Green Biotechnology and Intellectual Property
An Ongoing Struggle for a Proper Balance

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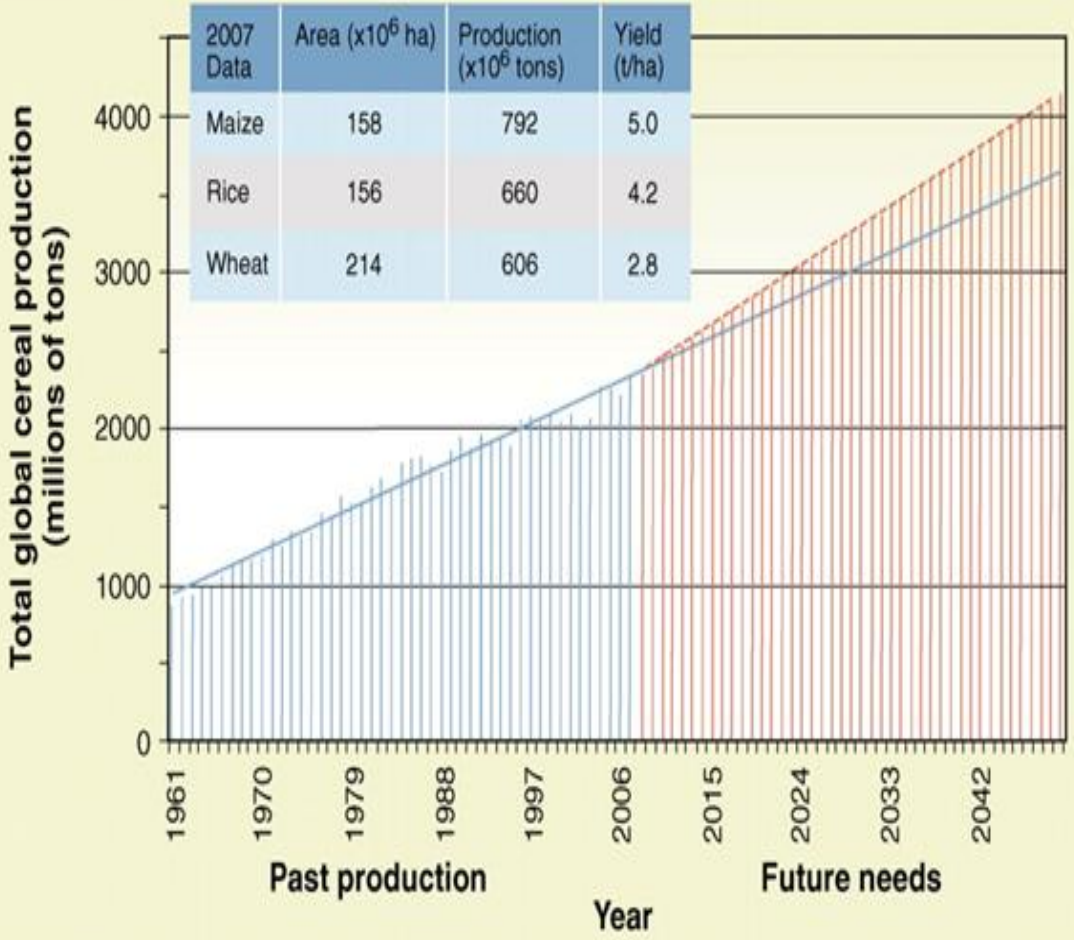
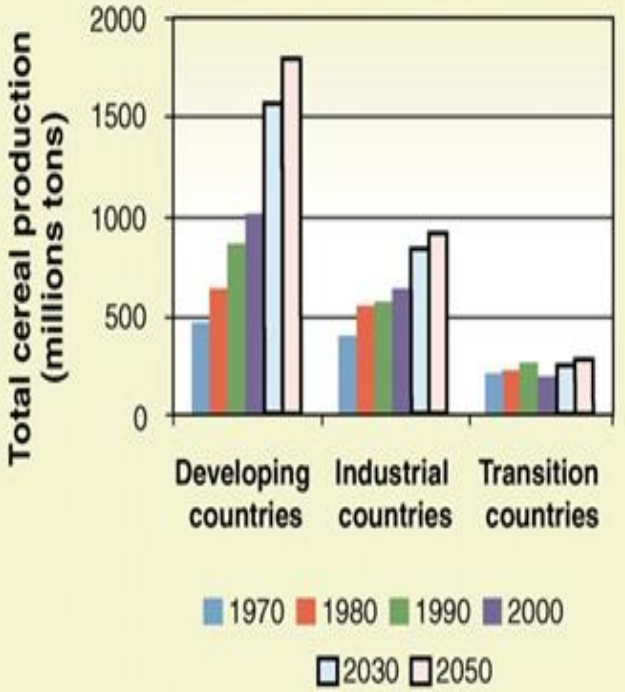
Points to Consider

- **Challenges for food production**
- **Technologies needed/available**
- **World-wide application of green biotech**
- **Patents vs. Plant Breeders' Rights**
- **Patents for biological material – legal framework**
- **Scope of protection under plant breeders' rights**
- **Search for the right balance**

Upcoming Challenges for Food Production

2007 Data	Area ($x10^6$ ha)	Production ($x10^6$ tons)	Yield (t/ha)
Maize	158	792	5.0
Rice	156	660	4.2
Wheat	214	606	2.8



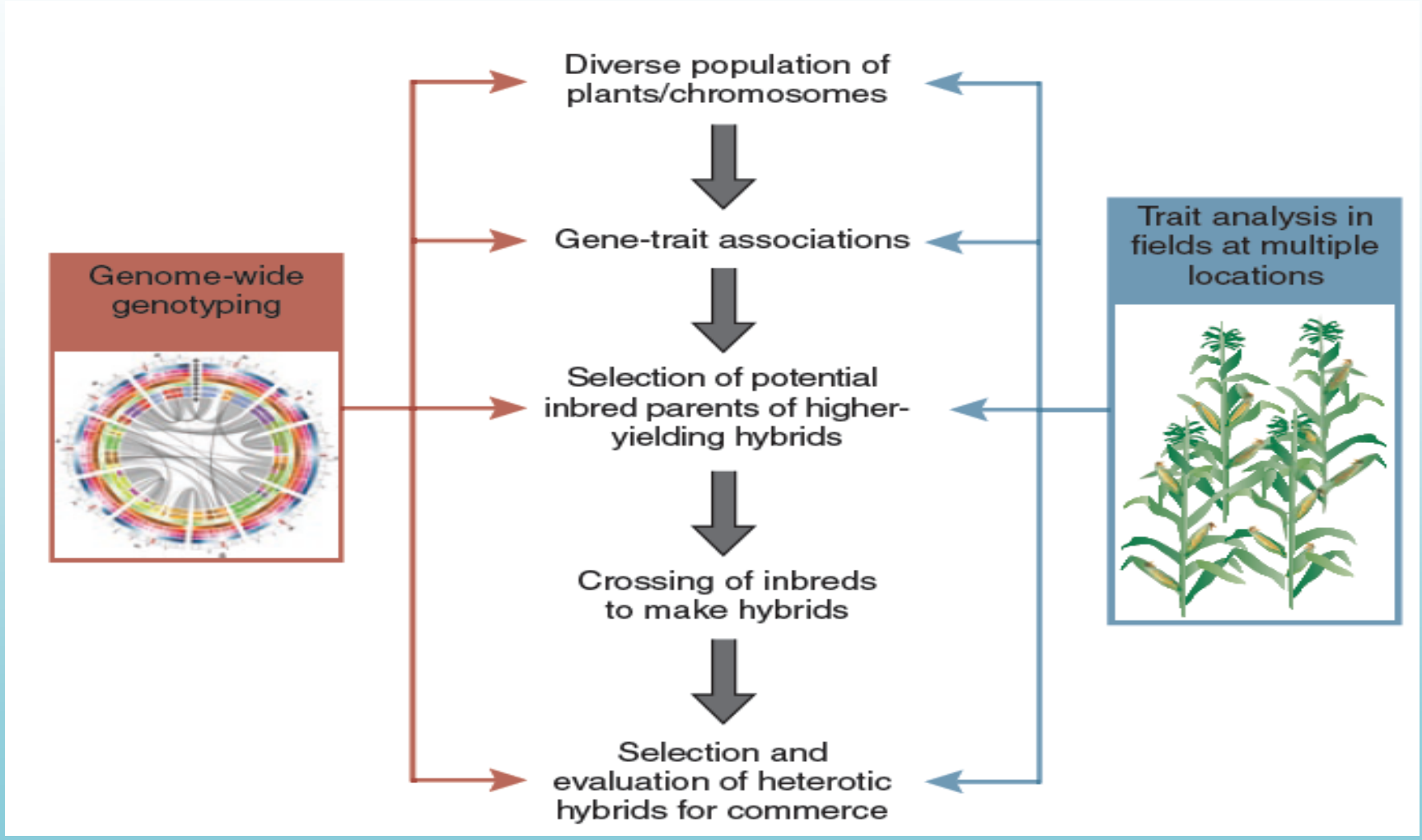


Source: Science Vol. 327, 12.2.2010 (FAO, Rome, 2006)

Technologies Needed/Available

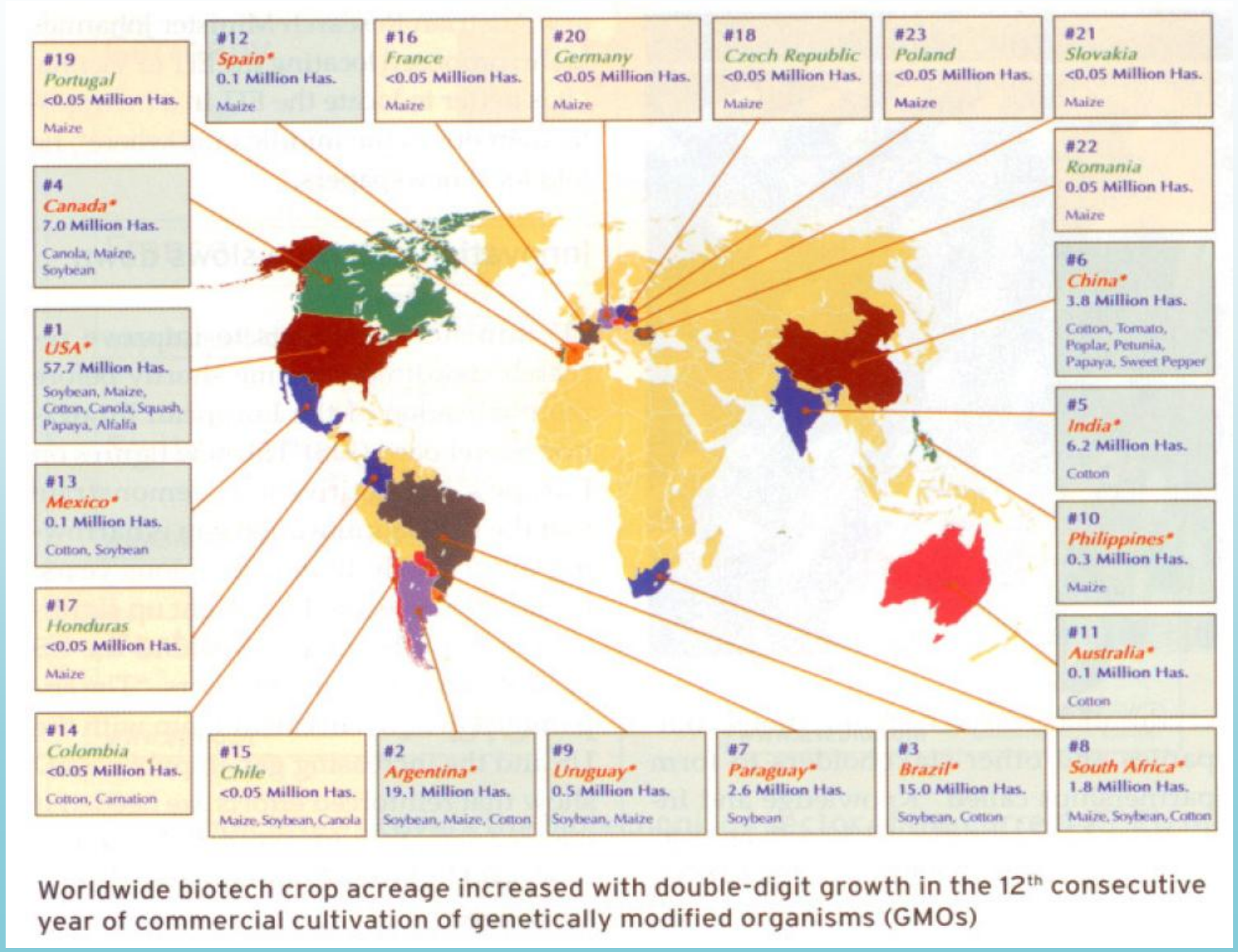
- **Traditional plant breeding methods, including hybrids, protoplast technology, tissue culture**
- **GMOs – rDNA technology**
- **Marker-Assisted Selective Breeding – MAS – as basis for**
  - **Gene pyramiding**
  - **Marker-Assisted Recurrent Selection (MARS)**
  - **Genome-wide or genomic selection**
  - **CIS-genetics**
  - **Apomixis**
  - **Direct targeting of key heterotic loci**

From Genomics to Crop Breeding



R. Flavell, 28 Nature Biotechnology, February 2010, p. 144

Acceptance of GMOs



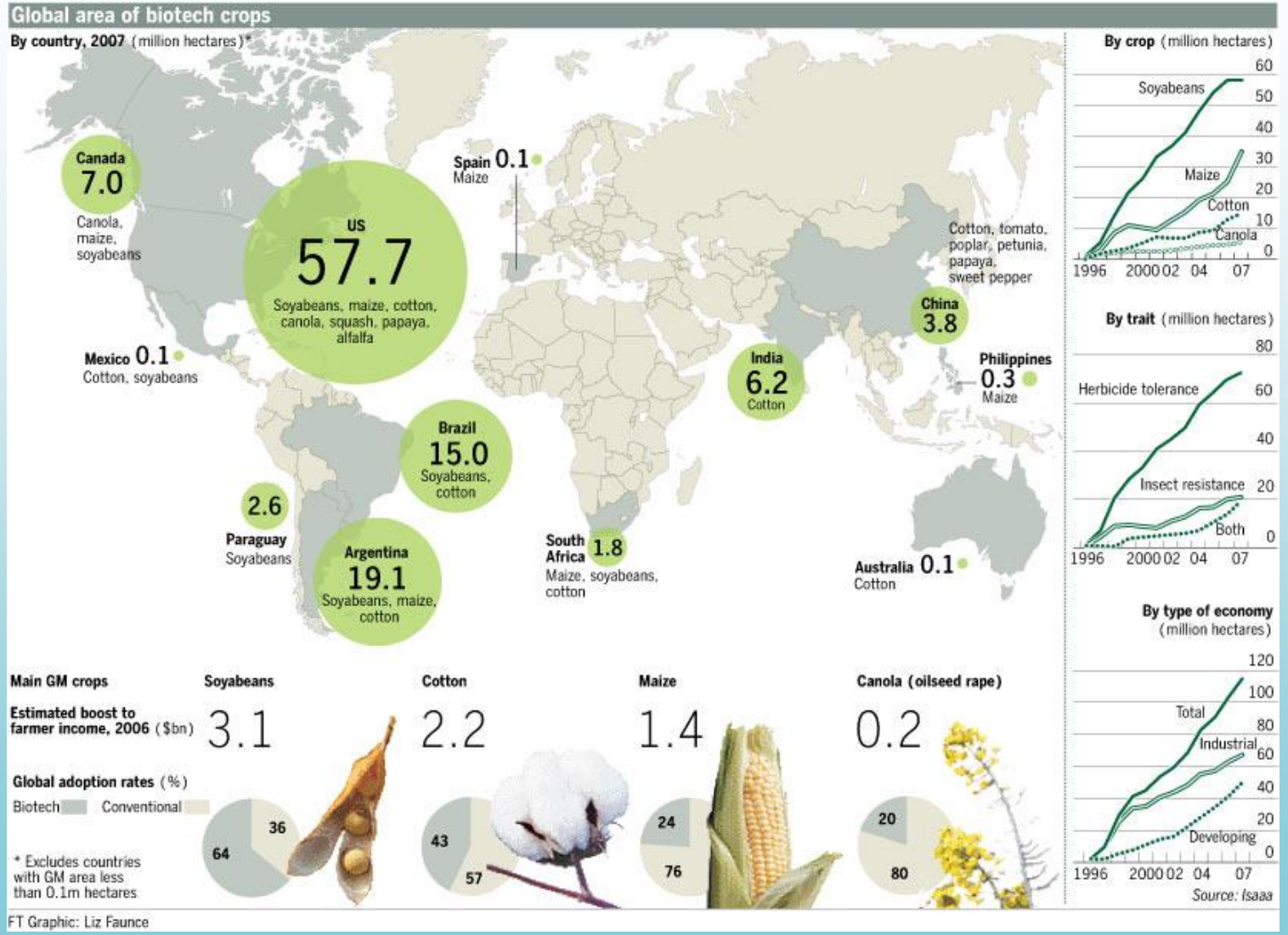
Worldwide biotech crop acreage increased with double-digit growth in the 12th consecutive year of commercial cultivation of genetically modified organisms (GMOs)

China's Transgenic Plants

PLANT	YEAR COMMERCIALIZED
Cotton	1997
Petunia	1997
Tomato	1998
Sweet pepper	1998
Poplar trees	2005
Papaya	2006

Slim pickings. Of the six plants that China has approved for commercialization, only cotton is grown widely. A new initiative could pave the way for GM versions of the biggest prize of all: rice.
PHOTO CREDITS: USDA/ARS

Europe – White Spot for GMOs



Patents vs. Plant Breeders' Rights

- **Different subject matters of protection: invention, i.e. generic teaching – products & processes (P), *a specific* plant variety – no processes (PBR)**
- **Different protection requirements**
- **Different scope of protection – commensurate to the contribution**
- **Both *exclusive rights* with certain limitations**
- ***No difference* as to ethical justification or objections**

International Mandatory Standards for Protecting Inventions in Plants under TRIPS Agreement

- **Patents must be available for inventions whether products (also foodstuff, pharmaceuticals, etc.) or processes in all fields of technology, provided the usual patentability requirements are met**

- **Members may exclude from patentability plants and essentially biological processes for their production other than non-biological and microbiological processes**

- **Members have to protect plant varieties either by patents or by an effective *sui generis* system or by any combination thereof**

- **However: *Plants have to be protected as direct products of patented non-biological and microbiological processes.***

EU Directive 98/44 & EPC & Patent Laws of EU Members

- **No patents for plant varieties or essentially biological processes for the production of plants**

- **Essentially biological process, if it consists entirely of natural phenomena such as crossing or selection**

EBA EPO December 9, 2010 – “Broccoli”

- **A non-micro biological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle excluded from patentability as being “essentially biological” under Art. 53 (b) EPC**
- **Such a process does not escape the exclusion of Art. 53 (b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants**
- **If, however, such a process contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing – patentable and not excluded under Art. 53 (b) EPC**

EU Directive 98/44 & New EPC Rules - Patentable

- ***Biological material*, i.e. material containing genetic information and capable of self replication, or reproduction in a biological system, isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature.**

- ***Plants* if the technical feasibility of the invention is not confined to a particular plant variety (plant varieties generally excluded).**

EU Directive 98/44 & New EPC Rules - Patentable

- **DNA sequences if their function indicated [a function not necessarily a „biological function“ but any function responsible for a technically applicable result].**

- **Industrial applicability is to be specifically disclosed in the (priority) application, e.g. as a specific marker**

- **Where a sequence or partial sequence is used for the production of a protein or partial protein, the protein produced or its function must be disclosed.**

EU Directive 98/44 - Scope of Protection

- **Product protection on a biological material extends to:**
  - **Any biological material derived from the patented one through propagation or multiplication in an identical or divergent form and possessing those same characteristics.**
- **Protection of a product containing/consisting of genetic information extends to**
  - **All material in which the product (e.g. DNA sequence) is incorporated and in which the genetic information is contained and performs its function.**

Monsanto v. Cefetra, ECJ C-428/08

Monsanto's EP 0546090 Claims

1. An isolated DNA sequence encoding a class II EPSPS enzyme…, which enzyme is capable of reacting with antibodies raised against a class II EPSPS…
2. An isolated sequence… [DNA fragments]
8. A recombinant double stranded DNA molecule comprising in sequence:…
15. A method of producing genetically transformed plants which are tolerant towards glyphosate herbicide, comprising the steps

    (a) Inserting into the genome…
21. A glyphosate tolerant plant cell comprising a DNA molecule of claims…
25. A glyphosate tolerant plant comprising cells of claim 21

Monsanto v. Cefetra, ECJ C-428/08

ECJ Holdings

- **Under Art. 9 of the Directive a product patent on a DNA sequence does not cover a product – here soy meal – where that sequence does not perform the function for which it was patented, but did perform that function previously in the soy plant, of which the meal is a processed product, or would possibly again be able to perform that function after it had been extracted from the soy meal and inserted into the cell of a living organism.**

- **The harmonization effected by Art. 9 of the Directive – exhaustive – prevails over national laws – also for old cases**

EU Directive 98/44 - Scope of Protection

- **Process protection extends to:**
  - **Biological material directly obtained through that process**
  - **To any other biological material derived from the directly obtained one through propagation or multiplication in an identical or divergent form and possessing those same characteristics**

Scope of Protection

The Product Directly Obtained by the Patented Process?

- **Is a product with which the process ends;**
- **It does not cease to be the product so obtained if it is subjected to further processing which does not cause it *to lose its identity,***
- **there being no such loss *when it retains its essential characteristics.***

[UK Court of Appeal – Pioneer Electronics/1998]

Monsanto v. Cefetra – Additional Questions

- **Would import of T-Shirts produced from bt-cotton harvested in Egypt infringe European patents on the DNA-sequences and molecules and bt-cotton as well as its production?**

- **Would import of polenta processed from maize grain harvested from bt-corn in the US infringe European patents on bt-corn and its production?**

EU Directive 98/44 - Limits of the Scope of Protection

- **Exhaustion of patent right**
  - **Where material put on market by the owner or with her consent, and**
  - **Multiplication or propagation necessarily results from the application for which the material was marketed, and**
  - **Provided no subsequent use of material for other propagation or multiplication**
- **Farmer‘s privilege**
  - **In line with that of Regulation (EC) No. 2100/94, i.e. for agricultural species only – as listed in Article 14 (2)**

EU Directive 98/44 - Compulsory Cross-licensing

Available

- **If unsuccessfully applied for a contractual one,**
- **If the variety constitutes significant technical progress and if of considerable economic interest**
- **Payment of an appropriate royalty**

Plant Breeders‘ Rights – Scope of Protection

Authorization Required for Production, Reproduction, etc. of

- **Propagating material**
- **Harvested material, if no reasonable opportunity to exercise the right in relation to propagating material**
- **Products directly obtained from the harvested material, if no reasonable opportunity to exercise the right in relation to harvested material (at discretion of UPOV Members)**
- **Same authorization required for production, reproduction, etc. of propagating material, etc., of a variety which is essentially derived from the protected variety where the protected variety itself is not an essentially derived variety**

Breeders' Exemption (PBR) – Research Exemption (P)

- **Breeders' exemption (PBR) – breeding for the purpose of discovering and developing other varieties – no dependency – except for essentially derived varieties**

- **Research Exemption (EU – Law)**
  - **Covering any use of patented material for its further development, improvements, detection of further uses (German Case Law - Clinical Trials)**

- **German & French patent law – Research exemption extended – to cover use of patented biological material for breeding purposes**

Patents vs. Plant Breeders‘ Rights – Inbuild Balance Interdependence

- **Patents on genes & non-essential processes for plant production**
- **The notion of essentially derived varieties & scope of protection**
- **Commercially available plant varieties → starting point for transgenic plants**
- **Transgenic plant → EDV as final product → commercialization with license of IV owner only**
- **Subsequent EDV dependent on license of IV owner only**
- **Commercialization of EDV dependent on gene patent owner‘s or process patent owner‘s license**

Breeders‘ Exemption & Research Exemptions

Consequences

- **Distorted competition?**
- **When & where protected material accessible?**
- **If competition distorted – either limitations in the scope of exemption or extension of protection term necessary**

Necessary Fundamental Understanding!

- **New biotech techniques – essential for securing the growing demand for food – incl. for fruits**
- **Patents the *only means for protecting these techniques*, i.e. for incenting R&D and securing the necessary investment**
- **Campaigning against patents = advocating socializing biotech R&D efforts and results = free riding**
- **Campaigning against patents = clearly against international & European & national patent protection standards**

Some Reflections on the Necessary Balance

- ***Abelson*'s vision: „Ultimately, the world will obtain most of its food, fuel, fibre, chemical feed stocks and some of its pharmaceuticals from genetically altered vegetation and trees."**
  [279 Science 219 (1998)]

  requires:

- **Equal treatment of those contributing generic inventions in plants and those breeding new varieties of plants**

- **Both necessitate and should have access to protected germplasm for R & D activities for the development of new plant material and new varieties of plants – commercialization may be dependent**

- **All contributing must get a fair share in resulting benefits – free riding at the expense of others not tolerable and counter-productive**

Thank you for your Attention!