly synthesis.

that may then be useful in the development of more knowledge. Industrial knowledge then develops out of a base of knowledge that includes traditional knowledge and a long chain of knowledge development.

Traditional knowledge systems have been relatively ignored in the push to develop protection for industrial knowledge. However, developments in the international arena, (particularly the Convention on Biodiversity) have sought to address the imbalance of property right development over genetic knowledge by explicitly describing sovereign rights to genetic information and knowledge. Countries can enter into contracts with firms to ensure the rights to access to biotechnology and revenues.

Industrial knowledge, Patents and PGR

Two factors have lead to increased privatization of PGR. First the ability of scientists to accurately describe DNA molecular structure has increased their ability to enclose this genetic resource. Without the capacity to describe specifically genetic code information individuals or companies could not claim legal ownership to particular gene sequences. With the evolution of modern biotechnology scientists using complicated computer programs and sequencing machines can create maps of gene sequences. Secondly, legal jurisprudence evolved over the 20th century to allow patenting of life forms.

The motivation for privatization through patents came from the belief that innovators would be more likely to invest in developing new technologies, if they knew that they would then have the temporary right to exclusive use and economic gains from that invention and be able to recoup their research investments. These rights allow exclusion of others from imitating, manufacturing, using or selling the invention over a specified period of time. In exchange for these rights, the patent holder agrees to make the detailed description of the invention publicly available, so others may benefit from this new knowledge. When a product has been patented, the patent extends to any subsequent use even if unforeseen. In theory, patents induce the development and commercialization of inventions that might provide societal benefits. Developments in the world trade policy such as TRIPS have increased the global use of patents as a form of IPR (see discussion below). Patents are the most tangible form of intellectual property and enjoy the strongest legal protection, however no international consensus exists about what products should qualify for patent protection.

In the current U.S. legal structure the unit of property is the gene fragment – pieces of genes that can produce a specific outcome. In the U.S. a patents requires that an invention be novel, non-obvious and useful. Given the requirement of novelty, IPR genetic materials protection is technically applicable to improved plant varieties but not really suited for landraces because these varieties have not been genetically altered (Evenson and Putnam 1990).

The U.S. patent system is very developed and since 1987 has allowed the patenting of genetically altered life forms. In the U.S. the government has the ability to grant rights to DNA sequences patentable because they have “a distinctive name, character and use” (Doll 1998)[3]. To distinguish patentable DNA sequences from

[3] US patent office patents alterations in single base pairs in DNA molecules. Because these variations exist naturally, they are discovered rather than invented. Therefore there is debate over the justification of

naturally occurring compounds they must be shown to be purified or isolated or part of a recombinant molecule (Doll 1998). Any non-naturally occurring manufactured or composition of matter, including plants and animals that are the result of human intervention could potentially qualify for patent protection.

EFFICIENCY AND EQUITY IMPLICATIONS OF PRIVATIZATION

The rationalization for granting temporary monopoly property rights to knowledge is based on the theory that the benefits of subsequent innovation will outweigh the social costs of monopolistic behavior by firms. Without property rights companies can free ride on other companies' research investments. While in theory privatization of genetic resources, encourages a socially optimal level of innovation, in practice the results of privatization are not unambiguously positive. Evidence indicates that patenting in many industries, but particularly within the biotechnology industry, may lead to inefficient and inequitable distribution of costs and benefits.

Some policy makers concerned with the potential distributive impacts of increasing privatization of PGR argue that granting proprietary rights to knowledge leads to hoarding of information, and altering the incentives for scientific disclosure. If this is the case then rather than promoting open disclosure of new discoveries, patents may encourage the research climate to become more secretive and competitive.

Defining a unit of genetic property is crucial to developing a coherent legal system for IPR. Currently biotechnology companies are claiming rights to genetic sequences without knowing exactly what the sequence can do or for what purpose the sequence might be valuable. This leads to potential conflicts over overlapping claims and contributes to general inefficiencies of the IPR system. Other related issues revolve around the identification of new forms that qualify for patent protection. For example, suppose scientists develop and patent a new plant that includes non-naturally occurring processes, but soon others advance the understanding of that plant providing a description of the plant as a complex of substances with discrete activities and properties. Patent law must define how the first patent will be narrowed and whether it will dominate subsequent findings (Sherwood 1990).

The complexity of patent law and the structure of the biotechnology industry combine to create conditions that may actually inhibit innovation due to inequitable distribution of rights and access to information. The biotechnology industry is composed of upstream developers and downstream developers. Upstream research (pre-market) develops new knowledge about gene sequences and their potential uses, whereas downstream developers use these discoveries to create products that have market value. Due the industry structure, allocation of private property rights and the direction of information flow from upstream, downstream users often must manage multiple patents on their inputs in order to produce a marketable product.[4]

The complexity of these legal relationships, including the liabilities and responsibilities introduces transaction costs to downstream production process. In the

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granting patent rights over these naturally occurring gene variations and the need to differentiate public and private rights to genome.

[4] Due to the transaction costs associated with acquiring many different licenses in the development of their product, breeders may under-produce new products. The cultivation of new plants might have externalities if there are unforeseen ecological effects that have negative value to society.

biotechnology industry companies may use “no stacking licenses” to control the use of their patented product by other possible competitors, inhibiting future innovation by forbidding companies from exploring the possible complementarities between new plant traits (Rausser et al 1999). For example, holders of IPR on proprietary research tools (upstream technologies) have the rights to deny universities the right to approach commercial developers for these technologies (Lawler and Erbisch 1999). In some cases, owners of upstream discovery are granted rights in subsequent downstream discoveries related to their product. This ability to claim rights over future, unintended, uses of their product, called “reach through”, may allow stacking of inconsistent claims among industry producers.

The rapidity with which new industrial knowledge about DNA sequences is being produced, the speed with which property claims may now be made, and the rate of change within the biotechnology industry also contribute to general inefficiencies in the patent system. Multiple firms may identify and claim ownership over the same individual discoveries that may obstruct future research. The rapidity of the change leads to situations in which writing complete contingent contracts is impossible and writing reasonably comprehensive contingent contracts that are incomplete is very costly (Rausser et al 1999). The speed of innovation raises risks of investing in innovation because it is possible that competitors may claim rights to products that are in the product pipeline (Scherer 1984).

Other potential strategic advantages exist related to general patent rights. Holders of these private patent rights can use them to enhance their position relative to their competitors by blocking competitors’ product development. Patents may also have innovation inhibiting effects due to the “hold-up problem.” The hold-up problem occurs when one party is reluctant to invest due to anticipated opportunistic behavior by another party. The hold up problem may be exacerbated by the presence of concentrated market power when firms bargain over economic relationships. Companies can create “patent thicket” by filing many patents on a single product, as a mechanism to deter other companies from pursuing innovation in their product area. These strategic uses of patents raise the general public policy issue of what level should a patent be held for effectiveness. (Rivette and Kline 2000)

Although the economic theory has traditionally advocated patents as a tool for promoting invention and the transfer and commercial application of new knowledge, there is evidence that strict legal protection of IPR can have detrimental consequences for discovery and invention. Weak and narrow patents encourage firms to cross-license and disseminate findings. Also, weak patent protection may support transfers of technical ability from more to less capable organizations (David 1993). In developing countries, stricter IPRs will increase enforcement costs and transactions costs that may already be high in countries that lack legal infrastructure. On the other hand, in countries with limited enforcement mechanisms, stricter IPRs may not have any effect on research and development that occurs in country (Frisvold and Condon 1998). Nevertheless the evolution of strong patent systems that enforce and monitor IPR compliance nationally and globally may exacerbate problems of equitable access to PGR.

Patents and the presence of monopolistic behavior may also distort the direction of new developments away from those areas that have broad public benefits and bias dissemination away from marginal agricultural users. For example private sector involvement in the development of agricultural inputs (using IPRs) leads to the development of products that have broad commercial value to farmers in developed countries while other potential products that could benefit LDC farmers are ignored. The ability to obtain patent rights over information also creates the situation in which companies may choose directions for research focus based upon those areas that might have limited possible infringement. Incentives to disseminate an innovation to other users, like agricultural producers in foreign countries, may conflict with private national benefits (Moschini and Lapan 1997). Finally, patent systems may discourage innovation by farmers and plant breeder using conventional breeding methods. Earlier systems governing access to PGR allowed farmers to save seed for own reuse and plant breeder to use them in research designed to produce further varietal improvement (see plant variety protection discussion below). Patents prohibit these uses (Herdt 1999).

INTERNATIONAL INSTITUTIONS GOVERNING ACCESS TO PGR

A wide array of institutions has evolved to address issues related to plant genetic property and innovation in the agricultural biotechnology industry. These institutions may be broadly categorized into two groups: 1) those that promote the privatization of PGR and seek to harmonize international approaches to protecting IPR on PGR and 2) those that focus on compensating owners of traditional knowledge and seek to address equity issues related to the distribution of benefits created by plant products through the biotechnology industry. These institutions strive to manage knowledge related to PGR but approach the identification of units of property and identification of property holders very differently. Developing an international system for equitably managing access to PGR is politically difficult, in part due to the supposed trade-off between technological progress and technological diffusion which has led to strong IPR protectionist view.

As mentioned above, the privatization of genetic resources has occurred gradually over the last century with the improvement of technology for altering the genetic code in plants has improved. In the late 1800's the U.S. Department of Agriculture had the policy of providing seeds free of charge to all requests. Since 1930, vegetatively propagated plants have been patentable in the U.S. In 1970, the Plant Variety Protection Act made sexually propagated plants eligible for intellectual property protection. Hybrid corn produces seeds that do not produce plants with the same characteristics as the original hybrid plants. If companies could keep the original lineage of the hybrids a secret then they could control access to the benefits from these new plants. In the United States the 1980 Supreme Court case "Diamond vs. Chakrabarty" ruled that agents could patent genetic "inventions" (See Figure 1).

As biotechnology techniques advanced over time the identity of property holders changed. The ability to identify and describe specific genetic code altered the property rights system so that plant breeders are no longer the primary holders of the property rights. Instead the biotechnology scientists that sequence genes can obtain patents for gene sequences holds the rights to DNA and DNA products.

FIGURE 1: Timeline of U.S. and International legislation on property rights.[5]

[5] Current IPR systems have been generated by a mixture of intended and unintended consequences of an undirected historical process that has been shaped by varied interest groups. See David (1993) for a comprehensive discussion of the political economy of international IPR evolution.

Date	Legislation and/or Institutions
1930	U.S. Plant Patent Act
1961	International Union for the Protection of New Plant Varieties (UPOV)
1970	U.S. Plant Variety Protection Act
1974	World Intellectual Property Organization
1978	UPOV amendment: Protection was granted to any variety distinct in one recognized characteristic
1987	FAO: International Fund for the Conservation and Utilization of Plant Genetic Resources
1987	U.S. Supreme Court case Diamond v. Chakrabarty: Any genetically engineered animal form was patentable provided its characteristics could not be produced through traditional techniques.
1993	Convention on Biological Diversity
1995	Trade Related Aspects of Intellectual Property Rights

Privatizing Industrial Knowledge

The assignment of rights to plant genetic resources for the purposes of enhancing industrial agricultural innovation began in the early 1900's. Initial property rights regulations focused on defining rights to particular plant phenotypes, while later when the agricultural innovation had reached the third stage of development property rights were assigned to DNA sequences.

Plant Patent Act

In the U.S. the earliest attempt to assign rights for genetic resources was through the Plant Patent Act in 1930. This regulation covered plant varieties that had been "asexually reproduced" from clippings or shoots. The regulation was intended to provide protection for breeders that were developing new types of ornamental plants and fruit trees. Only a small subset of plants qualified as patentable under the Plant Patent Act. The patent definition depended upon the phenotype rather than genotype to distinguish different products.

Plant Variety Protection

The Plant Variety Protection (PVP) act, established in the U.S. in 1970, was a follow up to the Plant Patent Act of 1930 that covered asexually propagated plant varieties. This regulation protects plant breeders' rights, but does not prevent others from using the variety to breed other varieties, nor from reusing harvested material. Hence PVP is essentially a breeders' rights system, and does not function as a patent system.

The USDA enforces PVP by issuing a certificate that allows owner of certificate to be exclusive marketer and producer of a specific variety. Certificate holders may license the production to others. PVP grants protection to varieties that are ‘new’, ‘distinct’, ‘uniform’, and ‘stable’(Barton 1998). PVPs are harmonized under the International Union of the Protection of New Varieties of Plant (see below). Some IPR critics argue the PVPs actually decrease the market position of the initial breeder, and hence do not offer enough protection for breeders. Many countries adopted PVP laws after the original U.S. law was enacted.

International Union for the Protection of New Varieties of Plants (UPOV)

In 1961 the diverse set of national PVP laws were harmonized under the International Union for the Protection of New Varieties of Plants (UPOV). UPOV is an intergovernmental organization that cooperates in administrative matters with the World Intellectual Property Organization (WIPO). Upon its inception, 28 countries signed the treaty and agreed to adopt legislation along the lines of the convention. This agreement established the basis for breeders to claim rights over new plant varieties and as such continued the development of patenting genetic resources, first begun with plant patent act. Breeders were granted the rights to special titles of protection or of a patent. In the early stages of this agreement only 3 developing countries belonged: Argentina, South Africa, Uruguay. Currently, forty-four nations are members of UPOV, including twelve developing countries.

In 1978 UPOV was amended so that protection was granted to any variety distinct in one recognized characteristic. This change granted rights to firms that improve upon already genetically altered varieties. In this version of the UPOV agreement nations are required to allow use of protected materials for breeding new varieties and gave farmers the privilege to hold seeds as a planting input for next season. This introduces a new understanding of the multiple uses of plants This version of UPOV establishes a research exemption for plant protection in which breeders can buy protected materials and use these plants as the basis for developing a new variety. These rights, however, are not generally applicable to wild plants used for pharmaceutical purposes.

The agreement was last modified in 1991 giving biotechnology firms more defined ownership over the new varieties of plants they are producing through recombinant DNA techniques. If a strain is given “initial variety” status, then derivatives can not be commercialized without permission (Lesser 1997a). Also, the UPOV convention was amended to allow nations to let farmers reuse seeds, but does not require that they do(Barton 1998). Hence, one of the main criticisms of the current agreement is that that the agreement ignores the rights of farmers while protecting breeders’ research exemption (Singh, et al 1999).

The rights created by this international agreement differ from the property rights defined through patent law. Patent law requires that patent filers prove that new varieties are distinct, uniform and stable. PBR confer a smaller range of rights to the plant breeder. The definition of the rights refers to distinct plant attributes but applies to the whole plant. PBRs are cheaper to apply for than patents, but provide limited protection for innovators in the biotechnology industry.

The purpose of UPOV purpose is to ensure national treatment for any breeder of the world at par with domestic breeders. The agreement defines situations in which it is permissible for a country to deny plant breeders patent rights. These exceptions include 1) inventions contrary to public order or morality 2) diagnostic, therapeutic and surgical methods for the treatment of humans or animals, and 3) plants and animals other than micro-organisms and essentially biological processes. However, if a country chooses to decline intellectual property protection to plant breeders, they must provide sui generis system of protection. [6]

World Intellectual Property Organization (WIPO)

Whereas UPOV deals with PBR, WIPO manages information on IPRs, including specifically plant patents. WIPO was created in 1974 to provide a clearing-house for information on national intellectual property laws. WIPO also provides mechanisms that encourage harmonization of IPR systems. Currently WIPO documents indicate that about 44 countries, including Brazil and India specifically exclude plants from patents. Other countries do not explicitly forbid patenting but no patents have been issued. WIPO expanded its role in 1996 by entering into a cooperative agreement with the World Trade Organization (WTO).

Many individual country patent systems explicitly preclude patent protection for plant and animal varieties. In South Africa patents are not granted to plants or animal varieties unless it is a microbiological process or product of a process, or a transgenic plant or animal (Wolson 1998). In Russia European Patent Convention of 1973 is followed, so plant varieties and animal breeds are excluded from patent protection. Like South Africa, Russia provides protection for microbiological processes and their products, which arguably includes plant and animal varieties produced by genetic engineering techniques (Baev 1998). In India only processes are patentable. Inventors must illustrate synergic properties of the ingredients of their new products. If properties of ingredients are additive then the product does not qualify for patent (Gangli 1998). The U.S. legal system is more expansive than most national IPR systems (Evenson 1999). In the 80's while many countries were satisfied with the regulations found in the international convention for plant variety protection, the U.S. was developing more explicit rules about patenting genetic resources. In 1987 the U.S. Patent and Trademark Office decided that any genetically engineered animal form was patentable provided its characteristics could not be produced through traditional techniques. Such a variety of approaches to property protection in the biotechnology industry may inhibit trade and technological diffusion, particularly if countries with strong IPR systems choose not to collaborate with countries that they perceive to have weaker IPR implementation.

Trade Related Aspects of Intellectual Property Rights (TRIPs)

TRIPS was negotiated during the Uruguay round of the international trade negotiations and in 1995 was created at the same time the WTO charter was passed. The agreement was intended to facilitate the international harmonization of utility patent policy to promote fair economic competition. The TRIPS agreement requires that member parties provide IPR protection and established a timeline for compliance for various groups of WTO members. Developing countries were given five years to adjust to the TRIPs provisions. According to TRIPs Article 27 3(b) countries are required to provide plant variety protection by patents or by sui generis system. This definition was

[6] The definition of sui generis is unique, individual, of one's own kind. See Lesser 1999.

seen as strengthening the developed countries' position. Like the UPOV, countries may opt not to use patents if they are deemed contrary to "public order or morality." The agreement specifies that microorganisms may not be excluded from patent and that changes to the current system of PGR management must be consistent with TRIPs. The agreement provides more universal recognition of breeders' rights and requires a minimum patent duration of 20 years of filing (Frisvold and Condon 1998).

In the North, legal protection of plant material has expanded rapidly over the past few decades. TRIPS, including Article 27,3(b) includes a specific provision that members "shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof". The force of this provision will depend upon the interpretation of the exclusions in this Article. In the South, property rights systems are moving in the opposite direction, by providing more access to currently proprietary resources rather than an increase in private property (Wright 1998).

Because TRIPS is part of the larger international legal framework of the WTO, disputes that arise over country compliance with property rights provisions will be addressed under the WTO's dispute settlement system. This structure raises compliance issues. Some critics of the system argue that the costly Dispute Settlement Mechanism biases legal protection of intellectual property rights away from developing countries since their income is low relative to the cost of defending a dispute. Other critics suspect that with the enforcement of TRIPs agreement farmers will have less access to seeds. TRIPS supporters counter that TRIPS may in fact provide farmers with the opportunity to access better seed varieties although at higher prices. (Sidhu 1999).

Protecting Traditional Rights

LDCs have depended upon international free exchange of germplasm and are in general poorly equipped to deal with rapid changes occurring in the biotechnology industry. A disparity in resources and negotiating power exists between them and private companies. The value of existing lines or varieties is often ignored when valuing the addition of new traits. If IPRs don't exist on preexisting lines compensation to plant breeders or institutions is unlikley (Herdt 1999). As IPRs evolved in the industrial sector to grant private ownership over pieces of DNA, developing country advocates argued that property rights systems needed to acknowledge the source of genetic material used in agricultural innovation and existing traditional knowledge concerning it's potential function.

Farmers Rights

In 1983, a majority of countries at FAO passed The International Undertaking on Plant Genetic Resources to address the concern that breeders were being compensated but the providers of germplasm were not. During the course of the debate developing countries demanded free access to commercially developed crop varieties, but developed countries didn't agree, arguing that IPR systems are necessary to encourage private sector research. The commission developed the concept of farmers' rights as a mechanism for compensating developing countries. The rights were conceived of as a retroactive compensation to farmers, rather than an incentive for future innovation like the breeder's rights. (Frisvold and Condon 1998)

FAO established an "International Fund for the Conservation and Utilization of Plant Genetic Resources" in 1987 to implement farmers' rights. Estimates of the needs of the fund to compensate farmers range from US$300 million to US$500 million. The intention was that the fund would provide support for breeding and conservation programs in developing countries (Esquinas-Alcazar 1998). As of 1993, no contributions to the fund had been made (ISNAR) and very few examples of national programs to provide funding for plant genetic resources exist. Although, India has proposed national legislation to institute a national seed tax to provide funds, no money has been collected. Clearly the broad political will to implement this type of a system is currently lacking.

Farmers' rights were first officially negotiated through the Commission on Plant Genetic Resources within the Convention on Biodiversity (see below). During the negotiations countries noted that a legal framework was needed to protect the traditional rights of farmers. Many countries wanted farmers' rights to be on equal footing as breeders' rights. Farmers' rights would include 1) the right to continue traditional practice 2) linking rights to a funding mechanism. 3) establishing the rights of traditional farmers and communities in as custodians of indigenous knowledge. The proposed system of rights was intended to form the basis of a formal recognition and reward system to encourage and enhance continued role of farmers and rural communities. These farmers' rights would operate as "moral obligation" rather than economic incentive (Lesser 1998).

Convention on Biodiversity (CBD)

The CBD addresses the rights of nations over genetic materials while promoting conservation. The agreement explicitly discusses indigenous/traditional people's rights and advocates measures to decrease the dependency of developing countries on developed countries. The CBD calls for the registration of land races and implementation of information exchange. Article 19 of the agreement states that nations have sovereign rights over their genetic materials, but that materials that were previously transferred to other countries are in the public domain and may be used freely. This agreement contradicts the idea behind farmers' rights since it does not require compensation to farmers that provided genetic material to developed country breeders in the past (Barton 1998).

The CBD defines a genre of technology transfer agreements, Material Transfer Agreements (MTA), to govern the relationship between collector nations and appropriate national authorities in the provider country. These agreements defining the arrangements under which the material is transferred are intended to allow the transfer of genetic materials in an equitable fashion while protecting genetic diversity. The CBD allows only limited use genetic materials by collectors when ownership has not been clearly established (Lesser 1998). Not all countries are investing in the development of the appropriate legal systems to deal with these types of agreements, and the current trend is that exchange of genetic resources among countries had decreased since CBD adopted in 1992 (Gupta 1999, Lesser 1997b). Some authors speculate that the CBD promote non-tariff barriers to biotechnology products, by allowing countries to mandate strict transfer and handling methods for imported Living Modified Organisms. Experts in the trade community are concerned about the potential economic impacts of the CBD on trade in biotechnology (Frisvold and Condon 1998).

While the CBD's primary focus is on access to raw materials for agricultural innovation, the Convention also addresses IPRs for finished crop varieties. In particular the convention states country policies must be consistent with TRIPs. In this way the CBD defers to the existing legal framework for privatization of genetic resources, rather than suggesting alternative approaches to intellectual property rights systems.

The CBD may have a role in resolving debates over the equity and efficiency of plant genetic resource management. The Convention on Biological Diversity addresses the need to share the benefits of acquiring, using and conserving biological resources. Distribution inequities arise when genetic resources are removed from common heritage societies to societies where they can be incorporated into intellectual property regimes without returning economic benefits to the place of origin. In response to the concern that granting private breeders free access to raw genetic resources leads to inequitable distribution of benefits, the CBD grants countries sovereign right to their indigenous genetic resources. The CBD discusses the potential for bio-prospecting contracts, however transaction costs associated with administering contracts, monitoring compliance, and resolving conflicts are likely to be high. For example, a contract for a seed company to claim exclusive rights to an invention from a specific group of farmers would require information about landraces and enforcement would be complex and costly (Brush 1998).

Consultative Group on International Agricultural Research (CGIAR)

In contrast to the emphasis on assigning rights to ensure equitable compensation that may be found in the CBD and the Farmers' Rights movement, the CGIAR has traditionally provided an institutional mechanism to ensure public access to agricultural innovations based on plant genetic resources. The CGIAR was founded on the idea that developing country farmers should have free access knowledge, technology, materials and plant genetic resources to be used to improve agricultural productivity and hence development. Plant germplasm is distributed to any researcher with a legitimate interest. The intent of the CGIAR is to promote sustainable agricultural development rather than to ensure the compensation for inputs into the biotechnological innovation.

One of the justifications for providing broad access to genetic resources to farmers in LDCs is that the North has historically been dependent upon "exotic germplasm" from centers of diversity. The institutional mechanisms supporting patenting of both process and product are inhibiting the ability of International Agricultural Research Centers to use basic scientific principles to make products of interest for the poor (Sergeldin 1999). In the tradition of agricultural development some policy makers argue that public goods should be left to the public and private goods that aid in achieving these public goods should be treated differently.

CONCLUSION

Currently national and international laws relating to the protection of genetic information are evolving towards increased privatization. International legal frameworks encourage this evolution, particularly the world trading system which emphasizes the need for policy harmonization in order to avoid the economic inefficiencies of trade barriers. This privatization will likely lead to inequitable access to agricultural innovation, without guaranteeing innovation. Therefore, policy makers should be actively considering new strategies for addressing the new challenges of genetic property and agricultural innovation.

The relationship between the public sector, which has historically been responsible for promoting agricultural innovation and ensuring equitable access to new technologies, and the private sector, which has rapidly taken on the new role of agricultural innovator creates new tensions. Although the private sector is generating more new agricultural products than it has done historically, it does not have the same long term goals as the public sector. The innovators in the private sector require that their efforts be compensated economically. In the context of genetic resources, without the ability to reap some of the economic benefits from agricultural innovations the private sector will not invest in the research necessary to produce these innovations. The public sector, on the other hand, while not completely unbiased by potential economic gains from particular lines of research, has the ability and often the mandate to invest in research that benefits smaller groups of marginal users. One potential solution to the tension between promoting innovation and ensuring access to new agricultural products would be to provide public institutions, particularly universities, with financial and legal mechanisms to pursue research that has broad social benefits.

In order to address inequitable distribution of benefits associated with biotechnological innovation, international institutions such as the World Bank and the CGIAR should support the development of national capacity in science and management of biotechnology, IPR and biosafety within less developed countries (Herdt 1999). With enhanced national ability to produce agricultural biotechnology products, countries would not be as dependent upon private firms for the introduction of biotechnology innovations and would be able to influence the types of products that would be developed and introduced into their agricultural systems. Another possible approach would be to encourage market segmentation so that poorer farmers in developing countries have access to improved varieties at a minimum cost.

The legal system that has developed around the patenting of DNA is still evolving. However, policy makers should carefully watch the direction of this evolution to ensure that private rights on DNA develop in a manner that can enhance innovation rather than impede it. The current legal patent system's definition of a unit of genetic property deserves particular attention. Since the biotechnology industry is rapidly evolving, legal frameworks are being forced to adjust to the needs of the biotechnology industry without having the time to fully incorporate the new types of relationships created between producers and users of biotechnology products. Although international institutions seem to be pushing the legal framework for IPR on PGR towards a system of patents, the PVP system may be better suited to LDCs because within this system farmers can reuse seed and use these seeds in research to create improved varieties. Rather than simply trying to fit biotechnology law into existing patent jurisprudence, legal experts should examine the characteristics of genetic property and the biotechnology industry to determine which types of property systems best suit the international and national economic and equity goals.

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