THE GLOBALISATION OF AGRICULTURAL BIOTECHNOLOGY: MULTI-DISCIPLINARY VIEWS FROM THE SOUTH WORKSHOP

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"Public research in the context of proprietary science –the case of the Consultative Group on International Agricultural Research"

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1. Background

Developments in biotechnology, molecular genetics, intellectual property regimes and access to genetic resources and related information over the last two decades are rapidly changing the conditions for public research. These conditions are global and comprises an evolving new global legal regime related to all biological matter. Here we will refer mainly to three international treaties (several others also matter) that have considerable bearings on public research, namely:

¤ the Biodiversity convention/CBD,

¤ the WTO-agreement and its annex on trade related intellectual property rights/TRIPS

¤ and the FAO international treaty on plant genetic resources for food and agriculture/FAO-treaty.

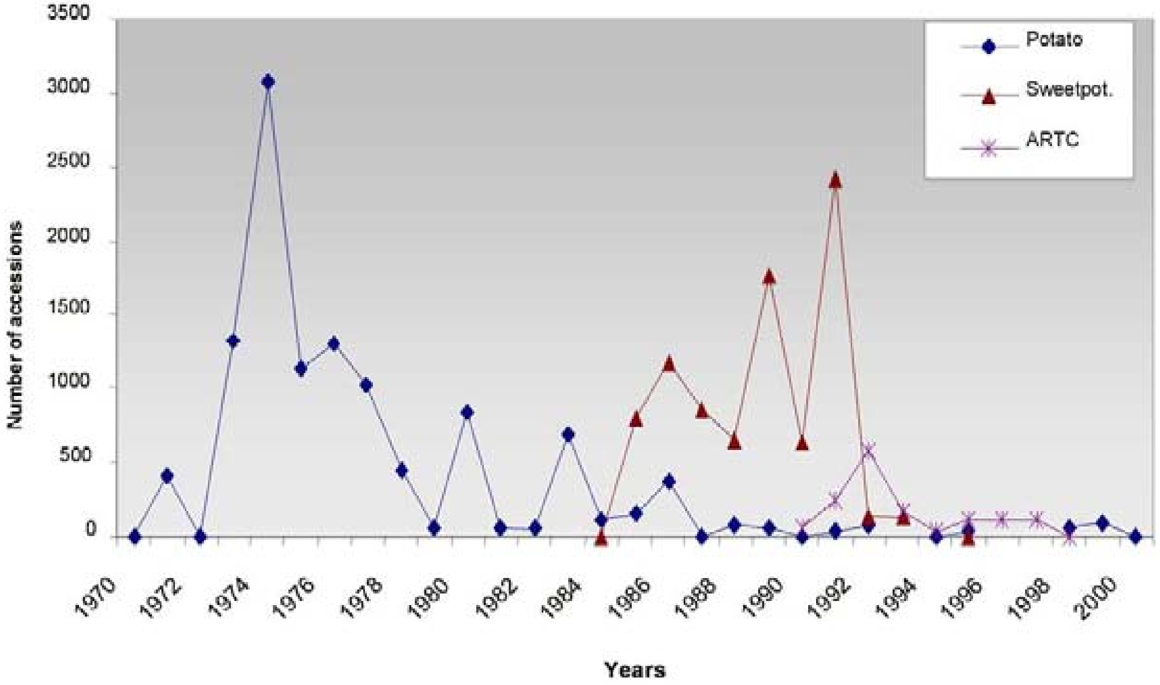
The two latter have (different) provisions for intergovernmental enforcement and sanctions, while the first (CBD) leaves this subject to national legislation. In short the CBD means nationalization of genetic resources (previously seen as part humankind´s common heritage), TRIPS sets minimum standards for what must be protected as intellectual property/IP and the FAO-treaty stipulates multilateral access and benefit sharing/ABS rules for some 35 crop genera of high country interdependence and for global food security. In short the new subsequent regulatory regimes on access and ownership means an enclosing of the biological and genetic commons. In this zero sum game the public domain is continuously reduced as more and more of the commons are proprietarized, thus move from being a free public good to private, corporate or state property. Biological common rights are thus replaced with regulated access. The emerging new legal regimes have deep impact on the freedom to operate/FTO for public science. In fact for public (and in fact also private sector) research we can summarize this in an equation: IP+ABS=FTO or in other words –proprietary science. Thus if we marry IP with ABS, how to create a viable offspring that has considerable FTO for science and scientists? In the following we will focus mainly on plant genetic resources. Animal genetic resources fall under CBD provisions while human genetic resources is subject to different other legal provisions mainly conventions and protocols under the World Health Organization.

2. A slowly shrinking public science domain?

National access legislation regarding genetic resources under CBD is today in operation in more than 30 countries, mainly in the South. There, access to genetic resources are subject to prior informed consent and mutually agreed terms. In South America the Andean Community in its decision 391/1996 agreed to apply a common regime on genetic resources with very strict and far reaching ABS-regulations. As stated above TRIPS sets a minimum standard for IP. The current IP-trend in biotechnology is that patents are granted on ever smaller pieces of biological matter/organisms. These patents are especially in the USA broad in scope (see Oldham, P., 2004) and restrict the use for third parties (the research excemption is in principle not valid in the USA) and the so called farmer´s privilege is not valid regarding reuse of patented seed. Until quite recently there was more or less a global reality that scientists/researchers could always access most biological matter and related information free of charge or for a symbolic fee –if its use was for research only, the so called bona fide use formula. Further, based on UPOV –the international convention on protection of seed varieties, farmers were allowed (subject to national legislation) to reuse protected seed without approval of the owner of the variety. Implementation of CBD- and TRIPS provisions in the national and international context have created complicated sector transgressing regulatory processes in which among others scientists and for example farmers have to operate. These global processes have arrested the international trans-boundary exchange of genetic material and related information (see also Fowler, C. and Hodgkin, T., 2004).

Collection of plant genetic material on sovereign nations territory by the Consultative Group on International Agricultural Research/CGIAR and its 15 research institutes has been reduced (although this varies for crops and region) after the enter into force of the CBD in December 1993. As an example please find below a graph from CIP (International Potato Centre) in Lima, Peru. Peru is member of the Andean Community.

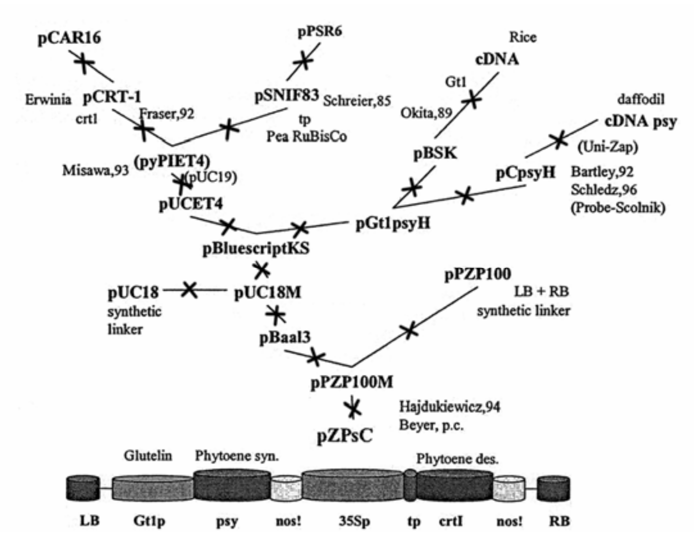
Evolution of germplasm acquisitions into CIP's gene bank (1970-2000)



Source: CIP 2004

International (multi-local) variety testing within the CGIAR is strangled as countries (mainly in the South) implement CBD-legislation, join UPOV (as part of the WTO/TRIPS-review) and become aware that elite material offered to other countries for variety testing can be subject to plant variety protection. Taxonomists/breeders/ethnobotanists who want access to other countries´ genetic material and ethno-botanical information are increasingly facing the fact that access is not granted or circumscribed with restrictions and that publications are no longer freely shared with reference to national access legislation. The severe result is that this situation creates legal uncertainties that greatly hamper international exchange of scientific information and biological material. Most threatened is the concept of international public goods/IPG, presently taken for granted, not least in the public sector.

3. What is in reality in the public domain and part of genetic commons?
A few years ago the Monsanto seed company released its Bt-soya which contains some 30 IPRs (patented gene traits, gene sequences, processes etc). The recently developed (and halted because of biosafety regulations) so called Golden rice, a Rockefeller Foundation initiated project involving for example the CGIAR member International Rice Research Institute/IRRI, contains around 70 IPRs (see Kryder, D. & Kowalski S, & Krattiger A., 2000).



Flow chart for tangible property transfers for pZPsC. The IP-pedigree shows for example: patented methods for isolation /cloning of DNA, patented synthesis/pathways for production of beta carotene and patented methods for regeneration of trans gene plants from transformed cells. Each line with a cross implies possible proprietary link –thus demanding access- and license agreement for use by non-proprietor

Source: Kryder, D. & Kowalski S, & Krattiger A., 2000 page vi

What is new here is that while UPOV permits the research excemption and the farmer´s privilege, this is less and less accepted regarding genetic material (i e GMO) which are wholly patented such as transgenic seed or contain patented parts. This is especially the case in the USA. The WTO/TRIPS-process creates serious concern that demands by the corporate sector for segmented markets and other restrictions for use by third parties of proprietary genetic material/information will negatively effect continued implementation of the research excemption and farmer´s privilege and thus in the long run public and international research collaboration and national food security. Starvation threatens the public domain. But scientists have so far only felt the first signals, often interpreting them as occasional –not part of an emerging permanent new global legal regime.

4. What is proprietary biological matter?
Taking into consideration provisions under CBD, FAO-IT, TRIPS and UPOV at least the following biological matter is proprietary:

Biological matter and related information under proprietary regimes

- plant seeds or other propagative plant parts collected after 1994;
- plant and animal cell lines;
- plasmids;
- other recombinant vectors;
- gene promoters;
- gene markers;
- transformed bacteria;
- isolated plant DNA;
- plant cDNAs;
- isolated animal DNA;
- bacteria (other than the transformed bacteria);
- isolated/purified proteins (other than those obtained by purchase of laboratory reagents);
- equipment for specialised laboratory purposes;
- information regarding laboratory methods;
- genomic sequence database(s);
- other nucleotides sequence database(s) such as PCR primer databases, cDNA sequences, etc.;
- ethnobiological information (traditional knowledge, indigenous knowledge); and
- farming systems information.

5. CGIAR's Role in International Agricultural Research

Formed in 1971, the Consultative Group on International Agricultural Research (CGIAR) currently comprises 15 international agricultural research centers focusing on natural resources management, agriculture, agro-forestry, fisheries and livestock. With an annual budget of more than US$400 in 2004, the CGIAR is the world's largest publically co-ordinated effort to address fundamental issues related to global food security and environmentally sustainable development. The institution was key to the Green Revolution during 1965-1985, introducing high yielding new seed varieties of maize, wheat and rice, which fed another 500 million people that would have otherwise starved. By increasing yields on existing farm land, the Green Revolution also saved rainforests and other biotopes including marginal lands that would otherwise have been brought under cultivation. This success was based on two basic features: free access to necessary genetic resources all over the world for selection and breeding; and free access to knowledge and technologies necessary to carry out the tasks. Furthermore, most of the necessary research and development in plant breeding was carried out in the public sector by universities and government agencies. But all those conditions have dramatically changed during the last 15 years.

6. Proprietary Science

The concept of 'proprietary science' was introduced to a wider international audience in the mid-1990s. However, the public sector and the scientific community still seems largely oblivious to the implications of the changes ushered in by this new approach. A 1998 CGIAR evaluation predicted that the private sector could account for around 75 percent of future investments in agro-biotechnology, not least in the field of plant breeding. Combined with national sovereignty over genetic material under the Convention on Biological Diversity, (CBD) this fact creates tremendous new challenges to international public agricultural research. Recent studies of the future niche for the CGIAR focus on its role to promote a 'Doubly Green Revolution': increase yields, maintain and increase agro-biodiversity and promote more environment-friendly agricultural practises. In order to perform this task the CGIAR finds itself at the crossroads of accessing genetic material under national sovereignty, as well as proprietary technology/gene contracts from the private sector regulated by a host different international agreements. Working with proprietary biological matter and related information creates considerable complexities and needs for revised policies as regards the CGIAR’s freedom to innovate and operate with a view to continuing to provide international public goods. Beyond the CGIAR: any public research dealing with biological matter (whether national or international) will face the same challenge. The CGIAR as a basically ODA-funded organization –in addition- needs to navigate with great skill in applying GM-technologies in its accommodation of agro-biotechnologies.

7. Agro-biotechnologies

With the break throughs in molecular genetics in the late 1970´s and early 1980´s a new dimension was added to biological and agricultural research. By using molecular precision technologies it became possible to refine and intervene in micro bilogical processes and to alter the genetic set up of plants and organisms. The resulting products were characterized by new genetic traits and properties that could not be created with earlier technologies. It now became possible to cross species barriers and incorporate genetic traits from species that earlier could not be made to mate. A standard word was created to name the new products: genetically modified organisms or GMOs. Applications of the new technologies took place as regards human-, animal- and plant development. In agriculture GMO-crops were introduced in the mid 1990´s (with insect/herbicide resistant/tolerant soybean and maize, later cotton). By late 2003 the global area for GM-crops were estimated at 67.7 million hectares out of which 30% in developing countries. The increase in area between 2002 and 2003 was 15% and is expected to continue.

The rapidly expanding use of GM-seed has created an intense public debate about biosafety and seed monopolies. This relates to concerns about impact on human health and ecological effects such as unintended outcrossing of GM-traits to non-GM crops and wild relatives with impacts on agro-biodiversity (=genetic monoculture) and ecosystem services and sustainability. Also issues related to use of patented genetic material in GM-crops as regards farmer´s and breeder´s freedom to operate have been raised. Many of these concerns are still unresolved. On the other hand GM-crops offer much new opportunities to match global challenges such as climate change and rapid population growth not least in Sub Saharan Africa. Agrobiotechnology offers the possiblitity of developing for example salt-tolerant rice, drought tolerant maize and wheat as well as new disease resistant varieties of major staple crops. It further promises the possibility to biofortify crops (add vitamins and proteins) and to improve plants´ capacity to fix nitrogen. It would be irresponsible not to dare to test all these new opportunities, while at the same time adhere to the precautionary principle. Therefore a future research and policy agenda emerges:

- As regards GM-crops recent studies by the CGIAR-system have shown that maize and the oilseed/rape complex (crosspollinating) are especially important to study with a focus on effects when cultivated in centers of origin/genetic diversity.
- It is further important to study the life cycle of the specific traits that characterizes a certain GM-crop. Biological and evolutionary processes always provide selection pressure and reproductive change that effect how GM-traits might or might not outcross in ecosystems. Further systematic research is necessary here.
- As regards impact by food and feed via animals from GM-crops on human health there are so far no proof that there are reasons to avoid GM-food. There are however reasons to take very seriously the ethical concerns raised in public debate as regards GM-food and GMOs.
- Also the issues of social and public control of patents in GMOs deserve much further scrutinization. Human rights, public domain and public goods issues now have to

address how much of former biological commons should stay as such in order to allow farmers and breeders to – as has always earlier been the case- replant and experiment (under safe biosafety regulations) with GM-plant material without risking being accused for infringement of intellectual property rights. Here such solutions as segmented markets and proprietary products free for humanitarian use offer ways forward.

7. Meeting the Challenge

In February 2004, the CGIAR's Genetic Resources Policy Committee considered the need to be proactive. The result was a decision to conduct a study on CGIAR's use of other institutions' proprietary biological matter and related information. In late November 2004, a questionnaire was sent out to the 15 CGIAR centres, as well as three CG 'challenge programmes' (see Thornström, C-G., Gale, M. Gardiner, P., Henson-Apollonio, V., 2004). Among the 90 questions are issues related to present and future access to genetic material regulated under the FAO's International Treaty or the CBD, and proprietary technologies regulated under UPOV, TRIPs and/or intellectual property law (see Henson-Apollonio, V. and Rao, H., 2004).The study is slated to conclude by mid-2005.

We expect that the study will indicate present and possible future use of proprietary biological matter and related information and how this may effect the conditions for the CGIAR centres to produce international public goods (IPG). We also hope that the study will give guidance about possible avenues to accommodate proprietary interests while maintaining IPG. We anticipate examples of use of CGIAR output in segmented markets or use of proprietary matter and related information free for research and development but with proprietary conditions for final commercial products.

8. The Need for Clear Proprietary Policies for Public Sector Biological Research

The challenges facing the CGIAR apply probably to any other (public) biological research on a global scale. National universities and research institutions cannot stand aside of these new realities. Thus any international transfer of biological matter, technologies and related information across national borders with a potential commercial use will be affected.

A proactive approach by the public sector (such as the upcoming CGIAR-study) will be necessary if public research entities want to remain active players in the proprietary science world. In this context open access to basic science and technology may even be a matter for a new international agreement (see Barton, J. and Maskus, K., 2004). The CGIAR´s role in a Doubly Green Revolution is in the end about intellectual property and the poor. The concept of 'humanitarian use' will be important if we are to find successful new partnerships between the public and the private sectors in fulfilling the objective to let science serve all members of society.

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