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CONDITIONS FOR THE DEVELOPMENT OF AGRICULTURAL BIOTECHNOLOGY IN BRAZIL - NATIONAL AND INTERNATIONAL CONTEXT, BIOSAFETY AND LEGAL ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

Lecture by Mr. Luiz Antonio Barreto de Castro,
Head of National Center for Genetic Resources and Biotechnology (CENARGEN),
Brazilian Agricultural Research Corporation (EMBRAPA), Brasilia, Brazil

BIOTECHNOLOGY- NATIONAL AND INTERNATIONAL CONTEXT

After a long period of silence since the Asilomar Conference in 1975, representatives from several Academies of Sciences (United Kingdom (UK), United States of America (US), India, Brazil, Mexico, Argentina, China and the Third World Academy of Sciences (TWAS)), almost a quarter of a century later, produced a document on the safety of state-of-the-art transgenics from the point of view of science. The document is generally favorable to the development of biotechnology. Except for the UK, Mexico and Brazil, none of the countries represented by the Academies of Science cited had campaigns against the use and approval of genetically modified organisms (GMOs). In all the other countries, the research and use of transgenic products are in rapid expansion, a fact which is somehow worrying for the two cited Latin American countries since the US, China, Argentina and India are our main competitors in the international production and commercialization of grain. This happened much later than the commercialization of the first genetically modified transgenic plant obtained through genetic engineering in 1995.

Genetically modified plants were released into the environment in the mid-eighties. Nowadays, over 30,000 field tests have been authorized all over the world, half of which are in the US, Canada and some European countries. Asia and Africa lag behind in this respect. In Latin America, most releases took place in Argentina (¾ of all the tests carried out in Latin America) and in Mexico. Brazil has authorized only about 1,000 field tests since 1996 because its biosafety legislation was not approved until 1995.

The commercialization of transgenic plants started in the mid-nineties with slow-ripening, genetically modified tomatoes, produced by Calgene, and the round-up herbicide resistant soybeans, created by Monsanto. Presently, transgenic plants of some species (soybeans, corn and canola, for example) play a significant part in the agricultural production of countries such as the US, Canada and Argentina. Glyphosate-tolerant transgenic soybeans already represent 62% and 98% of all the soybean plantations in the US and Argentina, respectively. Transgenic plants of many other species such as tomato, potato and cotton are also becoming popular. The total area covered by transgenic crops worldwide has increased from 1.7 million ha in 1996 to 60 million ha in 2002. The main characteristics of the plants mentioned above are resistance to insects, viruses and herbicides, as well as better nutritional qualities. One example of the latter is the modified canola which has a different lipidic composition intended to control the potential adverse effect of that oil in human cholesterol. Most of these plants (around 90%) have been developed by private enterprises already operating in Latin America, such as Monsanto, Syngenta, Aventis, Dupont, BASF, Dow and recently Bayer, amongst others.

Nevertheless, genetic engineering is considered to be in its initial phase since, until very recently, it has not used more than half a dozen genes, mainly from bacteria. Moreover, it has not yet solved the most serious agricultural problems, such as nitrogen fixation in gramineous plants and resistance to different forms of stress in plants, nor has it managed to alter the main physiological process that regulates the energy flow in plants, i.e. photosynthesis. The reason for this is that the main physiological and biochemical processes are very complex and have not yet been deciphered at molecular level, which is required before their manipulation through genetic engineering. The advent of genomics, however, has caused this picture to change rapidly, particularly after the sequencing of the *Arabidopsis thaliana* genome. Recent advances in genomics have shown an unequivocal fact: biotechnology is an important tool to deal with the intensification of competition resulting from a globalized agricultural market,

which demands cost reductions and the ability to produce crops in adverse weather and soil conditions, using varieties that are resistant to droughts and to aluminum and that are more efficient in the absorption of phosphorus. The so-called 'gene revolution,' is opposed to the 'green revolution,' which depended heavily on providing inputs. These issues are those which will really change food supply all over the world, but they have been avoided by biotechnology companies because they demand long-term projects.

Due to its concerns with biosafety, the development of the agricultural biotechnology industry in Brazil follows a different route from that of other industrial sectors. **It must provide the consumer with accurate information about the safety of the products derived from this new technology, making reference to the most reliable scientific bases**. Three main strategic reasons present obstacles to such an approach:

1- Agricultural Biotechnology offers products to the market which incorporate radical modifications to those already available, thereby affecting consolidated markets, such as the seed and the pesticide markets.

2- Many governments, eager to promote the fast development of agrobiotechnology in their countries, have not established a specific legal and institutional framework to deal with biosafety issues in direct relation to biotechnology. Instead, the option has been to adapt previous legislation and infrastructure. This choice prevented an open and formal participation of the scientific academia in the decision-making process related to biosafety. Relevant scientific information is, however, now being offered to the public by organizations such as the International Food Information Council Foundation (IFIC) and the Council for Information in Biotechnology (CIB) in the US and other countries.

3- Other countries, particularly those within the European Union, were late to establish the institutional infrastructure and legal framework to deal with biosafety of GMOs and were apparently unprepared to take decisions when millions of tons of genetically modified grain arrived from the US, Argentina and Canada in the mid-nineties; and when, at the same time, the general public strongly rejected GMOs due to the influence of non-governmental organizations such as Greenpeace .

Although it is impossible to ignore the fact that market protection plays an important role in the decisions taken by the governments with respect to biotechnology and new technologies in general, we will omit this discussion from the present document and focus on the approach given to agricultural biotechnology in countries where it has developed rapidly, such as the US, in contrast to the situation in Europe. Finally, we will make a comparison with the situation in Brazil, with the objective of suggesting some elements to help the construction of a strategy to be followed in the development of this sector in Brazil.

BIOTECHNOLOGY AND BIOSAFETY– BACKGROUND

When genetic engineering began in the United States, in the early seventies, only a few dozen research groups were familiar with the technology, and there were only nine biotechnology companies operating in the whole country. Since then, the US have developed a strong biotechnology industry with financial operations exceeding ten billion dollars per year, predominantly in the area of human health (Biotech 91: A Changing Environment, Editor: Ernst Young). Seventy percent of these companies have their headquarters in the vicinities of the main health centers of the country: California, on the West Coast, and Boston/New York/Washington, on the East Coast. The investments in this area have, over the years, reached several dozen billion dollars, mainly from the private sector.

However, the advent of genetic engineering soon led society to develop a growing concern over the issues of biosafety and bioethics, both in relation to the activities and experiments developed in the laboratories, as well as in connection to possible environmental and ecological damage that might result from contact with transgenic organisms. Such worries derive from the fact that genetic engineering enables scientists to combine genes of phytogenetically distant and incompatible organisms within plant and animal genomes.

The immediate reaction from the American scientific community to these new possibilities was rather strong and led to the proposal, during the Azilomar conference, in San Diego, California, of a moratorium on the use of genetic engineering on organisms which are highly pathogenic to human beings. This decision was maintained until the National Institute of Health (NIH), at the request of the US Academy of Sciences, developed a set of biosafety guidelines for the use of genetic engineering in laboratories. These guidelines were soon adopted by countries all over the world, including Brazil and other Latin-American countries, satisfactorily guaranteeing laboratory safety.

Meanwhile, North American and European organizations established mechanisms to evaluate and manage the potential hazards involved in the release of transgenic organisms into the environment. As a follow-up, many countries, including Brazil, established biosafety rules through specific institutional infrastructure and legislation based on those guidelines, with the objective of regulating the use of genetic engineering and the release of genetically modified organisms into the environment. Other countries, such as, for example, the United States, preferred to adapt previously existing laws and institutions to deal with this new scientific issue. Some European countries and Japan, however, have not yet taken either step, and are still simply following Guidelines and Directives.

Although different countries use different approaches to evaluate the biosafety of genetically modified organisms, it is a fact that governmental authorities have been following and controlling biotechnology activities and their products worldwide for more than two decades, with very good results: **since the advent of this science, thirty years ago, there have been no records of any sort of environmental or human damage in the countries which obey the principles of evaluation and risk management supported by biosafety norms**. In fact, genetic engineering has produced some very important developments, particularly in relation to health and agriculture. Developing countries wishing to practice genetic engineering or to cooperate with leading industrialized countries need to adopt guidelines or specific laws dealing with biosafety as a requisite for receiving funds from international agencies. This requirement was also included in the Biological Diversity Convention (CBD), which led to the Cartagena Protocol, recently approved in Canada.

BIOSAFETY IN EUROPE AND IN THE UNITED STATES

There has been a very strong reaction, particularly in Europe, against human consumption of GMOs and derived products, as well as general concern about the potential harmful effects of such organisms on the environment. Such negative reactions result from campaigns mostly organized by non-governmental organizations. It is important, though not always easy, to distinguish genuine concerns over the possible effects of these plants on the environment from other initiatives which, despite seemingly ecological, are only interested in defending their market share. One important example to be considered is the possibility that the transfer of genes from transgenic plants to similar species could result in so-called "super weeds." Exploratory articles, published in scientific journals, deal with this issue as if developmental biology did not have rules to guarantee evolution and speciation. Species have proper mechanisms, developed over hundreds of millions of years, to 'watch over' their genome at molecular level so as to minimize the possibility of strange genes being introduced into their genetic heritage. The fact that one gene may be transferred from a transgenic plant to a wild species does not necessarily result in a "super weed." The fundamental question to be considered in relation to such transfer is: what would be the advantages in terms of adaptation and evolution?

Two cases that have not followed a sound scientific route are the GM potato expressing a gene that codifies a leguminous lectin, and the effect of a 'Bt' toxin in lepidopterans (Monarch butterfly). The reaction to the first case in the media was totally incompatible with the quality of that scientific experiment, which was later refuted by the British Academy of Sciences. The second case reports a preliminary experiment carried out in conditions different from those naturally found in a corn plantation. Later experiments reduced entirely the potential impact of the initial research. The scientific quality of such experiments is therefore highly questionable and appears to be typically opportunistic.

The effect of these experiments represented, however, a major disaster for agricultural biotechnology. Some European supermarket chains announced that they would no longer sell transgenic products after Dr. Pusztai's experiment with potatoes. Trials of transgenic plants were literally destroyed in Belgium, Brazil and the United Kingdom. France, Austria and Luxembourg demanded a moratorium on transgenic products and reserved for themselves the right to reject GMOs that had been previously approved for commercialization in Europe, such as corn and canola. After these experiments, no new transgenic products were added to the list of those approved by the European Union. On the other hand, those experiments had no effect in the United States.

There is more than one explanation for such different attitudes. In many European countries, the government's reputation for keeping the consumers well-informed is questionable since the outbreak of mad cow disease with its transmissibility to humans, the commercialization of meat contaminated with bacteria pathogenic to humans, and with dioxin, a carcinogenic substance, and the distribution of HIV contaminated blood. This questioning does not exist in the United States. The Americans have no strong reasons to distrust the USDA, the United States Department of Agriculture (FDA), the Food and Drug Administration (EPA) or the Center for Disease Control (CDC), the agencies in charge of controlling and approving GMOs.

The American Government has an additional interest in developing agricultural biotechnology, namely to seek competitiveness for their agricultural industry demanding subsidies. In Europe, on the other hand, agriculture receives subsidies from the government

and is currently going through a retraction process, depending more and more on the importation of products, such as soybeans, for instance. This whole scenario, as we can see, goes much beyond the discussion of whether or not GMOs are safe for human consumption; Europe and the US will be taking the matter before the WTO if the present retaliations concerning the importation of agricultural products continue.

BIOTECHNOLOGY AND BIOSAFETY IN BRAZIL

Brazil has developed scientific competence in practically all areas related to the state-of-the-art biotechnology, such as genetic engineering, genomics and proteomics. For decades, Brazil has demonstrated competence in plant genetics and genetic breeding for the tropics. The country is attractive, being one of the last ones where agriculture will develop substantially and being, at the same time, a mega-biodiversity subcontinent, where most genes needed for the development of modern biotechnology for the tropics can be found.

Compared to other countries, Brazil presents the greatest biodiversity of all, with around 250,000 known plant species, 30% of which are potentially edible. Throughout the centuries, human beings have used no more than 1% of these plants for consumption. In fact, the basis of human nutrition consists of only 0.2% of these species. The tropical rainforest – an area covering around 7% of the planet – contains, according to some studies, about 50% of the world's biodiversity. Other ecosystems and regions, such as the *caatinga* and the Atlantic forest, are equally important sources of genes.

In order to enable the safe development of biotechnology, Brazil has established, through specific legislation, biosafety rules to control the use of genetic engineering and the release of genetically modified organisms into the environment. That law created and established the obligation, competence and composition of the Biosafety National Technical Commission – CTNBio - as an integral part of the Ministry of Science and Technology. It is formed by representatives from the executive branch of government, from the biotechnological business sector and from consumers, as well as by a legally constituted agency for the protection of laborers' health. Finally, 18 scientists, selected specialists in every scientific field related to biotechnology, are members of the Commission. The CTNBio was created in June 1996 and has been acting in this area ever since. The Brazilian biosafety legal and institutional infrastructure, which deals with the control of the release of transgenic products into the environment, was thus created. Since then, CTNBio has operated through monthly meetings and produced most of the necessary biosafety rules for the enforcement of that law, acting with great timeliness and discernment. In addition, it has authorized, under those norms, over 1,000 field tests with transgenic plants, and has licensed several public and private laboratories and institutions to act in various areas of genetic engineering. Unless recognized and licensed by CTNBio, no laboratory dealing with genetic engineering may receive public funds for research.

The opposition to biotechnology in Brazil started in 1997. Greenpeace found other NGO partners, such as IDEC (Consumer Defense Institute), within the Governmental institutions (IBAMA – Brazilian Environment Institute – a branch of the Ministry of Environment), within the Judiciary system, not to mention the role played by the media, which rarely treats this issue without being pejorative and sensationalistic. It is not surprising, therefore, to see, in the state of Rio Grande do Sul, where the Labor Party rules similar

reactions to those observed in Europe, where experimental fields tests were destroyed and companies invaded.

As we have seen, Brazil has been facing a number of difficulties which have prevented, by legal action, the release of transgenic products in our country since 1998, as opposed to what happens in the United States, Canada, Australia, Argentina, India and China, all great exporters of commodities and strong competitors in the international market. Who will gain from the moratorium and the campaigns against biotechnology in Brazil? The pesticide industry and Brazil's competitors in the market of commodities. Who is to lose? Brazil alone.

THE LEGAL INTELLECTUAL PROPERTY RIGHTS BIOTECHNOLOGY CONTEXT IN BRAZIL

THE BRAZILIAN VARIETY LAW

Brazil established a legislation to protect breeders' rights, (Plant Variety Protection Law #9456/97) which follows almost entirely the 1978 Act of UPOV - International Convention for the Protection of New Varieties of Plants. Three Articles of UPOV 1978 are cited below for reference:

Article 1: Purpose: to recognize and to ensure to the breeder of a new plant variety a right ....

Article 2: Forms of protection: a title of protection or a patent - one of the two.

Article 5: Scope of protection: vegetative propagating materials ..., authorization not required for the utilization of the variety as an initial source of variation for the purpose of creating a new variety.

We have chosen in the Brazilian legislation not to extend the scope of protection to the marketed product. So the scope of protection falls on the propagating material only. Thus, according to the Brazilian legislation, the plant variety protection certificate is the sole form of protection right for plant varieties, that may inhibit the free utilization of plants or of their reproductive or vegetative propagating material (Article 2). Equally, according to Article 8, the protection covers the reproductive or vegetative propagating material of the entire plant. In Article 10, the Brazilian legislation establishes that the right to property of the plant variety shall not be deemed infringed by whoever:

(i) stores and plant seeds for private use on his premises or on the premises of third parties whereof he holds possession;

(ii) uses or sells as food or raw material the product obtained from the planting thereof, except for purposes of reproduction; and

(iii) utilizes the plant variety as a source of variation in genetic improvement or scientific research.

These principles fall entirely within UPOV 1978 Act and underpin the right of the farmers to use their own seed and the right of the breeder to use a protected variety to breed and commercialize a new variety without any restriction except, as we shall see, when the product obtained by the breeder is an essentially derived variety. The Brazilian legislation adopted the concept of an essentially derived variety from the UPOV 1991 Act, assuring the right of the breeder of an initial protected variety, where this variety is used by a second breeder to obtain a variety which is essentially derived from the initial protected variety. The Brazilian legislation concept of an essentially derived variety does not follow entirely that of the UPOV 1991 Act because it does not include Article 14(5)(c) of the Act as will be demonstrated: The definition of an essential derived variety in the Brazilian legislation is stated in Article 3:

- Article 3(ix): A plant variety is essentially derived from another plant variety provided that it is:

(a) predominantly derived from the initial plant variety or from another essentially derived variety, without losing the ability to exhibit the essential characteristics resulting from the genotype or from the combination of genotypes of the plant variety from which it derived, except regarding the differences resulting from the derivation.

(b) clearly distinct from the plant variety from which it derived, by a minimum margin of descriptors, in accordance with criteria established by the competent agency.

Thus, although Article 10 (iii) of the Brazilian legislation permits the utilization of a protected variety as source of variation in genetic improvement or in scientific research, if the protected plant variety is repeatedly used in this process of genetic improvement, and/or if the resultant product is an essentially derived variety from a protected plant variety, the commercial exploitation thereof shall be conditional on authorization from the holder of protection of the initial protected variety (Article 10, paragraph 2, ii).

So the Brazilian framework of the variety law combines principles of UPOV 1978 Act and 1991 Act based upon the concept that a law must not only be fair, but must be enforceable. In addition, it is understandable that any country, particularly if it is a developing country, when establishing its legislation, takes into consideration what is best for the country, in terms of technology development and the need for investment in this new technology from foreign countries as well as from the "domestic" industry. Three main factors were the basis for designing the law in accordance to the concepts cited above, and as opposed to the patenting of plants:

(1) Brazil is a very large country with millions of agricultural properties, the majority of which are very small. The enforcement feasibility of a plant variety protection right which would extend beyond the reproductive or vegetative propagating material was considered to be extremely difficult.

(2) Essentially derived plant varieties would be the fastest and easiest way to combine the best genes available from genetic engineering with the best genetics developed by national and regional plant breeding programs, such as the ones produced by the public and private institutions which have been established in Brazil for decades.

(3) A patent law which allows for patenting of biotechnology products introduced in conjunction with a plant variety protection law is a big challenge, but will favor the best business environment and competitive open trade for gene companies and plant breeding companies, offering the possibility for the same patented gene to be introduced in several protected varieties, as well as transformation of the same protected variety with several patented genes.

It was decided to adopt the principle of essentially derived varieties (EDV) from the 1991 Act of the UPOV Convention, because EDV obtained by back-crossing transformed plant elite events (plant elite events are plants modified successfully by genetic engineering in the sense that they express adequately and stably the gene of interest) to commercially adapted varieties in the process of breeding genetically engineered varieties, has important advantages:

1. it provides excellent biosafety confinement conditions to prevent the unintended release of engineered genes into the environment because the introgression of the genes can be done in the greenhouse;

2. it provides for a very fast and easy introduction of engineered genes of interest in a number of elite, commercially well adapted varieties;

3. lengthy genotype/environment field testing is not required since the resulting essentially derived varieties are, as the name indicates, very much like the elite commercially adapted varieties previously selected for the introgression of the engineered genes.

THE BRAZILIAN PATENT LAW

Brazil adopted a new Patent Law # 9279/96 in 1996, a year before the variety law described above, “stimulated” by the negotiations of the WTO/TRIPS Agreements. Before this patent law was enacted, the Brazilian patent legislation of 1973 did not, of course, consider the possibility of patenting living organisms. Biotechnology began in 1973, when Herbert Boyer, in California, expressed an insulin-coding gene from humans in *E.coli,* an intestinal bacteria. So the Brazilian Patent Law was obsolete the same year it was enacted. In addition to this circumstance, the Brazilian Patent Law of 1973 was very restrictive, prohibiting patenting of pharmaceuticals and other processes and products, in conflict with the WTO/TRIPS Agreement. It was not surprising then that the performance of Brazilian residents in terms of patenting abroad was very modest during the period preceding the new law as compared to other developing countries:

International patents granted by USPTO compared to patents granted to Brazilian Country Residents (1980 - 1995)[*]

BRAZIL	475
SOUTH KOREA	3473
INDIA	406
MEXICO	1139
TAIWAN, PROVINCE OF CHINA	7608

New statistics are more positive following the introduction of the new Law, although it is recognized that the Law alone will not stimulate the general attitude towards patenting . An innovation Law is in Congress to complement the scenario. The fact is that, although the number of patents deposited in Brazil in the gene area soared in 2001 to 7,850, only 8% of these patents are from Brazilian residents. However institutions such as EMBRAPA that historically deposited some 21 patents until 1995 deposited 144 in the last 6 years after the new patent law.

The new Brazilian Patent Law deals with the biotechnology issue in Article 18: Are not patentable: the whole or part of living organisms except transgenic microorganisms which satisfy the general principles of patentability. Article 18 has a definition of transgenic microorganisms: **organisms, not the whole or part of plants or animals which, due to direct human intervention, express in its genetic composition a characteristic normally not expressed under natural conditions.** So the Brazilian Patent Law will not allow for patenting of genetically modified plants or animals, but biotechnology processes are patentable.

Despite the legal biosafety problems which inhibit biotechnology development in Brazil, following the adoption of the patent and plant variety protection Laws, several foreign public institutions, non-profit organizations and commercial private companies, are in the process of negotiating cooperative agreements in the area of science and technology, technology transfer and transfer of patented genes to EMBRAPA protected varieties. The challenge, as mentioned before, is to establish a coexistence of the right under the Variety Law, which protects a variety, with the patent right, which protects products and processes, when both are ultimately incorporated in the seed of a protected variety.

[*] Eduardo Albuquerque – Domestic Patents of Brazilian Residents (1980-1995) : Statistical Description, Comparisons Between INPI, and USPTO Data. An Introductory Analysis (SPRU-SUSSEX, TAGS Program and IE/UFRJ)

THE BRAZILIAN VAREITY AND PATENT LAWS – ARE THEY COMPATIBLE?

The experience of patent laws with variety laws based on the UPOV 1978 Act are somewhat limited worldwide because:

1 – many countries adopted the UPOV 1991 Act, which poses less conflict with patent laws,
2 – many agricultural countries have not revised their patent laws to include patenting of biotechnology products and processes,
3 – some developing countries, which are important grain producers, have been slow to adopt biotechnology.

The particular case described in this paper is restricted to experience gained in Brazil, particularly by EMBRAPA, where negotiations with large multi-national companies increased substantially after the three laws, which are the object of this paper, were enacted in the mid-nineties. So we will restrict our position to the recent experience of EMBRAPA in a soybean case study.

Over many decades, Brazil has developed considerable competence in the area of plant breeding, particularly for tropical conditions. As a consequence, the participation of EMBRAPA in the seed business scenario is particularly relevant:

SEED PRODUCTION IN BRAZIL: EMBRAPA VARIETIES VS
TOTAL VARIETIES. YEAR AVERAGE DURING 1995 TO 1997 – IN TONS *

CROP	TOTAL	EMBRAPA	%
	(A)	(B)	B/A
COTTON	27.487	2.983	10,9
RICE	96.480	137.091	69,8
BEANS	59.012	25.452	43,1
POTATO	136.770	2.040	1,5
FORAGE	247.776	170.441	68,8
CORN	325.581	72.965	22,4
SOYBEAN	1.716.886	865.770	50,4
WHEAT	449.979	225.275	50,1
TOTAL	3.159.971	1.502.017	47,5

* Source : EMBRAPA

The number of protected EMBRAPA varieties increased substantially, particularly after the new Variety Law was adopted. EMBRAPA operates many of its plant breeding programs, including, in particular, the program for soybean, in partnership with non-profit foundations located in several states. These foundations not only perform the regional field trials, but also coordinate seed certification production programs in a similar way to the American Crop Improvement Association in the US. The tendency in Brazil to date has been that EMBRAPA is approached by gene companies with patented biotechnological processes, such as the processes which make plants resistant to herbicides or insects. The process is incorporated into plants (plant elite events) by transformation of the plants with genetic “constructs” which contain the genes needed for the process to take place. The consequence is that the process is patented, (it must be patented in Brazil) and the genes in the construct

cannot be used, as these are elements which determine the functioning of the process. Breeding companies use these plant elite events and breed varieties which are protected by the Variety Law in Brazil. In consequence, seed companies must pay royalties to the breeding company and a technology fee for the owner patented technology and then add a certain margin of profit on top of the seed cost. To build a scenario which brings together all these three stakeholders in the development of biotechnology, (genetically modified) products, breeding (variety development) programs and finally the seed industry, we have constructed the following simple matrix:

Soybean Case Study

This is an EMBRAPA matrix system to describe the soybeans business stakeholders and their expectations in relation to the marketing of genetically modified, glyphosate resistant soybean cultivars

INSTITUTIONS	SC&T	SEED	GRAIN
GENE COMPANY	TF	-	-
PLANT BREEDING COMPANY	-	CR	-
SEED COMPANY	-	-	AV+P

TF=TECHNOLOGY FEE
CR=VARIETY ROYALTY
AV=AGGREGATE VALUE PLUS PROFIT

Considering that each stakeholder is one specialized institution, some conditions are needed in order for the matrix to operate. If these are not met, business will not develop and all stakeholders will lose. In the specific case study:

1. the gene company is a multinational company which provided the patented technology as an plant elite event,
2. EMBRAPA is the breeding company generating the protected variety,
3. private seed companies apply to produce seed under contract to EMBRAPA which offers Foundation Seed according to rules described in public bids. Seed companies then market the seed to farmers.

The first step is that the gene company and the breeding company come to a contractual agreement establishing the rules and which abides by both Brazilian Laws: the Patent and Variety Laws. There are rules in this agreement, for instance, which assure the right of farmers to save their seed. It is impossible in Brazil to take a farmer to Court for saving seed. The gene company and the breeding company negotiate freely and independently with the seed producers for both the royalty and the technology fee. Common sense dictates that the limits for charging seed producers will be such that the product comes to the market and is able to compete with other technologies. This particular contract does not touch the breeder's exemption principle because it is not part of the process of breeding

varieties which will be dealt elsewhere in this paper. We can distinguish three general conditions for the matrix to operate:

(1) gene companies and plant breeding companies must devote the best efforts to enforce both legislations in a harmonized and cooperative way, e.g. the enforcement of the patent law cannot ignore the limitations of the Plant Variety Protection Law, and vice versa;

(2) plant breeding companies will be in the best position to negotiate with gene companies if they own the exclusive rights for protected varieties, particularly if the final product is an essentially derived variety;

(3) all three stakeholders must fully exercise the "open architecture" (non-exclusive) principle and, as far as possible, concentrate on the roles for which they have most expertise, to avoid unnecessary duplication of efforts. The approach should be such that the new technology develops at a rate that does not disturb the international competitiveness of the seed and grain business.

It is hard to predict if this system will operate in Brazil because, unfortunately, as previously mentioned, GMOs have been prohibited since 1998. However, EMBRAPA has identified some pitfalls in the matrix system to be avoided for Brazil:

1. several patented gene technologies were deposited many years ago and, therefore, only have a few years of effective patent rights remaining before they enter the public domain;

2. grain producers have the tendency to save and replant seed continuously, which, although not illegal in Brazil, reduces the rate of return for all three stakeholders;

3. essentially derived varieties, although being the fastest and easiest way to introduce the gene technology into adapted genotypes, are limited by the traits exhibited by the initial variety from which the essentially derived varieties originate;

4. plant breeding/genetics is of strategic importance for Brazil. The stakeholders must operate within the relevant laws in a way that ensures sustainable competence in this area, and results in the gradual build up of competence in the gene technology field in the country, taking into account the interests of the public and industry.

The last aspect concerns an elegant way of suggesting to gene companies that they should not try to play all the roles in the matrix. This is dealt with by laws on monopolistic behavior to prevent practices which would be detrimental for the adoption of a new technology. When one single company covers all the three roles, the control of the royalties and technology fee comes under a single control and the tendency is for the seed price to become high. We have the feeling that the technology could be adopted much faster worldwide if this tendency was not exercised by the main life science companies, which are offering the first products. We will present two exercises to demonstrate this possibility. Estimates made in 1997 predicted that the replacement of pesticides by GMOs would cut 1/3 of the insect control of selected crops. In addition, experts had predicted that the size of the genetically modified market would be around US$1.3 billion by 1998.

INSECTS CONTROL COSTS AND VALUE OF REPLACEMENT BY TRANSGENICS

CROP	INSECT CONTROL COSTS	TRANSGENIC COSTS
COTTON	1,870	1,161
CORN/MAIZE	620	158
RICE	1,190	422
FRUIT&VEGETABLES	2,465	891
OTHER	1,965	*
TOTAL (US$ million)	8,110	2,632

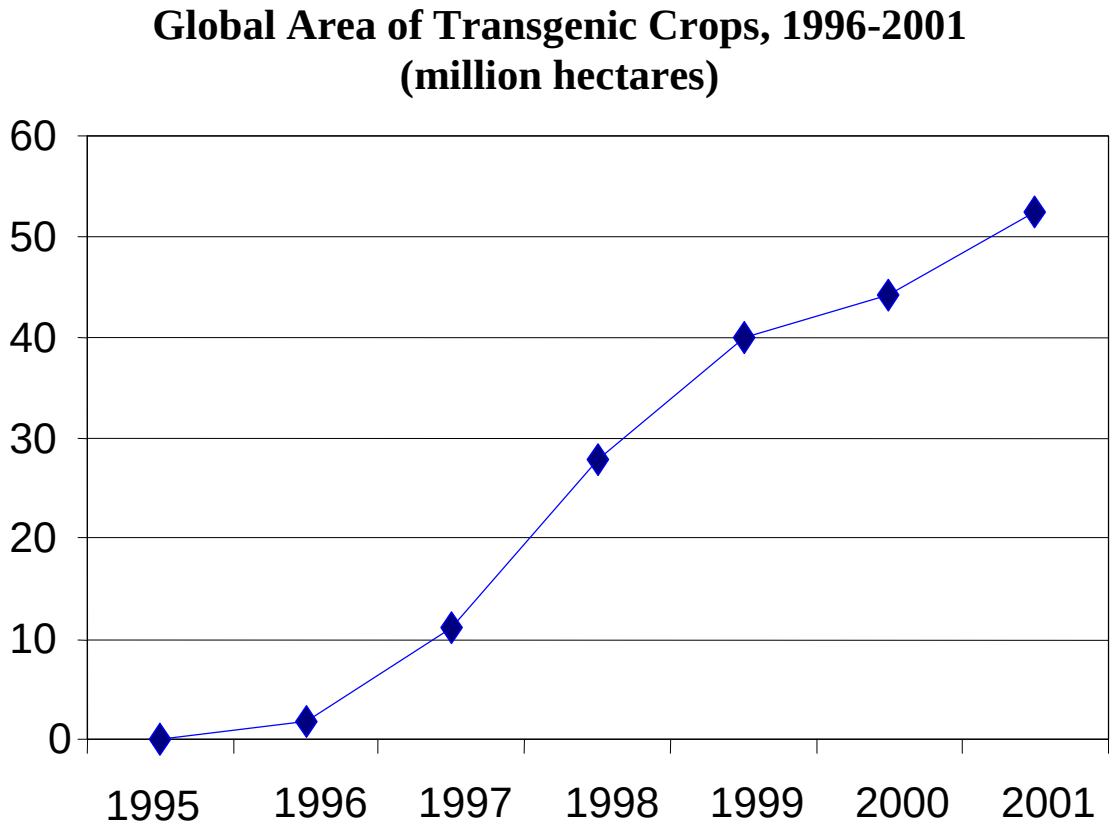
Modified and extended after James (1991) by Krattiger (1997).* Cannot be estimated because are related to many different species

If we use updated figures corresponding to the area cultivated with GMOs, as shown in the figure below, it is possible to estimate the value of the GMO market today.

ESTIMATED VALUE OF THE GENETICALLY MODIFIED CROP MARKET

YEAR	US$ MILLLION
1995	75
1996	235
1997	670
1998	1,350

Source: Clive James, 1998



A simple calculation reveals that the area cultivated with GMOs doubled from 1998 to 2001. Thus, the updated estimate of the size of the market will be 1.35 X 2 = US$2.7 billion, 50% of which can be estimated to be 'Bt' varieties (varieties containing the 'Bt' toxin which confers insect resistance). This market corresponds to seed incorporating the new technology. If we adopt this approach, the seed cost of Bt varieties, incorporating resistance to insects, will be around 50% of the predicted replacement cost of insecticides by this kind of GMO, which was estimated in 1997 to cut 1/3 of the insect control of selected crops (50% of US$3.0 billion). This explains why, worldwide, the adoption of cotton Bt varieties is moving so fast and that of corn Bt varieties is not. Corn farmers are not stimulated to pay more for the new technology seed, because insects harmful to corn cannot be predicted to occur every year.

A more general exercise starts with the area cultivated with GMOs today, which is, in fact, around 60 million Ha. Average grain production is estimated at 3 Tons/Ha and the average value is estimated at US$100/Ton, thus the value of the grain market will be approximately US$18 billion. Brazil imports US$ 2.5 billion worth of pesticides, which is applied to 40 million Ha for the control of pests and weeds. Thus, pesticides cost US$62.5/Ha for Brazilian agriculture. If we extrapolate this for the 60 million Ha of GMOs cultivated worldwide, the cost of pesticides without the new technology amounts to US$3.75 billion. If the adoption of the technology is stimulated by a reduction of pesticides of the order of 30% of this cost, this reduction corresponds to US$1.125 billion, which is close to the figures available. The question then is how much the farmer is paying for the seed which incorporates the new technology? The profit margin for farmers is narrow, between 10 and 20%. So, if we estimate the size of the grain GMO market to be US$18 billion, 10 to 20% corresponds to US$1.8 to 3.6 billion. A reduction of US$1.125 billion may correspond to a profit increment of 31.25 to 62.5%; however, this figure for cost reduction is below the predicted GMO seed market estimated to be

US$2.7 billion. These are just exercises. Of course, if the technology is being adopted as shown above, it is because other benefits are incorporated with the pesticide reduction costs. No-tillage, for instance, associated with herbicide resistance, is extremely profitable to the soybean farmers and the financial return goes much beyond the herbicide substitution. The final question is: Is the adoption fast enough? What could be done in countries like Brazil to reverse the ban? Perhaps reduce seed costs.

IS THE BREEDERS EXEMPTION PRINCIPLE COMPATIBLE WITH THE PATENT SYSTEM IN PLANTS ?

There is no answer, or there will be no consensus in relation to this question, unless we exercise the best common sense by assuming that it is vital to have co-existence of the two principles for the adoption of agricultural biotechnology. If we have the Patent and Variety Laws in effect in Brazil, it is because we are convinced that this is the best IPR approach for plants. Legislators considered alternatives, but the option was to establish the two systems for the reasons already mentioned. Let us explore how these two basic concepts could be made compatible. We mentioned before how a breeding company, such as EMBRAPA, agreed with a gene company to introduce herbicide resistance into its soybean varieties. The question, now, is what will be the right of other breeders to use the protected variety of EMBRAPA which has the gene for herbicide resistance incorporated in its genome? According to the Variety Law in Brazil, the breeder is free to breed and commericalize a new variety unless it is an essentially derived variety. It is understood that breeders cannot use the gene, or probes of the patented gene, or the promoter in the construct, to speed up their breeding program. However, if a breeder has no interest in herbicide resistance, it would be unfair to deny the breeder's exemption in relation to that variety because even if the gene is patented, the whole genome of the soybean plant is not. According to my view, if the breeder uses that herbicide resistant variety to breed another soybean variety, without the herbicide resistance trait, and consequently for that reason, does not make use of the gene or parts of the gene as probes for their breeding program, the Variety Law in Brazil would assure the breeder this right. Again, a law must be fair and enforceable. It is not fair to prevent the breeder from using all other parts of the soybean genome for a breeding program because a single gene of this genome is patented. The gene itself, however, cannot be used. This principle is easily enforceable when the breeders presents their new variety to be protected.

We have seen, therefore, that Brazil has the opportunities, the competence and the legal and institutional infrastructure that are necessary for the development of agricultural biotechnology. This new context has led EMBRAPA, among other institutions, to be approached repeatedly by genetic engineering companies from all over the world, eager to introduce genes of agricultural interest into the best genetics (developed over the past 25 years) for the tropics.

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* The author is an Agricultural Engineer graduated from the National Agronomy College in 1962, MSc. in Seed Technology from the Mississippi State University in 1970, Ph.D. in Plant Physiology from the University of California, Davis, in 1977, and Post-Doctorate in Plant Molecular Biology from the University of California, Los Angeles. He was the President of CTNBio from 1996 to 1999, and was elected President of the Brazilian Biotechnology Society in 1999.