Intellectual Property Rights: Key to Access or Entry Barrier for Developing Countries

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During the past two decades, improvements in agricultural productivity have been largely based on the introduction of a technology package that includes high-yielding plant varieties, intensive use of chemical fertilizers, herbicides and pesticides, and an abundant supply of water. Despite undeniable success in raising productivity, concerns exist about the environmental sustainability of this model. Use of large amounts of agrochemicals has caused severe soil and water pollution, and the development of strains resistant to pesticides. Water resources are becoming increasingly scarce. Moreover, the genetic base of important high-yielding varieties is increasingly uniform and, as a consequence, they are susceptible to unpredictable outbreaks of disease and to the harmful effects of plant pests. Thus far, however, relatively few farmers in developing countries have had access to this new technology and capital-intensive methods of production.

Nonetheless, the emerging biotechnology revolution is stimulating hope that it will provide the basis for more sustainable agriculture in developing countries. This is because biotechnology today is different from previous agricultural technologies in two ways. First, biotechnology can enhance product quality by improving the characteristics of plants and animals. Second, biotechnology may potentially conserve natural resources and improve environmental quality by using organisms for degradation of toxic chemicals and wastes, fertilizers and soil improvement, and the development of insect- and disease-resistant plant varieties. Many of these applications are, or will soon be, a reality, and they can have far reaching consequences for the solution of important problems of developing countries. It is paradoxical, however, that although developing countries are perhaps the main beneficiaries of agricultural biotechnology, its development is almost exclusively concentrated in highly industrialized countries. That is not surprising in light of the high-level scientific research and the capital it embodies (Solleiro 1995). Moreover, innovation is increasingly controlled by large multinational companies.

In these conditions, it can be expected that the adoption of new biotechnologies by the developing economies will be concentrated in sectors of greatest economic development potential, will increase internal social differences, and will bring greater poverty to small producers and hired personnel.

Faced with this perspective, the only way to confront the above risks while taking advantage of existing opportunities will be by having a greater control over biotechnology in developing countries. That will depend to a great extent on the level of scientific and technological knowledge already attained in this area. But developing countries must not believe that they will be able to go "shopping" to the technology supermarkets of the industrialized countries (Deo 1991). On the contrary, given the barriers erected against the transfer of biotechnology, Third World countries will have to confront the problem of technology diffusion and define policies and practices that will make its use possible.

One of the most important policy instruments for the promotion of biotechnology development deals with intellectual property rights (IPR) protection. Developing countries are increasingly confronted with the fact that a number of bilateral and multilateral initiatives have been taken or are being implemented to "harmonize" intellectual property protection worldwide. "Harmonization" for most if not all countries will mean introducing much stricter intellectual property protection that can have far reaching consequences for the access to and the likelihood of broad diffusion of biotechnologies. This paper presents a brief analysis of the potential consequences to developing countries by the introduction of IPR regulations in accordance with these international trends.

Recent Development in IPR Protection for Plant Biotechnologies

Attempts to strengthen IPR protection regimes have been underway for more than a decade. Initially, the World Intellectual Property Organization (WIPO) served as the main forum. A committee of experts on Biotechnology Property and Industrial Property was established in 1984. Efforts to develop a new treaty on the protection of industrial property have been on-going since 1985. Conventions, however, require wide approval. Industrialized countries have been unsuccessful in getting the higher IPR standards they would like adopted in other countries through WIPO (Belcher and Hawtin 1991).

Some countries, led by the U.S., have subsequently embarked on bilateral negotiations to secure stronger protection for the intellectual property of their nationals. The U.S. has used its General System of Preferences, granting favored-trading status only to those nations that meet rigid IPR protection standards. European countries have had similar commercial policy instruments available to deal with IPR issues.

An extension to these bilateral actions has been the multilateral negotiation of trade-related intellectual property issues under GATT. Indeed, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement is the most comprehensive international instrument on intellectual property ever negotiated and adopted. The provisions contained in TRIPS constitute minimum standards. Thus, members cannot be obliged to provide a more extensive protection (Correa 1994).

In the area of patent rights, TRIPS contains a number of important provisions. According to article 27.3.b, parties may exclude from patentability:

> plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. 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. This provision shall be reviewed four years after the entry into force of the World Trade Organization (WTO) Agreement.

This exception reflects the outstanding differences, even among industrialized countries, on the patenting of plants and animals. The European Economic Community (EEC) proposals in GATT are aimed at maintaining the present position of the European countries which are members of the European Patent Convention. This position has so far been confirmed by the still-under-discussion draft directive on patents relating to biotechnology.

Various elements of article 27.3.b need to be considered (Correa 1994). First, unlike European law and other legislation that followed the same approach, the article refers to "plants and animals" and not to certain classification thereof (*varieties, races or species*)[1]. In the absence of any distinction — and the fact that the second sentence of the same article introduces an exception for one particular classification (plant varieties) — the exclusion is to be interpreted in broad terms as being inclusive of animal and plants — animal races and animal and plant species.

Second, the reference to "essentially biological processes" is limited by the exclusion of "non-biological and microbiological" processes. The concept of microbiological processes as an exception to the exception is present in the European legislation and in the laws of various other countries. Its aim in the TRIPS context is to limit the exclusion of patentability to traditional breeding methods, while preserving the possibility to obtain protection. For example this is evident on developments based on cell manipulation or, with the

[1]The distinction is important. Thus, the prohibition to patent a variety does not prevent European countries to patent a plant, as such. The acceptance of a patent application on the "Harvard mouse" by the European Patent Office was, similarly, based on the judgment that it is not a "race" but a specifically altered animal which is patented.

advances in biotechnology, the transfer of genes. Under the commented text, processes employing microorganisms (such as fermentation) are also patentable, in accordance with current practice in most countries.

More complex and new is the concept of "non-biological process." How a plant or an animal can be produced by a process that is not totally or in part biological? The source and grounds of this text are untraceable. It will probably create more problems than it may solve.

Third, and as an exception to the general authorized exclusion, members must provide protection for "plant varieties" either by patents or by "an effective sui *generis* system or by a combination or both." This obligation is another important basis for the expansion of the scope of intellectual property in a field that most developing countries keep as a part of the "public domain" till now. Although there is flexibility regarding the form of protection, the fact is that all GATT member countries will be bound to protect plant varieties. The flexibility is here, again, a reflection of the lack of consensus among the industrialized countries themselves. While in the U.S. and in Japan a plant variety may be patentable, this is not the case in Europe. The reference to a *sui generis* system suggests the breeder's rights regime. However, the possibility is open to combine the patent system with the breeders' rights regime, or to develop other sui *generis* form of protection. It is unclear why in an instrument aimed at establishing universal standards, the form of protection of plant varieties has not been settled in a more straightforward way, like in other matters of equal or similar importance[2]. In any case, considerable freedom has been left for national legislation to design the system of protection in this area.

Fourth, article 27.3.b is the single provision in the whole TRIPS Agreement that is specifically subject to an early revision — four years after the entry-into-force of the Agreement. This period is even shorter than the transitional period contemplated for developing countries (article 65). This solution suggests how difficult a compromise on the biotechnology-related issues has been and the need for a deeper examination of the matter.

Two other provisions of the TRIPS Agreement should be mentioned here. On the one side — as indicated above — protection of a process is extended to the products directly made with said process (article 28.1.b). On the other, in civil proceedings relating to process patents, the reversal of the burden of proof is established (article 34). This principle may have a substantial impact in the biotechnology field, given the importance of process patents and the often broad claims admitted in this field.

[2]The UPOV (International Union for the Protection of Plant Varieties) convention is not mentioned in the TRIPS draft text nor are breeders rights considered a form of "intellectual property" under the Agreement. Another forgotten modality of protection are the utility models recognized in many developed and developing countries to protect "minor" inventions.

Within this international framework, it is widely accepted that an invention consisting of or using living matter should be protected by IPR. With respect to agricultural biotechnology, the main instruments for protection are patents and plant breeders' rights. Patents are available on processes used to develop modified organisms or to produce biological products.

Patent protection is also available in a number of countries for plants that contain a novel gene. Patents covering genes are not generally confined to the sequence of a gene. The patent typically claims first, a gene or protein, standing alone, corresponding to that sequence; second, a vector or plasmid incorporating the sequence; and, possibly, third, a plant (of a particular range of species) that has been transformed by means of such a vector (and the descendants of the transformed plant). Thus, the patent holder gains effective control over use of the specified gene in genetic engineering (Barton 1994)

In this way a broad scope for protection is granted, which raises concerns about the possibility of extending it to many varieties and even to entire species. This can certainly pose serious threats to breeding activities in developing countries, which have been based rather upon capacities to adapt existing varieties to local conditions. Moreover, scope of protection can be also extended to characteristics of crops, which means that the patent holder could claim a monopoly over any variety expressing the same trait.

Due to these concerns, uncertainty still exists about the final validity of such patents. But, clearly their enforcement would erect important obstacles for biotechnology development and diffusion mainly in developing nations.

On the other hand, Plant Breeders' Rights (PBR) are granted by governments to plant breeders to exclude others from producing or commercializing material of a specific plant variety for, minimally, 15 to 20 years. In order to be eligible for PBR, the variety must be novel, distinct from existing varieties, and uniform and stable in its essential characteristics.

The legislation for both patents and PBR contains provisions for limited unauthorized use of the protected matter. Patent legislation includes a research exemption that allows others to study the protected subject matter without reproducing or multiplying it for commercial purposes. PBR law has important limits designed to facilitate continued improvement of protected varieties. Under the so-called Breeders' Exemption, any protected plant variety can be freely used as plant genetic resource for the purpose of breeding other varieties. Another important feature of PBR is a provision that allows farmers to re-use in their own exploitation the seeds they have obtained, a possibility that patents would exclude.

Demands exist to strengthen the minimum standards for protection of PBR under the International Union for the Protection of Plant Varieties (UPOV). The main change introduced by the 1991 conference included the exclusion of the farmer's privilege. The change also allowed member countries to adopt such provision while allowing the right-holder to prevent such a use on the

grounds that its legitimate interest will be prejudiced. Another important provision is made to prevent the unauthorized exploitation of any variety that is considered to be "essentially derived" from a protected variety. (A variety is considered essentially derived for this purpose when it is derived from the protected variety and retains virtually the entire genetic structure of the protected variety.) In this regard, the revised convention may contribute to dissipating some of the breeders' fears on the eventual impact of the patenting genes that may be incorporated in their protected varieties.

In summary, these new provisions respond to industry's claims for a protection more similar to that conferred under the patent system. Again, these new provisions are meant to protect interests of multinational seed companies and seem to erect new barriers for developing countries' access to agricultural biotechnologies.

Expected Effects of Stronger IPR Protection

As mentioned before, the new international framework for the protection of biotechnologies under IPR has brought some of peace in mind to those who had pressured for change. In a situation where strong IPR protection has been established, foreign biotechnology companies can be expected to be more interested in exporting their modem products, plant varieties and technologies to the country in question. The new framework could also be expected to produce an increase in private research activity, thanks to the economic incentive of the possibility of having a temporary monopoly position granted by different IPR mechanisms. International Property Rights protection can also facilitate the rapid availability of technology and foreign modern varieties, via licensing agreements and other contractual agreements (DG1S 1991).

On the other hand, extension of patent protection to all subsequent generations of a patented living organism by broad claims or stronger PBR protection through the "essentially derived" principle will increase production costs for breeders and may also lead to a control over segments of cultivated crops by IPR holders. This will pose severe difficulties for most plant breeders and small farmers of developing countries to access the benefits of new agricultural biotechnologies.

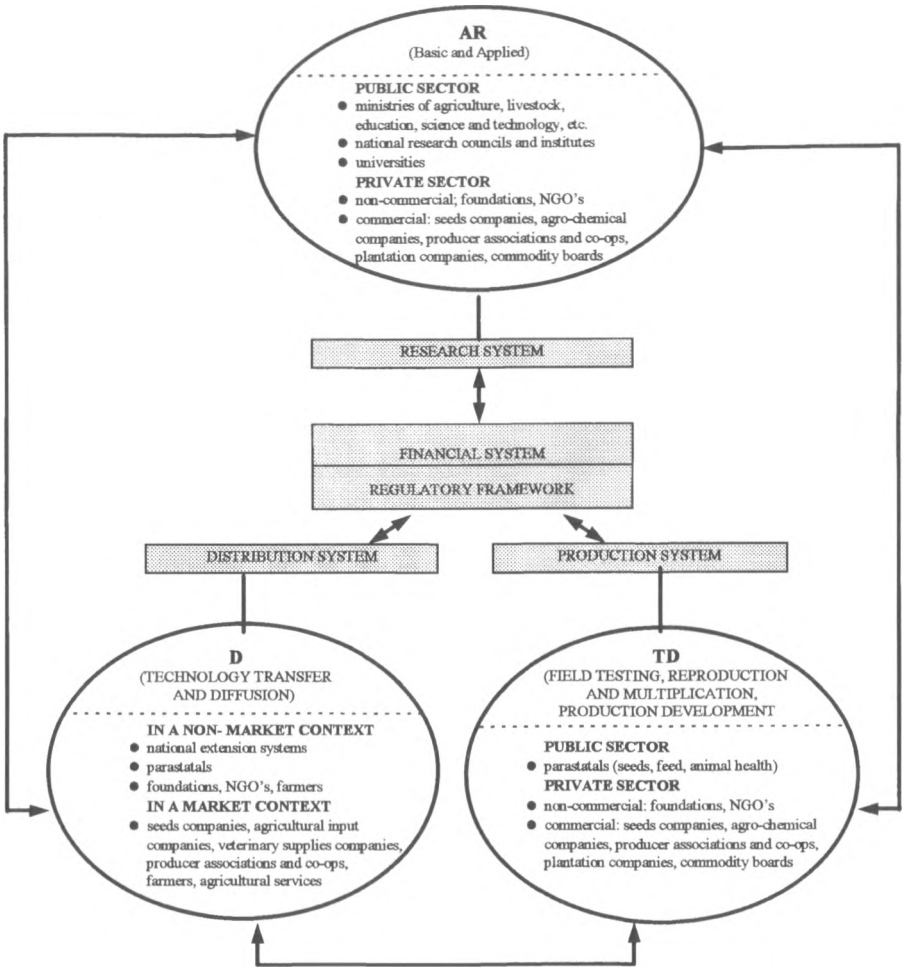
Unfortunately, in most developing countries, lack of a competitive market, limited research facilities and lack of participation of private companies in innovative activities represent serious obstacles to capitalize the benefits of a modern system of IPR protection. Despite the evident progress made by many developing countries to adapt their regulations to TRIPS, it still will be difficult to enforce them. Most countries lack the institutions and personnel for safeguarding IPR. Under present conditions, with a weak innovation system, such protection will mainly benefit large foreign firms wanting to protect an export monopoly and not necessarily interested in manufacturing their biotechnology products in these countries.

If innovation is to be encouraged, IPR protection is an important mechanism. But, it will not work in isolation. New regulations must be conceived within the framework of a national innovation system. This links research, technology development and diffusion as a continuous, interactive process in which local scientific and technological effort is crucial (Brenner and Komen 1994). Figure 1 presents a simplified scheme of a system in which biotechnology and its regulatory framework should be integrated.

FIGURE 1

BIOTECHNOLOGY IN A NATIONAL SYSTEM OF INNOVATION

PUBLIC AND PRIVATE ACTORS AND INSTITUTIONS



Implementation of an innovation-system approach is not only a question of increasing investments in R&D in order to have greater capacity for scientific research. It is also critical to facilitate the adaptation and assimilation of biotechnology developed in other countries. Protection of IPR will then play an important role creating a safe climate for technology transfer. But it has to be integrated to a new biotechnology strategy that should involve closer relationships between science, technology and the market for fostering innovations and their dissemination.

This process for formulating strategies and policies should follow a certain logical order so that the main actors of biotechnology development become committed to certain common objectives and obstacles to technology diffusion can be removed. Thus, the first thing is establishing long-term objectives and priorities, a necessity for making strategic decisions. The second step would involve establishing coherent programs for strengthening the institutional and managerial framework to address these priorities. Sound policy instruments are needed to ensure that researchers, enterprises, Non-Government Organizations and farmers participate in priority projects for introducing biotechnology. Finally, implementation requires continuous monitoring and assessment of achievements and obstacles to maintain quality of technical aspects. Implementation must also include an awareness of the socioeconomic impacts on the introduction of biotechnologies, and make timely corrective actions for attaining general objectives.