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INTERNATIONAL UNION FOR THE PROTECTION OF NEW VARIETIES OF PLANTS GENEVA

SYMPOSIUM ON CONTRACTS IN RELATION TO PLANT BREEDERS' RIGHTS

Geneva, October 31, 2008

SESSION II: EXPERIENCES OF BREEDERS: ROLE OF CONTRACTS IN THE EXERCISE OF BREEDERS' RIGHTS

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Mr. Chairman, and members and guests of this distinguished organization; it is an honor to be with you today to talk about contracts. As a research scientist for twenty years, and a licensing professional for nine, the interdependencies of research and licensing is of special interest to me.

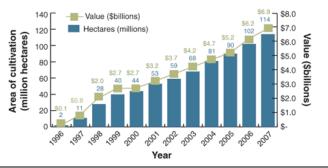
Seed and/or trait licenses may perform any number of functions, depending upon the parties involved, the subject of the license, and the goals to be achieved. For example, the parties may be public institutions, private companies, germplasm banks, NGOs, or farmer-customers. The subject may be commercial or experimental; genetically modified or conventional; hybrid, inbred or variety; trait, construct or promoter; or it may even be a process, know-how or confidential information. The goal may be to in-license or out-license material protected by any number of means (patent, PVP, trade secret, the International Treaty for Plant Genetic Resources for Food and Agriculture, the Convention on Biological Diversity) for some consideration and with documented terms of use. The purpose of this document is to focus on agreements between private companies and the farmer customer during the sale of commercial seed, and specifically Technology Use Agreements (TUAs), primarily in the United States.

TUAs are used widely in industry, primarily for GMO traits. GMO acceptance worldwide (Figure 1), and especially in the United States (Figure 2), has been dramatic. The adoption

pace for GMO corn, soybeans and cotton has been unparalleled in agricultural history. For comparison purposes, in the U.S., hybrid corn took twice as long as GMOs to reach similar levels of adoption (Figure 3).

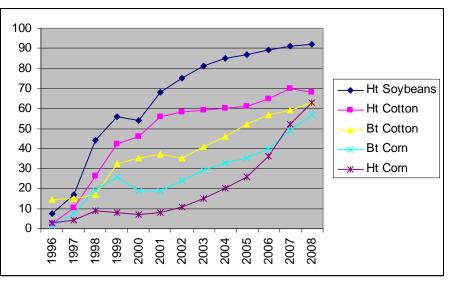
FIGURE 1. HISTORICAL GLOBAL AREA OF TRANSGENIC CROPS ¹

The area planted with transgenic crops rose by 12% in 2007, with estimated crop value climbing by \$700 million.



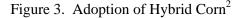
Source: International Service for the Acquisition of Agri-Biotech Applications, Cropnosis

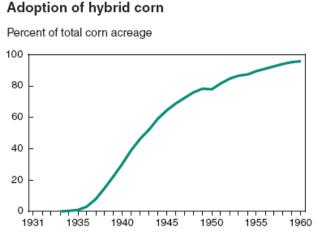
Figure 2. Rapid growth in adoption of genetically engineered crops continues in the U.S.

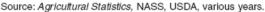


Data for each crop category include varieties with both HT and Bt (stacked) traits. Source: 1996-1999 data are from Fernandez-Cornejo and McBride (2002). Data for 2000-08 from USDA's National Agricultural Statistics Service (NASS) in the June Agricultural Survey for each year, 2000-2008.

¹ Stacy Lawrence, <u>Brazil surpasses US in new transgenic crop plantings</u>, *Nature Biotechnology*, 26, 260 (2008).







The percent of acres planted to GMOs implies that these GMO traits are typically licensed broadly to the industry, resulting in the traits being available from a large number of companies. A search of seed advertisements will generate large numbers of parent companies and even larger numbers of brands of products delivering patented transgenic traits to the farmer-customer (Table 1). However, it must be noted that the figures presented only represent a snap shot in time of products advertised for sale. Some of these traits may be licensed more broadly in 2009. Further, research licenses may not be represented in this list. Traits are patented, but they are licensed broadly. John Gerard presented similar information to the WIPO-UPOV Symposium on Intellectual Property Rights in Plant Biotechnology in 2003.

Trait	Companies	Brands	
Corn			
BT11	32	45	
DAS-59122	46	79	
GA21	30	39	
MIR604	16	23	
MON810	91	147	
MON863	80	130	
NK603	93	150	
T25	67	110	
TC1507	60	100	
Soybeans			
40-3-2	74	144	

Table 1. Number of sources providing selected traits to farmer-customers

² Jorge Fernandez-Cornejo, The Seed Industry in U.S. Agriculture, USDA ERS Agriculture Information Bulletin no. 786, (2004).

The adoption of GMO products by farmer-customers and the licensing between companies to support that adoption indicates the farmer-customer has found value in the product, at the prices offered, and under the required terms of sale. There is no requirement that a farmer-customer plant a GMO. Rather it is the farmer-customer's choice based upon perceived value. This document focuses on contractual terms seed companies present to farmer-customers, why they are used, and in particular the kinds of terms that are in use.

Intellectual Property-related reasons for bag language and other TUAs

While TUAs may vary slightly from company to company and trait to trait, they have a number of commonalities (for a detailed comparison, see Attachment 1). Some common terms are largely unrelated to intellectual property protection per se. As examples, these may include terms such as warranties, limitation of liability, notice of claim and reference to any applicable TUA, stewardship agreement and/or product use guide. While beyond the scope of this document, these provisions are important in confirming standard practices and avoiding frivolous litigation. In a society such as the U.S., that requires that hot coffee served in paper cups come with a warning that the coffee is in fact hot, it comes as no surprise that there are important terms in the contract(s) between the buyer and seller of agricultural seed that are unrelated to intellectual property protection, but that still need to be specifically stated.

However, many of the terms on the bag and/or in a TUA are potentially useful for intellectual property protection purposes. These purposes can be split into three areas. They

- a) increase the sustainability of the subject trait through appropriate stewardship;
- b) grant a license for the use of intellectual property; and
- c) outline the limits on the granted license.

Sustainability/stewardship. The owner of an invention has a vested interest in its stewardship. Without the cooperation of the farmer-customer, the value of the invention may be significantly reduced, or even lost. Therefore, TUAs and associated stewardship and product guides, when applicable, try to ensure that appropriate guidelines are known to the farmer-customer, and that the farmer-customer will adhere to them. Obvious examples include refuge requirements to prevent the development of tolerance in the insect population, any pesticide restrictions (same) and grain channeling restrictions to keep GMO grain in countries where the trait is approved. One could envision geographic limitations, as was proposed for Roundup Ready® Alfalfa. These stewardship provisions make good sense for preserving the usefulness of the trait, and/or are required by federal/national, state/province or local authorities. In any case, the protection of the intellectual property requires that the farmer-customer use good trait stewardship practices, or else the value of the trait will be lost.

The Biotechnology Industry Organization has a Statement of Ethical Principles, which principles include (not an exhaustive list):

- We respect the power of biotechnology and apply it for the benefit of humankind.
- We listen carefully to those who are concerned about the implications of biotechnology and respond to their concerns.
- We place our highest priority on health, safety and environmental protection in the use of our products.
- We develop our agricultural products to enhance the world's food supply and to promote sustainable agriculture with attendant environmental benefits.
- We continue to support the conservation of biological diversity.

Note that every actual or perceived GMO non-compliance and performance gap is felt not only in the marketing of a particular trait, nor solely by the developer. Issues, valid or perceived, impact the whole industry. Sometimes the impact is in the public view of GMOs and industry behavior. Sometimes the impact is through additional legislation, oversight and paperwork. Often the impact is in both public perception and government regulation.

Stewardship of GMO traits receives much attention, and is taken very seriously.

Limited License and Intellectual Property Language. Through the purchase and opening of the bag of seed, the farmer-customer is granted a license under the "shrink-wrap" language printed on the bag to the technology in the bag. Separate TUAs also include this provision. For the price of a bag of seed, the license is a *limited* license to grow a single commercial crop from the purchased seed, consistent with the applicable patent protection.

USE RESTRICTIONS AND LIMITED LICENSES: THE ONLY PERMISSIBLE USE OF THE SEED CONTAINED IN THIS BAG IS FOR THE PRODUCTION OF FORAGE OR GRAIN FOR FEEDING OR PROCESSING. PURCHASER AGREES THAT IT IS GRANTED SOLELY A LIMITED LICENSE TO USE THIS PRODUCT TO PRODUCE GRAIN AND/OR FORAGE. ABSOLUTELY NO RESEARCH OR BREEDING MAY BE DONE WITH THE SEED CONTAINED IN THIS BAG.

In the United States this limited license would typically not allow breeding use, including research or seed production of any inbred seed that may happen to be in the bag. The limited license may also contain language seeking to restrict or prohibit specific activities such as marker profiling of the seed. The desire is to prevent the unique genetics in the bag, genetics that may represent twenty years or more of basic research, from being used to create competing products without the permission of and benefit sharing by the owner. Consider the analogy of computer software. Many would consider it inappropriate to install the purchased software on multiple machines, or take a section of code in a purchased program and use that code to write another program. In a 2006 position paper, the International Seed Federation stated that proprietary parental lines of hybrids that incidentally happen to be included in bags of commercial hybrid seed must not be used by third parties for the purpose of breeding, except when agreed upon by the owner. To protect themselves against the unauthorized use of proprietary parental lines, for the purposes of breeding, breeders may use any relevant legal mechanisms including bag tag warnings and/or shrink-wrap agreements.³

This same provision seeks to prevent the re-plant of self-pollinated varieties by the purchaser of the seed, so that the owner may continue to be compensated for their research investment through future seed sales. Seed sales means funds for future research.

Bags will frequently contain export restrictions, consistent with UPOV 1991. Bags may also restrict the transfer or sale of the material to a third party. While I understand there is some debate regarding whether this restriction is appropriate, the 1961 International Convention for the Protection of New Varieties of Plants, revised in 1972 and 1978, said that the breeder's prior authorization shall be required for the offering for sale and/or marketing of the variety.

³ Use of Proprietary Parental Lines of Hybrids, ISF Position Paper, Copenhagen, May 2006.

UPOV 1991 maintained this restriction. One might reasonably conclude that if a variety is transferred for commercial purposes, that the transfer would be considered sale or marketing.

EXPORT OF THIS SEED OR ITS PROGENY, INCLUDING THIS BAG, FROM THE COUNTRY OF PURCHASE OR ACQUISITION IS STRICTLY PROHIBITED.

RESALE OR TRANSFER OF THIS SEED IS LIKEWISE STRICTLY PROHIBITED.

Typically there are terms intended to encourage compliance with the contracts. For example, monitoring or audit policies may be outlined, which allow the checking of fields or storage bins in order to prevent the saving of seed and the replanting of the harvested crop. If a breach of contract terms occurs, there can be financial ramifications as well as the potential loss of the use of the company's technology in future years.

Monitoring producers through random audits induces compliance among most producers as over 300,000 growers in the United States and 30,000 in Canada adhere to the contract stipulations (Maxwell, Wilson and Dahl, 2004; Agweek, May 26, 2003).

Importance of Intellectual Property Protection

One of the world's most difficult challenges is how to provide a safe and abundant supply of food, feed and fuel materials for a growing population while using less land, water, chemicals and nutrients. There may be disagreements about the best way to accomplish that goal, but all can agree that creating more food using fewer resources is a critical worldwide need.

In order to reach that most important goal, continuing and arguably greater investment in agricultural research is required. Since the 1980s in the United States, spending for agricultural research in the private sector has been greater than spending by the public sector (Figures 4 and 5). Private spending on crop variety research and development (R&D) increased 14-fold between 1960 and 1996 (adjusted for inflation), while public expenditures changed little. Private sector spending on overall agricultural R&D in the U.S. jumped from \$2 billion in 1970 (expressed in 1996 dollars) to \$4.2 billion in 1996, while Federal and State spending flattened out at around \$2.5 billion since 1978.⁴ Government spending for agricultural research is under yearly pressure not only in the United States, but also globally. Further, the success of private industry in efficiently delivering high performing products to the marketplace can be seen in market share, and in the (unfortunate) loss of plant breeding positions in the public sector. Encouraging private investment seems required in order to attain the goal.

⁴ <u>Jorge Fernandez-Cornejo</u> and <u>David Schimmelpfennig</u>, Have Seed Industry Changes Affected Research Effort?, Amber Waves, USDA ERS, February 2004.

Figure 4. Public and private food and agricultural research spending relative to agricultural $\text{GDP}^{5/5}$

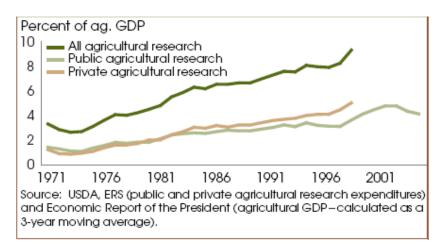
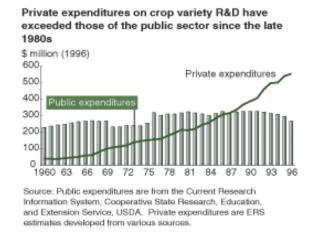


Figure 5. Private expenditures on crop variety R&D.



Unfortunately, in many places worldwide effective intellectual property protection remains elusive, and the U.S. is not immune from this challenge. The replanting and "brown bagging" of seed harvested from PVP'd varieties, without royalty payment, contributed to the exit of much of private industry from hard red wheat breeding in the United States. The USDA Wheat Baseline, 2008-17 updated March 12, 2008 said: "The pace of genetic improvement has been slower for wheat than for some other field crops, resulting in little growth in wheat yields, which makes wheat a less attractive option for farmers. Genetic improvement for wheat has been slower because of genetic complexity and because of lower potential returns to commercial seed companies, factors that discourage investment in research."

Major U.S. companies stopped their soybean breeding efforts in Argentina for this same reason. In developing nations such as India and China, private breeding efforts are increasing.

⁵ Keith O. Fuglie and Paul W. Heisey, Economic Returns to Public Agricultural Research, ECONOMIC BRIEF NUMBER 10, USDA ERS, September 2007.

However, investments remain modest, due in part to the uncertainties around the effectiveness of intellectual property protection in those countries.

Effective intellectual property protection creates social benefits from increased investment and innovation, not only in new traits but also by encouraging development and improvement of germplasm. Social benefits come from invention placed into the public domain following patent expiration, from greater farmer return, and from a more stable, less expensive food supply. Lence et al determined that the U.S. patent system is slightly sub-optimal in maximizing social benefits⁶.⁶ Any breeder exemption undermines intellectual property protection, reduces the incentive to invest in research, and reduces social welfare. Note that there is no requirement that PVP'd parental lines enter the public domain after the expiration of protection.

To meet the food production needs noted earlier, innovative research by the private sector will be required. To encourage the private investment, intellectual property needs to be protected so that the research investment can be recouped. Part of the protection is in the form of contracts, that set clear expectations, and allow access and benefit sharing under specific, transparent, and mutually agreed conditions. The parties may agree to the terms and conduct a seed sale transaction, or not, as it seems useful to both. In general, in the United States, the farmer-customer has spoken. They want technology, and the private sector has delivered them in superior products.

⁶ Sergio H. Lence, Dermot J. Hayes, Alan McCunn, Stephen Smith, William S. Niebur, Welfare Impacts of Intellectual Property Protection in the Seed Industry, <u>American Journal of Agricultural Economics, Vol. 87</u>, <u>No. 4, pp. 951-968, November 2005</u>.

Table 2. Technology Agreement and Stewardship Guidelines

Technology Agreement	Monsanto	Syngenta (NK Brand Seeds)	Dow Agrosciences	Dupont/Pioneer	BASF	Bayer Crop Science
Yes/No	Yes	Yes	Yes	Yes	Yes	No
Crops	corn, cotton, soybeans, canola, sugarbeets		corn, sunflowers, soybeans,	corn	corn, soybeans, canola, sugar beets, rice, sunflowers wheat	corn, rice, canola, cotton
Crop System Characteristics	Bt, Roundup Ready®	Bt (Knockout*), Liberty Link	Protection), Clearfield Sunflower**	Bt (YieldGard, Herculex I)	Clearfield system is a non-GM natural mutent selection herbicide tolerant system	
Refuge Zone Requirements (IRM)	Bt in non-cotton growing areas and 50% in cotton belt in U.S. Refuge zones mandated by Environmental Protection Agency. Roundup Ready® crops do not have a refuge zone requirement. Refuge	All Bt crops require 20% non- Bt in non-cotton growing areas and 50% in cotton belt in U.S. Refuge zones mandated by Environmental Protection Agency. Liberty Link herbicide system does not have any refuge requirements. All refuge zones must be within 1/2 mile of the Bt crop.	Bt in non-cotton growing areas and 50% in cotton belt in U.S. Refuge zones mandated by Environmental Protection Agency. Refuge must be			No refuge zone requirement.
Pesticide Requirements	Insecticide applications prohibited in non-Bt refuge zone unless economic thresholds are met. Only Roundup brand herbicides allowed to be applied over Roundup Ready® crops. All other glyphosate brands are not approved and Monsanto disclaims all responsibilities.	Insecticide applications prohibited in non-Bt refuge zone unless economic thresholds are met. Liberty herbicide must be applied over Liberty Link varieties.	Insecticide applications prohibitted in non-Bt refuge zone unless economic thresholds are met.	Insecticide applications prohibitted in non-Bt refuge zone unless economic thresholds are met.	Specific brand Group 2 (ALC inhibitors) not required but strongly encouraged for best results.	All Liberty Link herbicides are tolerant to the group 10 herbicide Liberty (Glufosinate), therefore only this herbicide may be sprayed on the crop.
"Brown Bag" Policy	Seed is not allowed to be replanted, supplied for replanting. All planted seed must be purchased and certified from an approved dealer.	Seed is not allowed to be replanted, supplied for replanting. All planted seed must be purchased certified from an approved dealer.	Seed is not allowed to be replanted, supplied for replanting. All planted seed must be purchased and certified from an approved dealer.	Seed is not allowed to be replanted, supplied for replanting. All planted seed must be purchased certified from an approved dealer.	For wheat, growers must purchase new certified seed every year. Other crops having similar guidelines established.	All Liberty Link crops are hybrids so brown bagging is not illegal, but rarely occurs due to the inability of hybrids to reproduce effectively. In "open pollinated" Liberty Link canola varieties, replanting is not illegal.
Monitoring/ Auditing Policy	farm to ensure compliance for	requirements or face loss of	IRM plan allows Dow Agro Sciences and its dealers the right to monitor farmers' crops and farm to ensure compliance with IRM requirements or face loss of technology use rights and/or penalties and fines.	farmers' crops and farm to	No specific monitoring policy.	No specific monitoring policy.

- Continued -

Table 2. Technology Agreement		yngenta (NK Brand Seeds)	Dow Agrosciences	Dupont/Pioneer	UPOV/SYM/GE/08 / BASF	Bayer Crop Science
Yes/No	Yes	Yes	Yes	Yes	Yes	No
Technology Fees	Technology fees charged on per acre basis for cotton, canola, and sugarbeet traits and included in per bag price for corn and soybeans. The price for the Bt trait is generally higher than the Roundup Ready® trait. In U.S., technology fee historically has included a pint of Roundup bundled with the seed at purchases.	No separate technology fee for Knockout brand or Liberty Link system.		Technology fees charged on a per acre or per unit basis for YieldGard and Herculex I varieties licensed by Monsanto and Dow respectively to Dupont.	No separate technology fee	No separate technology fee charged.
Patent Protection	Monsanto gene technologies protected by U.S. patent law. Monsanto licenses the grower, allowing use of the	Liberty Link and Knockout gene technologies protected by U.S. patent law. Syngenta licenses the grower, allowing use of the technology but not ownership subject to the conditions in the technology agreement. Violators are subject to penalties/fines to cover damages.	by U.S. patent law. Dow	Herculex I and YieldGard varieties protected by U.S. patent law.	BASF works with a number of private and public institutions establishing varieties protected by U.S. patent law.	Liberty Link crops protected by U.S. patent law.
Product Warranty Policy/Notice Requirement	Monsanto warrants product will perform properly in accordance with directions. Roundup Ready® Risk Share program in Canada will refund entire technology fee if crop is removed due to environmental reasons by a specified date within that crop year. In U.S., has guarantees on net per acre benefit of certain varieties over conventional varieties.	No limited warranty policy available.		that the Mycogen gene technology licensed will perform as set forth in the	No limited warranty policy available.	No technology agreement, so no specified warranty available.
Grain Channeling Restrictions	All grains, including YG corn, RR Corn, canola, sugarbeets, are open to domestic use including on	All Syngenta (NK) corn and soybeans are approved for human food and animal feed use in the U.S, Canada, EU, and Japan.	Dow Agro requires that grain produced from Mycogen or Herculex I technologies is channeled to appropriate areas that accept GM crops. Grain must be consumed for feed or grain purposes in accepted markets.	Grain can be channeled according to YieldGard and Herculex I channeling restrictions.	Clearfield varieties that are not stacked with GM trait are considered non-GM and are available to export to any country as non-GM.	accept the Liberty Link GM gene, so should only be distributed to these markets.
Stewardship	Technology Use Guide outlines pollen flow	Product use guide indicates non-Bt refuge crop should be similar to Bt variety. 1/4 mile refuge zone distance is preferred over 1/2 mile distance.	Product use guide indicates non-Bt refuge crop should be similar to Bt variety. 1/4 mile refuge zone distance is preferred over 1/2 mile distance.	Product use guide indicates non-Bt refuge crop should be similar to Bt variety. 1/4 mile refuge zone distance is preferred over 1/2 mile distance.	Clearfield system relies on herbicide application. Recommendations include herbicide and crop rotation practices to avoid weed resistance.	No specific stewardship recommendations available.

Table 2 Technology Agreement and Stawardship Guidelines (Continued)

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* Knockout is a Sygenta Seeds brand. Liberty Link is from Bayer CropScience.
**Dow AgroSciences Seeds produced by Mycogen Seeds, a subsidiary of Dow AgroSciences. Herculex I is a DAS trademark.