

Biotechnology and Development: A Balance between IPR Protection and Benefit-sharing*

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The paper discusses various aspects of protection of agricultural innovations specially after the applications of biotechnology have taken place in the agricultural research. Describes the relevant article of TRIPS Agreement in respect of agricultural innovations and new problems of their protection. Apart from protecting innovations, the access to genetic resources is another basic aspect affecting biotechnology as new tool for the conservation and sustainable use of plant genetic resources for food and agriculture. Paper describes the international framework for IPR related to genetic resources and access to these resources. The legal tools available with the Latin American region for protection of IPR, access to genetic resources and fair distribution of benefit are described and the problems faced in achieving these goals are identified. Several suggestions for improving the performance of the system of protection of access to genetic resources and protection of IPR are given.

In the IVth Century B.C. Aristoteles presented moral and philosophical arguments to reward inventors for their innovations. Since then and until the industrial revolution in Europe, only Philosophers dealt with these issues. With the industrial boom in the 19th century in Europe the need arose to protect inventions from being copied and thus ensure that the investment in innovations would be rewarded. On the other hand, there is a need to disclose innovations to

the public to promote/facilitate further development based on existing innovations (Tansey, 1999). To ensure the both aspects of innovation (protection and publication) a legal protection, an Industrial or Intellectual Property Rights (IPR) system was created. During that time, the legislations on IPR were designed to protect only industrial products since agricultural innovations did not play such an important role.

In the beginning of the XXth agricultural

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innovation gained importance and consequently its protection but the mechanisms developed by then for this purpose (patents), were not appropriate to protect new plant varieties, basically for three reasons. First, one of the requisites to obtain a patent is, that the invention should really incorporate an inventive step (non-obviousness) what does not apply to new plant varieties created by selection and crossing of already existing varieties. Second, a patent requires an exact description of the innovation and the process to obtain it. This resulted not only difficult but in most cases impossible. However, a pure publication of the description of the material, in contrast to industrial innovations, is of no use for further investigation – the protected variety must be physically available. Third, patent protection was considered to be too strong for new varieties and thus hinder a more dynamic development of the agricultural sector since there are traditional and accepted rights and habits of farmers as for instance the saving, re-use and exchange of seeds which are restricted under patent protection. To overcome the above-mentioned constraints, a new concept to protect plant varieties, the Plant Breeders' Rights (PBRs) system, was designed. This concept proved to fulfill its purpose and was developed further resulting in the most advanced mechanism to protect new varieties nowadays - the 1991 Act of the UPOV Convention.

In the last 15 years, biotechnology applications in agriculture boomed enormously, which also looked for protection of IPR for its innovations and

did surely find it in the patent protection system.

With the globalization and the aperture of the market new problems are arising in respect of the protection of innovations. Before the era of the globalization the flow and therefore the protection of new technologies was limited to industrialized countries, nowadays there is a strong need for a global and multilateral protection of those innovations. As the result in April 1994 the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was signed and came into force on 1 January 1995. The most relevant article in respect to agricultural innovations of the mentioned agreement is the Article 27, which defines patentable subject matter and possible exclusions from patentability.

TRIPS oblige to provide patents to all products and processes that are new, involve an inventive step and are capable of industrial application. However, governments are allowed to exclude from patentability plants, animals and essentially biological processes for their production. In the case of plant varieties, however, governments are obliged to protect them by patents, "an effective *sui generis* system" or a combination thereof. Microorganisms and microbiological processes are explicitly not allowed for exclusion from patentability. Nevertheless, the lack of definitions leaves the interpretation of the terms used in this article to national legislation.

Apart from protecting innovations, the access to genetic resources is another basic aspect affecting biotechnology as new tool for the conservation and

sustainable use of plant genetic resources for food and agriculture. This topic came up on the international agenda in the early eighties, as it became clear that the (agro) biodiversity is rapidly decreasing and a strong need was felt for conservation and sustainable use. The FAO International Undertaking on Plant Genetic Resources (IU), approved in 1983, was the first important international intent to recognize the rights of farmers derived from their contribution to conserve and develop agrobiodiversity and the implementation of these rights. It is expected that in November this year the IU will be approved, becoming a binding agreement and, for the first time the Farmer's Rights and the need for fair and equitable benefit-sharing mechanisms for the use of plant genetic resources for food and agriculture are recognized and granted (Reuters, 2001). Although respect to the access to plant genetic resources the IU is supposed to be a great success there are still some important points left for negotiation. So for instance the Article 13.3 (d), which refers to IPR and the list of crops, covered under the multilateral system for facilitated access. Particularly the EU member states are "very disappointed" about the fact "... that crops of major importance^[1] to world food security... are not included on the list" (Statement by the EU member states at time of the adoption of the text of the IU).

In December 29, 1993 the Convention for Biological Diversity (CBD) whose objectives are the protection, conservation and the sustainable use of genetic resources and related knowledge entered into force and since than 178

countries (not including the United States) have ratified the agreement. Both agreements (CBD and IU) assign to national governments the responsibility to regulate the access to genetic resources and to create mechanisms to reward those who traditionally use, conserve and develop these resources which are the source of all modern, mostly biotechnological products protected by already established IPR legislation.

After having described the international framework for IPR related to genetic resources and the access to these resources, difficult question arises: How governments apply these concepts at national level in Latin America and the Caribbean? How do they get the balance right between protection of IPR of innovations, access to genetic resources and the fair distribution of benefits? Answering to these questions and at the same time, pointing out the main practical problems of the implementation of the mentioned concepts, require an analysis of the previous and on-going Latin American experiences.

The Legal Framework

A FAO survey conducted in 2000 on the implementation of legislation of PBRs and access in Latin American shows, that there are 8 countries (the Andean Group, Brazil, Costa Rica and Paraguay) which have legal mechanisms to regulate the access to genetic resources. All these regulations are linked with IPRs including articles demanding any applicant for an IPR based on genetic or traditional resources to prove that the original resources, if accessed within the

country, were obtained in concordance with the national legislation on access (Dutfield, 1998).

Respect to the TRIPS Agreement and in particular its Article 27.3b, all Latin American countries, with the exception of Guatemala, exclude plant varieties from patentability and opt to protect them by a *sui generis* system (PBRs) although the level of protection differs from one country to another. Most of these countries have PBR systems in place, which follow the UPOV system. The countries which have a PBRs based on the 1991 Act of the UPOV Convention are the members of the Andean Community. Most of the other countries of the region are members of the UPOV Convention under the 1978 Act, or, in case of Costa Rica, Honduras and Nicaragua, are preparing PBRs legislation to access the 1991 Act of the Convention^[iii] (Correa, 1999).

Regarding biotechnological products, the scope of patent protection also differs from country to country. For instance in El Salvador and Guatemala, because of lack of specification in the current IPR legislation, it is possible to patent all types of genetic resources including plants and genes. The Mexican Industrial Property law excludes subject matter identical to that found in nature from patentability but genetic material, when isolated and characterized is susceptible to patenting. On the other hand the Andean Community (through Decision 486), Argentina, Brazil, Cuba and Honduras explicitly do not consider plants or part of plants, including isolated

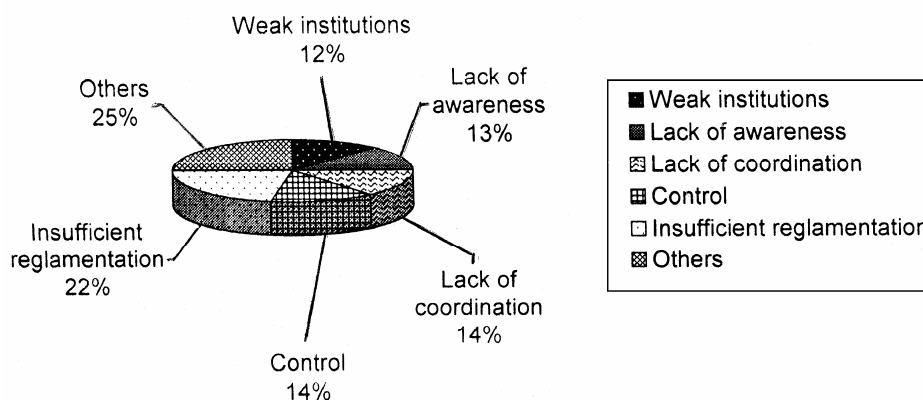
genes, as patentable subject matter (WIPO, 2001).

As mentioned, several countries in the region possess the legal tools for the protection of IPR, access to genetic resources and the fair distribution of benefits. However, the mentioned FAO survey clearly shows, that there are still multiple obstacles to overcome although the problems are consistent among countries and/or institutions. Basically three main problems were identified: (i) insufficiency of the regulations *per se*, (ii) the lack of awareness of and respect for IPRs and access regulations, and (iii) the efficient application/control of these regulations (Wendt and Izquierdo, 2000).

Insufficiency of Regulations

Equally, access to genetic resources and protection of PBRs denote an insufficient level of reglamentation that is perceived by the stakeholders as a problem but having intrinsic background limitations behind. Regarding the access to genetic resources, the incipient national experience in how to apply regulations and how to design a system, which is, on one hand efficient to protect the resources but on the other hand not too bureaucratic, is the main issue. The same refers to mechanisms that ensure equitable benefit sharing for the use of genetic resources and related traditional knowledge.

Regarding the protection of PBRs, the protection offered by reglamentations based on the 1978 Act of the UPOV Convention also shows some deficits as for instance no consideration of the concept of "Essentially Derived Varieties



Problems with regulating the access to genetic resources

(EDV)”, the scope of protection and the scope of the “farmers privilege”. So for instance the concept of EDV balances the rights of plant breeders and biotech companies respect to the modification of already existing and protected plant varieties. Respect to the scope of protection it often occurred that harvested products were exported and then, illegally used for reproduction. Therefore, the 1991 Act extends the protection to the harvested material, provided it is used illegally for reproduction and the plant breeder has not had reasonable opportunity to exercise his right in relation to the said harvested material.

Lack of Awareness

The lack of awareness regarding the need to protect the diversity of genetic resources and the related traditional knowledge as well as the respect for IPR are prominent factors affecting regulation development. On one hand, modern biotechnology and seed sector that are using genetic resources and traditional

knowledge to develop new products should recognize and respect the rights of the traditional users of these resources resulting from their contribution in terms of conservation and development, on the other hand the producers should respect the rights of the plant breeders. In general, this lack of awareness is perceived in all the levels of decision making.

Application and Control

Due to the reasons given above and mainly to the limited experiences and capacities of the officials in the application of the new regulations (legislations on access to genetic resources in Latin America that are recently introduced) the process results in an insufficient implementation of the existing regulations. In the case of the access to genetic resources this imply that there are strong difficulties in proving biopiracy or unauthorized use of genetic resources and related traditional knowledge because of lack of experience,

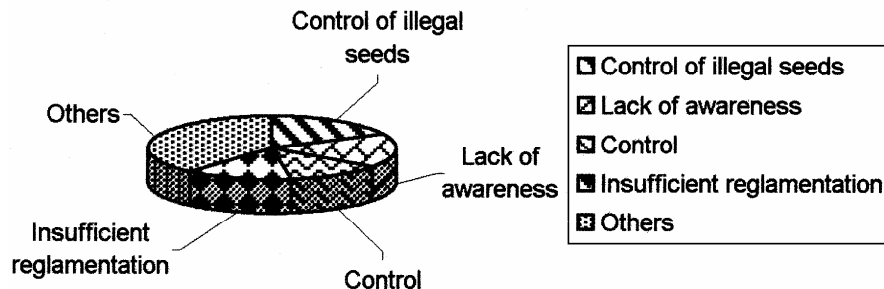
technical limitations and lack of human and financial resources to enforce this control. The same applies to the protection of PBRs where the biggest problem mentioned by plant breeders is to control the illegal commercialization of seeds.

In most of the cases the main reason for the problems of insufficiency of the regulations *per se*; lack of awareness of the necessity to protect IPR and genetic resources/biodiversity and biotechnology derived products and processes; and the efficient application/control of the regulations, are the lack of a national authority (or the coordination between national authorities) and the deficiency in human and financial resources within these authorities. The result is insufficient application of the regulations regarding IPR and access to genetic resources and thus disincentives for conservation, innovation and transfer of technology.

There are many practical examples, which underline these results. In a GTZ project in Paraguay for instance was developed a new variety of *Desmanthus virgatus* (slender mimosa, virgate mimosa), forage based on wild species originated in Paraguay. The GTZ applied

for a PBR on this species but did not comply with the national legislation on access to genetic resources (Ley 96). The Office of Registration of new varieties, depending on the National Seed Department of the Ministry of Agriculture could not file the PBR but, because of lack of experience (it was the first case in Paraguay), was not able to indicate the right procedure to make a protection and commercialization of the new variety possible. This case illustrates very well the problems, present in many countries and its consequences. As to the problems identified in this case they are: lack of experiences of national authorities, lack of knowledge about existing regulations and how to interpret them and the lack of coordination between authorities. The consequence: long procedures in obtaining a PBR and thus delay in the availability of a new, superior variety for the farmers (Wendt and Izquierdo, 2000).

The results of the survey make it clear, that any improvement of the performance of the system of protection of access to genetic resources and protection of IPRs is strongly related to capacity building and improvement of coordination



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between the stakeholders on national level, as well as on international level (Byerlee and Fischer 2001; Salazar, 2001). These capacity-building programmes should be directed to all stakeholders (Farmers, Seed companies, Biotech companies, Governmental Organizations, NGOs, CSOs, Universities and NARS) and should put emphasis on:

- Need for the conservation of biodiversity,
- Need for the protection of IPR,
- Access to and transfer of genetic resources and technology, and
- Training of human resources.

In addition to capacity building there are other areas where external support is needed. To facilitate the control, databases to register genetic resources and traditional knowledge should be established. Further on, networks for exchange of experiences and information as for instance the Technical Co-operation Network on Plant Biotechnology (REDBIO/FAO) shall be formed and can be an appropriate vehicles to implement the above mentioned capacity building programmes. A central element is also to assign clear mandates to the national authority and provide them with the tools necessary to enforce the existent regulations. As a crucial element such an authority should provide space for the participation of all stakeholders in the most important decisions such as the design of the regulations and its interpretation or to establish means of communication (Wendt and Izquierdo, 2000).

With further experiences the governments have to adjust their legislations according to their own, specific needs to achieve a balance between efficient protection of genetic resources, efficient protection of IPRs and mechanisms to regulate the access to genetic resources and traditional knowledge including benefit-sharing mechanisms. To achieve this, institutional capacity building as well as assignment of sufficient financial and human resources are essential (Salazar, 2001). The solution of these problems are not only depending on the activities on national level but are strongly dependent on how a better regional cooperation could be achieved. Therefore, the support of international organizations such as FAO, WIPO, UPOV, ISNAR and others are indispensable since national governments in developing countries lacking capacities and resources.

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Abbreviations

CBD	Convention for Biological Diversity
CSO	Civil Society Organization
EDV	Essentially Derived Variety
EU	European Union http://www.europa.eu.int/
FAO	Food and Agricultural Organization of the United Nation
GTZ	Gesellschaft für Technische Zusammenarbeit
IPR	Intellectual Property Rights
ISNAR	International Service for National Agricultural Research

IU	International Undertaking on Plant Genetic Resources
NARS	National Agricultural Research System
NGO	Non-Governmental Organization
PBR	Plant Breeders' Rights
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UPOV	International Union for the Protection of New Varieties of Plants
WIPO	World Intellectual Property Organization

Notes

*The views on this article are solely those of the co-authors and not necessarily of the organization where they work.

^[i]Not included are for instance soybean, peanut, tomato, sugarcane, quinoa, cotton, pineapple and mango

^[ii]With the entry into force of the 1991 Act of the UPOV Convention, countries wishing to adopt an UPOV-like PBRs system can no longer join the 1978 Act.

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