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Disclosure of Origin and Access and Benefit Sharing:

The special case of seeds for food and agriculture

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The seeds world: status and trends in a nutshell

I can summarize the current status and trends in 12 main points

- 1. New plant varieties are not built up from scratch, but are developed from existing varieties that themselves have been obtained from existing varieties. Several of the most performing varieties employed by the seed industry for development of new varieties have been developed by an alliance of international agricultural centers (such as the International Maize and Wheat Improvement Centre, CIMMYT, and the International Rice Research Centre, IRRI), coordinated by the Consultative Group on International Agricultural Research (CGIAR)
- 2. Patents are not appropriate for protection of plant varieties; the UPOV system provides a substantially more balanced system for the protection of plant varieties, because of the breeder's exception principle.
- 3. The Convention on Biological Diversity is not a suitable Access and Benefit Sharing (ABS) system for use of plant genetic resources in food and agriculture. Instead, the International Treaty on Plant Genetic Resources for Food and Agricultural is the *sui generis* system of choice to achieve the objectives of ABS, sustainable use of plant genetic resources for food and agriculture and the preservation of these resources. The Treaty does not require prior informed consent. Regretfully, several important species, such as soybean, cotton and tomato are not covered by the "List of crops covered under the multilateral system" (Annex I of the Treaty)
- 4. The seed industry (the International Seed Federation) has no problems with disclosure of origin of plant genetic resources used in the development of new plant varieties. This was stated in a Position Paper of ISF on "Disclosure of Origin in Intellectual Property Protection Applications", 2003, which was unanimously endorsed at the ISF World Congress in Bangalore, 2003. Seed companies can not run the risk of using material they have not legally accessed it may cost them a fortune and breeders have to write down in their notebooks what material they used. Disclosure of origin (in the sense of source) is not an extra burden for seed companies. It does also not reveal trade secrets.
- 5. The Biotechnology Industry Organization (BIO; US), which is primarily dominated by pharma industry, is against mandatory Disclosure of Origin at present. Most if not all known cases of "biopiracy" have little commercial value. Why, then, should BIO come up with an item that is not important for them and could impair their negotiation position for more important issues?

- 6. Due to the different positions of ISF and BIO the International Chamber of Commerce (ICC) was unable to publish a common position on disclosure of origin and prior informed consent.
- 7. Pressures for Intellectual Property Rights (IPRs) to become stronger, as research costs increase and technology gets more sophisticated.
- 8. The two biggest companies, Pioneer (seed sales US\$ 2,600m in 2004) and Monsanto (seed sales US\$ 2,803m in 2004) are not happy with the level of intellectual property protection given for plant varieties under the UPOV Convention. They strive for a delayed access to commercially available for breeding purposes, thereby consolidating their position. Their ultimate goal is one intellectual property system for plant varieties, the patent system. The US Administration seems to pave the way for that by having this in their negotiation package for bilateral agreements.
- 9. A weak point of the UPOV Convention is that it does not provide rules for preservation of plant varieties at the end of the period of protection. Most seed companies are presumably happy with that situation. Indeed, UPOV does not require release of protected varieties. Inbred lines, the crown jewels of seed companies commercializing hybrid crops, often do not become available after expiry of the protection under UPOV (this is different for patents). The practice should be that such plant material is deposited in well run gene banks. This points, however, to the following question: who should finance such gene banks.
- 10. The maintenance, production and storage of seeds are cost factors. Seed companies can and must achieve cost reduction by a reduction of the number of plant varieties commercialized per plant species. Only the most profitable seed varieties are kept on the market and the price of these plant varieties will increase. Depending on the availability of the discarded material, this trend can be either an opportunity for smaller seed companies or in the long run a disaster because of lost biodiversity.
- 11. Monetary benefits, arising from implementation of the CBD or the Treaty will never suffice to meet the needs of developing countries. Capacity building is important and more resources are needed, for example for training and equipment.
- 12 In 2006, it is the 10th anniversary of the Global Plan of Action for the Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture and the Leipzig Declaration on Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture agreed upon in Leipzig, Germany 17-23 June 1996 (ref.8). We should use this anniversary to reactivate the Plan and to remind States of what they committed to.

Some general considerations

In this paper, the term seeds is intended to refer to plants domesticated for food, including the parts of plants, such as seeds used to produce plants having nutritional value.

Several plant species have been domesticated and gradually improved for human consumption over thousands of years. Such improved varieties of a given plant species

are nowadays referred to as "cultivars" or simply "plant varieties". For example the plant species "apple" exists in the form of many plant varieties, such as Jonathan, Jonagold, Jacques Lebel, Golden Delicious, etc.

Existing plant varieties are used to develop new improved plant varieties. Often the improvements may appear incremental, but over the years such incremental improvements add up and can result in for example substantial yield increases. This process is still ongoing, and it is important that it continues, not only because the global population keeps growing and its needs for an adequate quality food supply will increase, but also because climatic conditions may change, and new plant pests and plant diseases may occur.

Plant varieties that are no longer satisfying the modern requirements, such as yield, may still help to solve new problems. Preservation of such apparent obsolete varieties is accordingly important.

The world needs better plant varieties to feed everyone. The world's population is growing rapidly, many people still suffer from malnutrition and the cultivable land per capita is expected to decrease from 0.45 ha in 1966 to 0.15 ha in 2050.

The role of the private sector is becoming more important, as the contribution of the public sector in plant breeding decreases. For example, the private sector investments in plant breeding increased from \$50m (1960) to \$500m (1997) (Smith St, Ref 13). Research in the area of crop improvement is getting more and more expensive, and the seed industry needs an incentive for continuing investment in research in plant breeding. Ultimately, the seed industry aims, logically, for a reasonable financial return for its investment in plant breeding research.

There is, however, a concentration within the seed industry. The leading seed companies have much weight in international organizations and can influence the long term future of the seed industry. Their aim is stronger intellectual property protection, to render access to their genetic resources more difficult and to increase the price of the proprietary seed by focusing on elite material and discarding less profitable plant varieties.

These aims are legitimate from their perspective. It is a major task of international organizations and institutions to make sure that the balance between the major seed companies and the thousands of small breeding companies is fair and that access to plant genetic resources for breeding purposes is and remains facilitated. Indeed, corporate control and ownership of seeds – the first link in the food chain – has far-reaching implications for global food security.

Access to Plant Genetic Resources for Food and Agriculture (PGRFA)

History

Before 9000 BC food was collected by hunting-gathering. The transition to domestication involved sometimes selection for features of varieties, like seed dispersal and seed germination features, by the then "farmers" that were vital to ensure survival of wild species but undesirable for domestication.

Domestication of plant species started about 8500 BC in Southwest Asia. Diamond (ref 1) calls this area the "Fertile Crescent"; it covers parts of Turkey, Jordan, Syria, Iraq and Iran. The species used for food production in that area were cereals (emmer wheat, einkorn wheat and barley) and pulses (pea, lentil, and chickpea).

From the Fertile Crescent area food production of these crops spread. It moved to the west via Cyprus, Greece, reaching Spain by 5200BC and Britain by ca 3500BC, to the east to reach the Indian subcontinent by 6500 B.C. and to North Africa, reaching Egypt soon after 6000 BC

Other important "Areas of Origin" of staple food are China for rice and millet, Mesoamerica for corn, beans, squash, the Andes and Amazonian area for potato and manioc and Eastern United States for sunflower and goosefoot.

"In ancient times, 2,000 to 4,000 years ago, there is evidence that rulers dispatched dedicated expeditions to acquire particularly valuable plants...But some evidence exists of efforts to obtain staples as well.

...colonial powers collected valuable species, sometimes with the consent of the "donating" country, but ...examples of theft are commonplace in the literature."

(Cary Fowler, ref 2, p 53)

The first Dutch vegetable seed company started its seed business between 1800 and 1810. Various other seed companies were founded in the 19th century. This started the switch from simple supply service to farmers by "seed companies" to real plant breeding. This change must of course be seen in the light of the publication of Mendel's heredity laws in 1856, which laws were rediscovered 1901 by de Vries and others.

The public and private sector started to do their home work: they collected seed varieties, exotic species, landraces to build up their private collections, seed banks, botanic gardens. (See below Gene banks)

Until the early 1980's, breeders practice was relatively friendly *vis a vis* competitors, with few exceptions relating to misappropriation of proprietary parent lines of hybrids. Sample-sized bags of seeds were sent, usually free of charge, to many competitors, on request, without restriction of use. As investment in Research and Development increased, the competitive behaviour became tougher.

Parent lines of hybrids are a special category, as such lines are normally not available on the market and kept as a trade secret by the seed company that developed them. Misappropriation of such material can have dramatic consequences: In a lawsuit in 1992, Holden Foundation Seeds had to pay Pioneer \$46.7 million and return breeding material. In 2000, Cargill agreed to pay Pioneer \$100 million and destroy breeding material.

The illegal use of plant genetic resources, by misappropriation or unauthorised use of IP protected genetic resources, can result in the pollution of a company's whole germplasm pool and have dramatic consequences. This is one reason why seed companies will normally demand that their breeders use only material that they can access legally. They must keep notebooks for that purpose, and are forbidden to use material in their breeding programme unless they are sure they are authorised to use it. This explains also why

declaration of source (as distinct from disclosure of country of origin) is not an additional burden for the seeds industry.

The Convention on Biological Diversity and the International Treaty on Plant Genetic Resources for Food and Agriculture

Access to plant genetic resources for the purpose of breeding new plant varieties was substantially free till about 1986, when the first patents on plant varieties issued in the United States

Subsequent negotiations in preparation of the Convention on Biological Diversity (CBD) went, from the seeds perspective, in the wrong direction. Proponents, basing their proposals within an ideological framework of "common heritage" and cooperation were unsuccessful. In the CBD the notion of national sovereignty, aiming to capture economic benefits on a national basis, dominates and is for Seeds inappropriate. This was recognized and the conference of the parties (COP) to the CBD called for the International Undertaking on Plant Genetic Resources for Food and Agriculture at the UN Food Agriculture Organisation (FAO) in Rome to be renegotiated in the light of the CBD and the special needs of food and agriculture.

The International Treaty on Plant Genetic Resources for Food and Agriculture (see http://www.fao.org/ag/cgrfa/itpgr.htm) (Treaty) will, hopefully, correct this as it is based on a multilateral system (MLS): "countries contribute what they have to the global larder, and in an open-access system, they get access to the diversity everyone else has provided while retaining their own." (Cary Fowler, ref 3)

The MLS covers Plant Genetic Resources for Food and Agriculture (PGRFA) listed in Annex I to the Treaty that are under the control of the Contracting Parties (CPs) and in the public domain. It also covers *ex situ* collections of International Agricultural Centres of the CGIAR. CPs also agree to take appropriate measures to encourage natural and legal persons within their jurisdiction who hold PGRFA to include such PGRFA in the MLS (Treaty Article 11).

Facilitated access is provided to the CPs and to legal and natural persons under the jurisdiction of any CP solely to utilize and conserve for research, breeding, and training for Food and Agriculture, as pursuant to a standard Material Transfer Agreement (sMTA) to be adopted by the Governing Body, which is composed of all CPs (Treaty, Article 12).

Benefits accruing from the facilitated access shall be shared fairly and equitably through information exchange, technology access and transfer, capacity building, and the sharing of gains arising from commercialization.

The benefits arising from use of PGRFA shared under the MLS should flow primarily to farmers in all countries, but especially to developing countries and countries with economies in transition that conserve and sustainably utilize PGRFA (Art.13.3) Monetary benefits generated under the Treaty will go into a "mechanism" and dispersed to support PGRFA conservation and utilization programs, primarily in developing countries.

An appropriate sMTA is a prerequisite for an effective, fair, and equitable share of the benefits arising from commercialization. In fact, there can be no implementation of the Treaty as long as the sMTA is not in place. It would appear that the participants at the discussions of the first meeting of the Contact Group on the terms of the sMTA, July 2005, in Hammamet (Tunisia) were committed to make progress in this respect. The discussions were very constructive and give rise to optimism. (See http://www.fao.org/cgrfa/cgmta1.htm)

Gene banks and their use

As Cary Fowler has commented

"Both the U.S. and Russia (then the USSR) constructed long-term facilities in the 1970s. During the last three decades, the growth in the number of gene banks and the size of collections they house has been remarkable....Today there are more than 1300 collections ...

During the peak period of PGRFA collecting for gene banks and scientific plant breeding programs (1972-1991), developing countries received from the CGIAR centers four times as many samples as they provided. By 1992, the 4 to 1 ratio had widened. For every accession provided by developing countries in 1992, those same countries received 60 samples. Today the ratio is certainly better than 100 to 1.

Many gene banks ... are not fulfilling their mandate, either to provide materials for breeders, or to conserve materials long-term. ... Conditions in most gene banks simply do not meet internationally accepted standards.... No gene bank ... has secure and formal multi-year funding.

Collecting is on the decline. And in-situ is not at the moment a major source of germplasm for breeding or research programs or even for farmers in other locales.

The Treaty is a gigantic breakthrough that covers most of the world's ex-situ PGRFA accessions. The Treaty, however, mainly takes care of the "access" question...; it does not ensure "availability". This is where the newly-created Global Crop Diversity Trust, an endowment fund aimed at securing the future of collections, enters the picture in support of the objectives of the Treaty as well as the Global Plan of Action." (ref 3)

The interest of seed companies in access to exotic germplasm, landraces etc for breeding purposes is very low.

The situation is different for traits of potential agronomic value. The potential interest is there, but the chances of success are low and investment risks high. There are few examples of valuable traits found in plant genetic resources for use in genetic engineering. (See ref 7, p9, footnotes 30 and 31). The commercially most attractive traits developed thus far, are from bacterial origin (primarily Bacillus thuringiensis traits) or interfere in the metabolic pathway of plants (herbicide tolerant crops).

Most seed companies rely on commercially available cultivars and on their own collections (if they have them) for development of new plant varieties. Of major concern is therefore the situation in the US, where the practice of patenting plant variety delays access to patented plant varieties till expiry of the patent.

Intellectual Property on PGR

From mid 20th century to today

Intellectual Property systems for plant varieties were mainly set up in the second half of the 20^{th} century. Some key dates are:

1930: US Plant Patent Act (35 USC §§ 161-164): exclusive right to asexually reproduce a plant variety (but not tubers) and amended various times since.

1961: International Union for the protection of new varieties of plants (UPOV); this Convention was revised in 1972, 1978 and 1991(see below). The cornerstone of the Convention is the Breeder's exception and it is common to all UPOV Acts. It exempts acts done for the purpose of breeding from the Breeder's right. The various Acts differ, however, in terms of the number of species to be protected, the scope of protection, and the minimum term of protection. Further, national laws and their implementation vary from country to country for any given Act.

1970: US Plant Variety Protection Act issued (applicant must submit breeding history)

1973: European Patent Convention provides that patents shall not be granted in respect of plant or animal varieties

1980: US District Court confirms that "living things" are patentable (Diamond v. Chakrabarty; USP 4,259,444)

The Miami Winter Symposium on "Advances in Gene Technology: Molecular genetics of plants and animals", in January 1983, triggered several filing of patent applications by various companies on plant transformation (including agrobacterium aided transformation, marker and promoter systems), and started a new area. The R&D budgets in major seed companies increased, new companies entered the business, often from the chemical industry, there was more at stake, the competition got tougher and the pressure for stronger or other intellectual property protection increased.

Plant biotechnology changed indeed the seeds world. Biotechnology does not only allow the design and production of new, genetically modified plants but it offers also tools for controlled and faster transfer of favourable traits from one variety to another (marker assisted breeding).

1985: US Court (Ex Parte Hibberd) confirms that utility patents for plants may be granted

June 1986: USP 4 594 810 issued the first patent on plant variety *per se* claiming "An inbred corn line having the designation HBA1" (claim 1)

1991: negotiation of the TRIPS Agreement which as adopted as a treaty administered by the World Trade Organization (WTO), established in 1995. It is the first and only IPR treaty that seeks to establish universal, minimum standards of protection across the major fields of intellectual property, including patents, copyrights, trademarks, industrial designs, integrated circuits and trade secrets. Article 27.3.b thereof provides that

members may exclude plants and animals other than microorganisms from patentability as well as essentially biological processes for the production of plants other than non-biological and microbiological processes; It then states "However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof."

December 20th, 1999 the Enlarged Board of Appeal of the European Patent Office held that "A claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b), of the European Patent Convention (EPC) even though such claim may embrace plant varieties. http://legal.european-patent-office.org/dg3/biblio/g980001ex1.htm

This decision is conform to the Biotech Directive 98/44/EC of July 6th, 1998. The decision makes plants, and therefore plant varieties, patentable.

December 10th, 2001: the US Supreme Court affirms that patents can be granted for any technological process or product as long as it is new (i.e. not already publicly known), inventive (i.e. not obvious to a person of ordinary skill experienced in that particular technology) and has an industrial application. Patents can be used for protection of newly developed plant varieties alongside existing systems specifically for new plant varieties that protect plant breeders' rights, such as the Plant Variety Protection Act (PVPA). The PVPA includes research and farmer-saved seed exemptions not found in patent law.

The SC held that "The requirements for obtaining utility patent under §101 are more stringent than those for obtaining a PVP certificate, and the protection afforded by a utility patent are greater than those afforded by a PVP certificate. Thus, there is a parallel relationship between the obligations and the level of protection under each statute." (S.C. on J.E.M. AG Supply, Inc., v. Pioneer Hi-Bred International, Inc.)

I do not share the opinion of the SC that requirements for utility patents under § 101 are more stringent (in the US) than those for obtaining a PVP certificate. In my opinion, patent protection for plant varieties *per se* is inappropriate from a global perspective, especially for developing countries, but the same may be true for the United States. (Ref 4)

IP threat and recommendation

As noted above, IPRs tend to get stronger, as research costs increase and technology gets more sophisticated.

Some major seed companies are loudly thinking about amendment of the Breeder's exception, which is the cornerstone of the UPOV Convention. The idea is to delay access to protected plant varieties for breeding purposes for a number of years, whereby the delayed access might be different depending on the species. It is clear that this would undermine the UPOV Convention and aims to move in the direction of one IP system for plant varieties, namely the patent system. It would appear that this strategy is in line with aims expressed by the US Administration in bilateral negotiations. This trend should be of a major concern, particularly for developing countries.

Although the UPOV system is not beyond criticism, it provides an excellent framework for a balanced and effective *sui generis* system for the protection of plant varieties. It

would, however, be desirable for UPOV to at least encourage its Member states to make deposition of plant varieties in a gene bank mandatory after expiry of the protection period. This would appear fair, after firms have enjoyed protection and a useful contribution to biodiversity conservation.

Commercially available cultivars as source for breeding

Disclosure of source

Plant varieties are products of many distinct genetic materials, usually developed over a long period of time. The genetic resources employed for the creation of a new variety may come from many countries. Quantitatively, the genetic contribution of each resource employed may be different, and it is in general not possible to determine the qualitative contribution of chromosome fragments in the end product.

The CBD approach to seek prior informed consent from the country of origin for access to such material cannot make sense. But why not disclose the source of the material for which IP protection is sought?

Stephen Smith of Pioneer disclosed in Berlin, the pedigree background of a Pioneer brand maize that is currently grown in commercial agriculture in France as follows: Reid Yellow Dent (15%), Flint OP (15%), French Pyrenees Flint (13%), SmithTC (10%), Pioneer Female Composite (8%), European Flint (7%), Leaming (6%), Lancaster Sure Crop (4%), Argentinean Maize Amargo (3%), D107 (3%), Midland (2%), Minnesota 13 (2%), Clarage (1%) and Lindstrom ear (1%). (Smith, ref 2)

He then stated "The very fact that I can disclose these pedigree data indicates that, while interesting data in respect of showing germplasm background, these data per se do not provide much, if any, useful information to help anyone to develop an improved variety". In other words, disclosure of source of a plant variety does not reveal secret know how.

It is therefore not surprising that seeds companies have no problem with disclosure of origin.

Patent protection on plant varieties derived from publicly available varieties

The private sector relied in the early days heavily on public lines for the development of new plant varieties. This is particularly true for field crops such as corn, wheat, rice. For example, Iowa State University used population improvement and early testing in Stiff Stalk Synthetic to develop three very popular corn inbreds: B14, B37 and B73. There is probably not one corn seed company that did not use one of these inbreds in a breeding programme.

One of the most successful rice varieties, IR64, was developed by the IRRI, and consists of 20 landraces from eight countries including China, Korea, India, Indonesia, and Vietnam.

Assuming a company develops an improved version of IR64 and gets patent protection for it, and is consequently authorized to exclude IRRI and others from breeding with the improved IR64 version. Is this a well balanced protection system for plant varieties?

Conclusions/Recommendations

Plant genetic resources for food and agriculture are extremely important for humankind. Access - for breeding purposes - to plant genetic resources for food and agriculture, and the conservation of such resources is vital, as it has far-reaching implications for food security.

Patents are inappropriate for intellectual property protection of plant varieties. They hinder access to plant resources for breeding purposes. Developing countries should not adopt this practice; it is against their interest and of its citizens.

Disclosure of source is not a problem at all for seed industry. However, seeds makes a distinction between source, meaning the material accessed, and the origin or country of origin, simply because it is impossible to adequately define the real origin of plant genetic resources (see above History of Access to PGRFA).

Plant varieties out of plant variety protection should be deposited in an appropriate seed bank. This should be mandatory. To achieve that is, in my view, substantially more important for mankind, than getting an agreement on disclosure of origin. In the light of pressure put by some seed companies on UPOV's breeder's exception, this should probably be handled independent from UPOV. There is of course a price ticket tied to maintenance of seeds in a seed bank. Here States may have a role to play, (see Global Plan of Action (8), if feasible and suitable with assistance of the Global Crop Diversity Fund (http://www.fao.org/newsroom/en/news/2004/51211/)

Background Information/ References

This paper relies heavily on information disclosed in the following references, some of which are referred to in the text, others given as background and sources for further reading:

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