

*PLANT BREEDER,s RIGHTS AND  
PATENT LAWS -Are they compatible ?*

Luiz Antonio Barreto de Castro - PhD  
CENARGEN- Chief General

*International Convention For The Protection Of New  
Varieties Of Plants As Revised At Geneva On  
October 23, 1978:*

- ARTICLE 1: PURPOSE: RECOGNIZE AND TO ENSURE TO THE BREEDER OF A NEW PLANT VARIETY A RIGHT ...CHOOSE THE MEMBER STATE OF THE UNION IN WHICH HE WISHES TO FILE HIS FIRST APPLICATION FOR PROTECTION.
- ARTICLE 2: FORMS OF PROTECTION: A TITLE OF PROTECTION OR A PATENT - ONE OF THE TWO
- ARTICLE 5: SCOPE OF PROTECTION: VEGETATIVE PROPAGATING MATERIALS..., OR UNDER ITS OWN LAW EXTEND IT TO THE MARKETED PRODUCT. AUTHORIZATION NOT REQUIRED FOR THE UTILIZATION OF THE VARIETY AS AN INITIAL SOURCE OF VARIATION FOR THE PURPOSE OF CREATING A NEW VARIETY

*The Brazilian Legislation: Plant Variety  
Protection Law # 9456/97*

- ARTICLE 2: 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 REPRODUCTION OR VEGETATIVE MULTIPLICATION PARTS ...THE PROTECTION SHALL FALL UPON THE REPRODUCTION OR VEGETATIVE MULTIPLICATION MATERIAL OF THE ENTIRE PLANT (ARTICLE 8)

*The Brazilian Legislation: Plant Variety  
Protection Law # 9456/97*

- ARTICLE 10: THE RIGHT TO PROPERTY OF THE PLANT VARIETY SHALL NOT BE DEEMED INFRINGED BY WHOEVER:
  - I - STORES AND PLANT SEEDS FOR PRIVATE USE IN HIS PREMISES OR IN 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
  - III - UTILIZES THE PLANT VARIETY AS SOURCE OF VARIETY IN GENETIC IMPROVEMENT OR SCIENTIFIC RESEARCH

*The Brazilian Legislation: Plant Variety Protection  
Law # 9456/97 - The Concept Of Essentially Derived  
Variety*

- ALTHOUGH ARTICLE 10 (III) PERMITS THE UTILIZATION OF A PROTECTED VARIETY AS SOURCE OF VARIETY 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 FINAL PRODUCT IS AN ESSENTIALLY DERIVED VARIETY FROM A PROTECTED PLANT VARIETY, THE COMMERCIAL EXPLOITATION THERE OFF SHALL BE CONDITIONED TO THE AUTHORIZATION FROM THE HOLDER OF PROTECTION OF THE INITIAL PROTECTED PLANT VARIETY { ARTICLE 10, PARAGRAPH 2, II }

*International Convention For The Protection Of New  
Varieties Of Plants As Revised At Geneva On  
March 9, 1991*

- ARTICLE 14, (5) THE CONCEPT OF ESSENTIALLY DERIVED VARIETY
- A VARIETY SHALL BE DEEMED TO BE ESSENTIALLY DERIVED FROM ANOTHER VARIETY IF:  
IT IS PREDOMINANTLY DERIVED FROM THE INITIAL VARIETY (ARTICLE 14, (5)(B)(I)), AND EXCEPT FOR THE DIFFERENCES WHICH RESULT FROM THE ACT OF DERIVATION, IT CONFORMS TO THE INITIAL VARIETY IN THE EXPRESSION OF THE ESSENTIAL CHARACTERISTICS THAT RESULT FROM THE GENOTYPE OR COMBINATION OF GENOTYPES OF THE INITIAL VARIETY (ARTICLE 14,(5)(B)(III)).

**The Brazilian Legislation: Plant Variety Protection  
Law # 9456/97 - The Concept Of Essentially Derived  
Variety**

- ARTICLE 3, (IX): A PLANT VARIETY IS ESSENTIALLY DERIVED FROM ANOTHER PLANT VARIETY PROVIDED THAT, CUMULATIVELY, 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

**The Brazilian Legislation: Plant Variety Protection  
Law # 9456/97**

- THE BRAZILIAN LEGAL FRAMEWORK COMBINES THEN PRINCIPLES AND CONCEPTS OF UPOV 1978 AND 1991 TO HAVE A LAW THAT IS FAIR, ENFORCEABLE AND WHICH PROVIDES THE BEST OPPORTUNITIES TO INTRODUCE INTO THE BRAZILIAN GENETICS THE ADVANCES OF AGRICULTURAL BIOTECHNOLOGY. SOME PARTICULAR CIRCUMSTANCES WERE CONSIDERED:

**The Brazilian Legislation: Plant Variety Protection  
Law # 9456/97**

- 1)- BRAZIL IS A VERY LARGE COUNTRY WITH HUNDREDS OF THOUSANDS OF AGRICULTURAL PROPERTIES, THE MAJORITY OF WHICH BEING VERY SMALL IN SIZE. THE ENFORCEMENT FEASIBILITY OF A PLANT VARIETY PROTECTION LAW WHICH WOULD EXTEND BEYOND THE REPRODUCTIVE OR VEGETATIVE PROPAGATING MATERIAL WAS CONSIDERED TO BE EXTREMELY DIFFICULT
- 2) A PATENT LAW COMBINED TO A PLANT VARIETY PROTECTION LAW FAVOUR THE BEST BUSINESS AMBIENT AND COMPETITIVE OPEN ARCHITECTURE FOR GENE COMPANIES AND PLANT BREEDING COMPANIES TO INTERACT. THE SAME PATENTED GENE PROCESS CAN BE INTRODUCED IN SEVERAL PROTECTED VARIETIES AS WELL AS THE TRANSFORMATION OF THE SAME PROTECTED VARIETY WITH MORE THAN ONE PATENTED GENE PROCESS.

**Seed Productions in Brazil  
EMBRAPA Cultivars vs Total  
1995 - 1997 tons**

CROP	TOTAL (A)	EMBRAPA (B)	% B/A
COTTON	27.487	2.983	10,9
RICE	196.480	137.091	69,8
BEANS	59.012	26.462	43,1
POTATO	136.770	2.040	1,5
FORAGE	247.776	170.441	68,8
CORN	326.681	72.966	22,4
SOYBEAN	1.716.886	866.770	50,4
WHEAT	449.979	226.276	50,1
TOTAL	3.169.971	1.502.017	47,5

(EMBRAPA distributes actually around 30 species and 140 cultivars)

**Agricultural Varieties Protection  
20/09/02**

Species	Number of entries	In Analysis	Status	
			Provisional Certificate	Certificate
Cotton	36	2	12	17
Rice	31	1	3	25
Potato	44	2	7	22
Sugar cane	41	0	5	36
Corn	22	1	1	20
Soybean	217	6	13	170
Sorghum	8	0	3	5
Wheat	39	2	7	32
TOTAL	438	14	51	327

**Embrapa Cultivars Protected by the  
Ministry of Agriculture Under the Cultivar  
Law 9456/97**

CROP	Deposits	Granted
SOYBEAN	76	57
WHEAT	12	8
RICE	18	11
CORN	24	2
COTTON	15	5
SORGHUM	9	3
TOTAL	154	86

*In The Process Of Breeding Genetically Engineered Varieties, Essentially Derived Varieties Obtained By Back Crossing Genetically Modified Plants To Commercial Adapted Varieties Has The Following Advantages:*

- 1- IT PROVIDES EXCELLENT BIOSAFETY CONFINEMENT CONDITIONS TO PREVENT THE UNINTENDED RELEASE OF ENGINEERED GENES INTO THE ENVIRONMENT SINCE THE INTROGRESSION OF THE GENES CAN USE GREENHOUSES
- 2- ESSENTIALLY DERIVED PLANT VARIETIES IS THE FASTEST AND EASIEST WAY TO COMBINE THE BEST GENES AVAILABLE FROM GENETIC ENGINEERING WITH THE BEST VARIETIES COMING FROM NATIONAL PLANT BREEDING PROGRAMS.
- 3- LENGTHY GENOTYPE/AMBIENT FIELD TESTING ARE NOT REQUIRED SINCE THE RESULTING ESSENTIALLY DERIVED VARIETIES ARE AS THE NAME INDICATES VERY MUCH LIKE THE ELITE COMMERCIALY ADAPTED VARIETIES PREVIOUSLY SELECTED FOR THE INTROGRESSION OF THE ENGINEERED GENES

## **The New Patent Law # 9279/96 Biotechnology Issues**

### ARTICLE 18: ARE NOT PATENTABLE

- ✓ The whole or part of living organisms except transgenic microorganisms which satisfy the general principles of patentability
- ✓ Transgenics microorganisms are organisms, not the whole or part of plants or animals which express due to direct human intervention in its genetic composition a characteristic normally not expressed under natural conditions

### **Patents Granted by USPTO to Country Residents (1980 - 1995)**

COUNTRY	# PATENTS
BRAZIL	475
SOUTH KOREA	3473
INDIA	406
MEXICO	1139
TAIWAN, Province of China	7608

### **Foreign Patent Application in Brazil (\*)**

PERIOD	APPLICATIONS
1992 - 1995	8.550
1996 - 1998	12.335

(\*) by Dannemann Siemsen Bigler & Ipanema Moreira  
(\*\*) In 2001 - 7850 deposits only in the gene area 8% by brazilians -source INPI

### **Patent Applications by EMBRAPA 1984 - 2002**

YEAR	APPLICATIONS
1984/95	21
1996/98	43
1999/01	67
2002	30
TOTAL	166

\* Fifty deposits in biology thirty five by CENARGEN

## **The Bayh - Dole Act**

### **A GUIDE TO THE LAW AND IMPLEMENTING REGULATIONS**

#### Abstract

Modern day technology transfer from universities to industry can be dated to the 1980 enactment of P.L. 96-517, the Bayh-Dole Act, and amendments include in P.L.98-620, passed in 1984. This paper provides a summary of the legislation and the implementing regulations, and describes some of the results to date.

*The Compatibility of the Cultivar and the Patent Laws Condition The Development of Biotechnology in Brazil*

GENE AND PLANT BREEDING COMPANIES MUST DEVOTE THE BEST EFFORTS TO ENFORCE BOTH LEGISLATIONS IN A CONCERTED WAY, e.g. THE ENFORCEMENT OF THE PATENT LAW CAN NOT DISCONSIDER THE RIGHTS OF THE PLANT VARIETY PROTECTION LAW AND VICE VERSA. GOOD BUSINESS FAVORS COMPATIBILITY OF THE LAWS

*An Example of Pitfall Related to The Cultivar Legal System , Which Affects the Development of Biotechnology in Brazil*

FARMERS HAVE THE HABIT TO KEEP THEIR SEEDS TO PLANT OVER AND OVER , WHICH IS NOT ILLEGAL IN BRAZIL ALTHOUGH REDUCES THE RATE OF RETURN FOR ALL THE THREE ACTORS.

TWO WAYS TO REVERT THIS TENDENCY :  
LOWER SEED COSTS AND EDUCATION

*Rate Of Seed Utilization (RSU) In Brazil For The Main Agricultural Species*

SPECIES	PRODUCTION	RSU
	1997-1998 (t)	(%)
COTTON	6,616	78
RICE	119,269	60
DRY BEAN	17,336	36
CORN	136,993	72
SOYBEAN	867,728	79
WHEAT	203,410	95

Source: ABRAEM

*Restrictions For The Use By the Breeder , of Patented Gene Processes \**

- THE BREEDER'S RIGHT SHALL NOT EXTEND TO:
    - I - THE DIRECT USE OF A PATENETED GENE RELATED TO A PATENETED GENE PROCESS TO PRODUCE A NEW VARIETY EVEN IF NOT AN ESSENTIALLY DERIVED VARIETY , TO BE PROTECTED CARRYING THE PATENETED TRAIT RELATED TO THE PROCESS WITHOUT THE CONSENT OF THE PATENT HOLDER
    - II - THE USE OF A VARIETY PROTECTED OR NOT WHICH HAS IN ITS GENOME A GENE RELATED TO A PATENETED GENE PROCESS TO OBTAIN BY WHATEVER METHOD A NEW VARIETY ESSENTIALLY DERIVED OR NOT ,WITHOUT THE CONSENT OF THE PATENT HOLDER
- \* Not in the law : author,s interpretation

*Breeders Right To Use a Plant Variety, Which Has in its Genome a Gene Related to a Patented Process \**

A plant breeder is free to use a plant variety which includes in its genome a gene related to a patented gene process , if cumulatively: the final product of the breeding process is not related to the patented gene process and the gene is not used directly in the breeding process

\* Not in the law : author,s interpretation

**GENES ARE STRUCTURED IN MODULES WHICH ARE INTERCHANGEABLE**

Transcriptional regulator    Coding region    3' Region



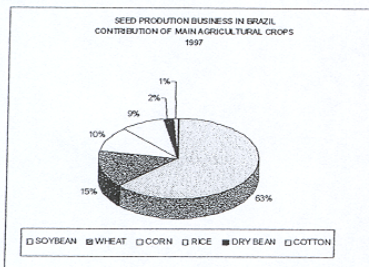

BRAZIL DEVELOPED AFTER MANY DECADES CONSIDERABLE COMPETENCE IN THE AREA OF PLANT BREEDING PARTICULARLY FOR TROPICAL CONDITIONS. AFTER THE PATENT AND PLANT VARIETY PROTECTION LAWS, SEVERAL PUBLIC INSTITUTIONS, NON PROFIT ORGANIZATIONS, AND COMMERCIAL GENE COMPANIES ARE NEGOTIATING COOPERATIVE AGREEMENTS IN THE AREA OF BIOTECHNOLOGY TO TRANSFER PATENTED GENES PROCESSES TO EMBRAPA

AMONG THEM CIAT, CSIRO, INIBAP, CORNELL FOUNDATION, BASF, SYNGENTA, MONSANTO, DUPONT AND AVENTIS, HAVE AGREEMENTS NEGOTIATED OR BEING ANALYSED BY THE EMBRAPA IPR SECRETARIAT. TO EXEMPLIFY HOW THIS IS BEING DONE LETS EXAMINE SOYBEAN AS A CASE STUDY

### WORLD SOYBEAN PRODUCTION 2002/03\*

COUNTRY	million tons
USA	72.2
BRAZIL	48.0
ARGENTINA	31.0
CHINA	15.6
OTHER	18.0
TOTAL	184.8

\* Source USDA



EMBRAPA OPERATES ITS SOYBEAN BREEDING PROGRAMS IN PARTNERSHIP WITH STATE FOUNDATIONS. THESE FOUNDATIONS NOT ONLY PERFORM THE REGIONAL FIELD TRIALS BUT ALSO COORDINATE SEED CERTIFICATION PRODUCTION PROGRAMS IN WAY SIMILAR TO THE AMERICAN CROP IMPROVEMENT ASSOCIATION IN THE US

### Soybean Case Study

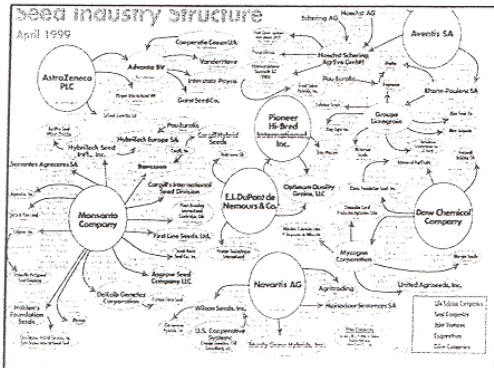
AN EMBRAPA MATRIX SYSTEM FOR THE TRANSGENIC SOYBEANS BUSINESS

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

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

PLANT BREEDING/GENETICS AND THE SEED INDUSTRY ARE STRATEGIC FOR AGRICULTURAL DEVELOPMENT IN BRAZIL. THE PUBLIC AND PRIVATE BIOTECHNOLOGY STAKEHOLDERS MUST EXERCISE THEIR ACTIVITIES IN A WAY THAT ASSURES LONG TERM FINANCIAL SUSTAINABILITY OF THESE AREAS AND THE GRADUAL BUILD UP OF COMPETENCE IN THE GENE TECHNOLOGY FIELD, TO SATISFY PUBLIC PERCEPTION AND INDUSTRIAL EXPECTATIONS

GENE COMPANIES, BREEDING COMPANIES AND SEED COMPANIES MUST COME TO AGREEMENTS SUCH THAT ALLOW FOR THESE ACTORS TO EXERCISE THE ROLES THEY HAVE THE BEST EXPERTISE. THIS REDUCES APPARENT MONOPOLISTIC TENDENCIES AND ALLOWS FOR THE STAKEHOLDERS TO PROPOSE THE NEW TECHNOLOGY AT A RATE THAT DOES NOT DISTURB THE INTERNATIONAL COMPETITIVITY OF THE SEED AND GRAIN BUSINESS AND STIMULATE FARMERS TO ADOPT IT



### Global Area of Transgenic Crops in 1996 - 2002

YEAR	HECTARES (MILLION)
1996	1.7
1998	27.8
2002	60.0

Source: Clive James, 1998

### Estimate Value of Transgenic Crop Market, 1995 - 1998\*

YEAR	VALUE (US\$ MILLION)
1995	75
1996	235
1997	670
1998	1,350

\* Source: Clive James, 1998

\*\* This estimate can be considered to have doubled because of the area devoted to GMOs in 2002

### World Transgenic Seed Market

Year	Value (US \$ million)	Increment (%)
1995	75	
1996	235	213
1997	670	185
1998	1,500	124
2000	3,000	100
2005	8,000	166
2010	25,000	216

Source: Clive James, 1998

**Insects Control Costs and Value of Substitution by Transgenics**

CROP	COST	SUBSTITUTION
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

**Estimated Value of the Insect Resistance Technology**

10 to 15 million Hectares cultivated with GMO resistant to insects x US \$ 62.5 to 100 US\$ /Hectare = US 625 to 1.5 billion .

Considering that essentially cotton and corn are the crops that have Bt genes so far ,the estimated cost of insecticides for these two crops is US\$ 2.49 billion and the substitution estimated to be 53 % of this value

According to the figures above 25.1 to 60.2 % of the insecticide costs may have been already substituted as predicted , depending on the crop species

**Global Crop Protection Market**

(\$ Billions)

Group	1995	1996
Herbicides	14,280	15,050
Insecticides	8,750	8,745
Fungicides	5,855	5,895
Plant growth Regulators & Others	1,380	1,325
Biotechnology Products	75	235
Total	30,265	31,250

- Brazil imports US \$ 2.5 billion of chemicals to use in 40 million hectares.
- The average cost of chemicals /Hectare = US \$ 62.5
- The cost for chemicals / 60 million Hectares of transgenics can be estimated to be : US\$ 3.75 billion
- The estimated value of 60 million hectares of transgenic crops ,assuming 100.00 US \$ /Ton is = US \$ 18 billion
- The profit margin for the farmer is 10 to 20% = US\$ 1.8 to 3.6 billion
- How much the farmer should pay for the seed to substitute chemicals and still have a profit?