IPRs in Agriculture:
Implications for Seed Producers and Users

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Conference Highlights

Introduction

The growing use of biotechnology tools in agriculture has brought to the forefront an issue that has languished in relative obscurity for decades—intellectual property rights (IPR). IPRs are a common thread in discussions of everything from food security and biotechnology to industry structure, crop genetic diversity and environmental matters.

Business and financial interests view IPR as one basis of a corporations' value and an incentive for investing in research and development. Critics see patents and other forms of intellectual property (IP) protection as the cause of high prices and needless—even dangerous—technologies. IPRs have directly contributed to increases in private sector investments, most notable in biotechnology. Some view the shift to proprietary research as consistent with a market-driven economy; others view it as problematic. The debates run through industry, academia, Congress and religious institutions, as well as the non-government organization (NGO) community.

Lack of a broad understanding, as well as the diversity and intensity of viewpoints and differences of opinion about the roles of IPRs in agriculture, means different observers reach vastly different conclusions with the same basic information. The resulting confusion poses risks to investment and technology research, as well as the public credibility of government and universities. It also creates the potential for increased transaction costs which could stymie access to technology.

To date, there has been no systematic assessment of the information and options available when considering the implications of current and future applications of all types of IPRs to agriculture. To fill that gap, Farm Foundation worked with William Lesser and Martha Mutschler, both of Cornell University, to organize a workshop on IPRs in agriculture. The intent was to solicit comments and opinions from a wide range of perspectives in the public, private and governmental sectors. Emphasis was placed on utility patents (UP) and plant variety protection (PVP). The situation in the United States was highlighted, but other regions received attention as well.

To initiate discussions, six speakers identified by the organizers provided background talks on: concepts, roles and issues of intellectual property; IPRs as an advancement or impairment for research; impacts of agricultural research and strategy in the public and

[1] Sponsored by Farm Foundation, the workshop preceded the annual meeting of the Crop Science Society. Statements made in this report do not necessarily represent opinions of individuals or organizations, including sponsors. For additional information contact: William Lesser, Cornell University, (607) 255-4595, whl1@cornell.edu, or Martha Mutschler. Cornell University, (607) 255-1660, mam13@cornell.edu.

private arena; industry structure of seed companies; and farm level issues. (Copies of all the papers are posted on the Farm Foundation Web site, *www.farmfoundation.org*.)

Workshop participants identified issues they considered relevant. There was consensus on some of these issues while on others, clear differences of opinion existed. The day after the workshop, a group of the program speakers and participants met to explore further the significant issues from the prior day. Those two days of discussions are summarized here. Every effort has been made to capture the diverse sentiments of the workshop participants. However, this document cannot be considered to represent a true consensus, nor the opinions of any individuals or entities. Rather, this information is intended to focus and stimulate further discussion.

ISSUES IDENTIFIED

The issues identified are described as (A) background matters of fact relevant to interpreting the subsequent recommendations, (B) public and private sector strategies, including IPR management, and (C) IPR issues related to federal policy.

A. BACKGROUND MATTERS

1. *Benefits of IPR*: Data presented at the workshop document that IPRs have contributed directly to the amount of private sector investment in plant breeding, increasing the resources the private sector can use for crop improvement. For the public sector, no direct statistical evidence has been presented demonstrating IPRs have increased the merit of released varieties. However, ancillary benefits were recognized, such as the ability to maintain seed integrity. In other words, through ownership, it is possible to regulate the use of protected materials to prevent damage to the user or the environment which might occur in the absence of IPRs. These and other benefits should be considered in any dialogue about the role of IPRs in the seed sector.

2. *IPR-based matters vs. other sources of change*: Many changes in the creation and development of new seed varieties have occurred concurrently with the expansion in IPR protection over the past two decades. Notable among domestic changes is the decline in federal funding for plant breeding. It is important to distinguish between those factors which are not really IPR matters or only very indirectly so, such as federal funding. Possible reforms of the IPR system must be evaluated carefully to determine if IPRs are really the root issue, or merely symptomatic of broader changes.

3. *Legal interpretation vs. public opinion*: Legal interpretation of some aspects of the application of utility patents to plants in the U.S. has become generally established over the past several decades. These components include seed saving (an infringement); research exemption (if it exists at all, very restrictive in most instances); and the use of 'bag tag' licenses to augment use restrictions (presumed to be valid in most applications, however not limited to patented materials). While this relative certitude applies to legal interpretations, it is not necessarily shared by public/interest groups. The opinions of the latter can be affected by lack of information or misinformation on intellectual property

and its proper applications. Even if fully informed about intellectual property, the opinions of domestic and international groups may differ based on their evaluations of needs and benefits. Some public/interest groups within and outside the U.S. have considerable unease over the use of utility patents for plant varieties. International unease is particularly notable since U.S. patent law presently combines an expansive view of protectible subject matter, including plant varieties, with a very restrictive notion of a "research exemption."

4. *Genetic resources and IPR:* Conceptually, some balance is needed between intellectual rights (perhaps better described as investment incentives) and rights over genetic resources, which serve both equity issues and incentives for conservation. The genetic resources of concern generally consist of wild species related to cultivated crops, or landraces of the cultivated crops. A number of international agreements focus in part on genetic resources—the Convention on Biological Diversity (CBD) and the International Treaty on Genetic Resources for Food and Agriculture are the leading ones. While further work is required to implement fully the CBD and the International Treaty, the failure of the United States, to date, to ratify the CBD is taken by many as a lack of interest in equity by the U.S. Approaches to link genetic resource protection with IPR systems are exemplified by a specific proposal to include an identification of sources of genetic materials in patent applications, but the specific use of that information is unclear. More generally and long-term, an impression of U.S. indifference to the expectations of genetic material providers could hamper domestic breeders from access to important genetic resources.

5. *Essential Derivation:* Plant Variety Protection (PVP) is an international system commonly used to protect plant varieties. PVP differs from patent law, particularly with regards to allowing research use of protected materials to develop new plant varieties. A key limitation of this so-called breeders' exemption is the absence of an incentive for investment in background breeding (also called development breeding or germplasm enhancement), the often lengthy process of incorporating desirable traits from landraces and wild varieties into commercial varieties. For that reason, the 1991 Act of the International Convention for the Protection of New Varieties of Plants (UPOV) introduced the concept of "essential derivation." It provides for two levels of PVP protection—one for initial varieties and a second for essentially derived varieties. Specifically, a new or initial variety deemed to have made a particularly significant contribution may be used in a breeding program, but commercialization of offshoot, essentially derived varieties requires the permission of the owner of the initial variety. In that way, close copycat varieties cannot appropriate the contribution of the initial variety without permission and/or compensation. However, essential derivation has not yet been implemented, despite considerable input by the scientific community. Effort must continue on either perfecting the application of essential derivation or identifying a workable alternative.

6. *Seed sector concentration:* The number of firms worldwide which produce seeds continues to decline at the same time that the role of the public sector is diminishing due to budgetary limitations. An even smaller number of firms own genetically engineered

traits, with a single firm being the dominant supplier worldwide. Many economists believe a small number of firms leads to higher prices, but there is no specific evidence that this has occurred. One reason may be that seeds are only one input into a production process, the ultimate value of which is determined by output supply and demand conditions. A second possible effect of high supplier concentration is a reduction in research intensity and productivity. Though no compelling evidence exists of that having occurred, the issue is of sufficient public and private importance for evaluations to continue.

B. PUBLIC AND PRIVATE SECTOR STRATEGIES

1. *Delayed publication:* Surveys of public sector researchers in the medical field indicate a relationship between private sector research support and delays to publishing. Similar information is presently unavailable for agricultural research although a survey is planned. Most universities have policies on external control over publishing, so if there is a problem, the harmonization of those policies across universities could reduce further the leverage private firms have to seek additional delays. Professional societies can assist in harmonization efforts within specific fields.

2. *Credibility of the public sector:* Public trust in university faculty, as well as government regulators, is higher in the U.S. than in many other countries, facilitating acceptance of new technologies. Loss of that trust would complicate the technology regulation and introduction process, and the public value of universities, and should be vigorously guarded against. At the same time, some observers believe that close association with the private sector will reduce trust. Yet, public and private sector collaboration has a strong history in the U.S., leading to the production of numerous products of immense public significance. Those collaborative relationships are evolving further in the area of biotechnology, with IPRs a core component. Separation of public and private sector research arrangements is neither possible nor appropriate, yet the clear disclosure of relationships in publications and at presentations will add transparency.

3. *University technology transfer offices:* University technology transfer offices, generally dating to the 1980s or thereafter, have multiple roles. The funds they generate make university inventions available, allow for control over those inventions, and reward/retain faculty who are producing valuable intellectual property. In all but a few cases, university technology transfer offices run deficits, with net income generation a distant goal. Some observers believe public sector ownership of IPRs has raised the transaction costs for access to inventions, thus reducing use. Conversely, a number of inventions from universities have been widely adopted, leading to public and private benefits. Determining a balance between pursuing protecting university-generated intellectual property and encouraging its use is an uncertain undertaking. However, interim steps can be taken, including:

- Careful consideration of university objectives and the role of IPR in achieving those objectives;

- Streamlining the licensing process by including in university technology transfer offices staff who are experienced with private sector needs; and
- Establishing standard Material Transfer Agreements (MTA) to simplify their interpretation and use within and among universities.

C. PROPOSALS FOR GOVERNMENT POLICY

1. *Plant Variety Protection (PVP):* As a result of the Trade-related Aspects of IPR (TRIPS) under the World Trade Organization (WTO), PVP is becoming the most common international form of IPR for plant varieties and hence warrants additional examination. Recommendations include:
   - Legislation limiting support of the PVP office to fee-based funding should be re-evaluated. The time to process PVP applications averages 3-4 years and can be up to 8 years. Even with interim protection, this creates uncertainty which could reduce private sector investment.
   - Descriptors required for securing protection should be sufficiently flexible to allow breeders to present the most consistent and significant bases of distinctness.
   - The breeders' research exemption under PVP, which follows that under UPOV, is a major departure from patent systems and some believe should be limited in light of technological advances. However, with widespread support for the breeders' exemption in both the public and private sectors, any change would be very controversial.

2. *Utility patents:*
   - In the U.S., broad research access for breeding exists under PVP but not under utility patents. There is debate on the need for and degree of research use exemption. Some feel that providing the most complete protection to lines and varieties is necessary to protect continuing investment in breeding activities. However, in the U.S., the unique blend an expansive scope of protectible subject matter for patents with a very narrow research exemption could reduce future germplasm access, hampering breeders in the long term.
   - Patent Office considerations of non-obviousness and claims supportable by the application applied to lines and varieties should continue.
   - Possible errors on improper utility patent grants for plant varieties may be further reduced by increasing use of a) foreign data bases, including SINGER (the System-wide Information Network for Genetic Resources) used by the Consultative Group on International Agricultural Research (CGIAR); b) crop advisory committees; and c) USDA/public sector expertise.
   - U.S. Federal Trade Commission proposals for reducing the costs of challenging questionable patents are another approach to consider to correct possible granting errors.

3. *Reduce transaction costs:* One source of costly negotiations is the multiple forms of Material Transfer Agreements (MTA) in use. USDA could contribute to standardization

by mandating a limited number of MTA forms for use with USDA grants, as the National Institutes of Health presently do for grantees. Examples for accessing "unimproved" materials are available from CGIAR and the International Treaty.

4. *Bayh-Dole:* The Bayh-Dole Act was intended to increase public use of inventions derived from publicly-funded research. While IPRs are often necessary for commercialization, the protection costs to universities often exceed revenues generated. Presently, only a few university licensing programs are in the black, and those cases are due to a small number of very valuable inventions. A means of providing public funding for the cost of more routine technology transfer, including IPR, should be considered. It should not impact research funding.

5. *Future of crop genetic improvements:* Universities provide key breeding services, including a) training; b) development or adaptation of cutting-edge breeding techniques; c) germplasm utilization, enhancement and transfer; d) variety development for minor crops; and e) continuity and competition in a volatile investment environment. Some suggest that public sector IPRs can generate sufficient funds to support public breeding, but this is not the experience. Furthermore, pressure on public programs to be self-supporting through generation of intellectual property has the potential to shift university breeding from complementing to competing with private-sector breeding. To achieve better the goals of public programs, current funding needs to be augmented. Expanded funding could be used more effectively by:

- Focusing attention on declining programs for minor crops of major national significance, such as vegetables, fruit, forage and wheat;
- Competitively identifying centers of excellence for such crops, and granting stable long-term funding (5 to 10 years); and
- Allowing public breeding-based projects to be funded competitively within USDA programs.

Concluding Comments

The issues discussed in this workshop are at the heart of future biotechnology research. The background discussion set the stage to identify public and private sector strategies, and some possible government policies. Careful attention to the issues raised will further the development of biotechnology in the agricultural seed sector.

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