Patenting Plants – New Challenges

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GM Workshop

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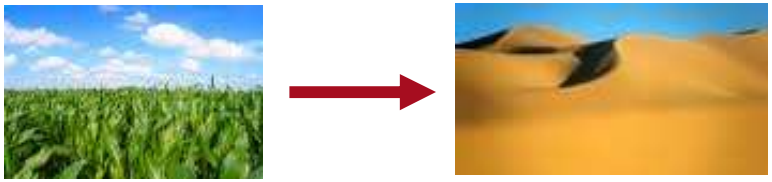
Facts Pushing Plant Innovations

- World population raise to > 8 billion in 2030‘

- Change of environmental conditions

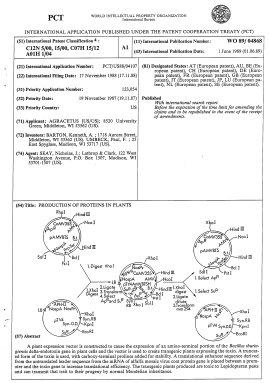


➔ Need of improved crops to meet new demands (yield, resistances, herbicide tolerance, nutritional value…)

➔ Need for innovations in plant breeding

➔ Biotechnology in agriculture is expensive, products are easy to copy

Basic Principle of Intellectual Property Rights



- Balancing interests of Society ↔ Patent Holder

  Benefit Society:
  - Access to innovative technologies due to publication of invention
  - Inventions are turned into tradeable goods

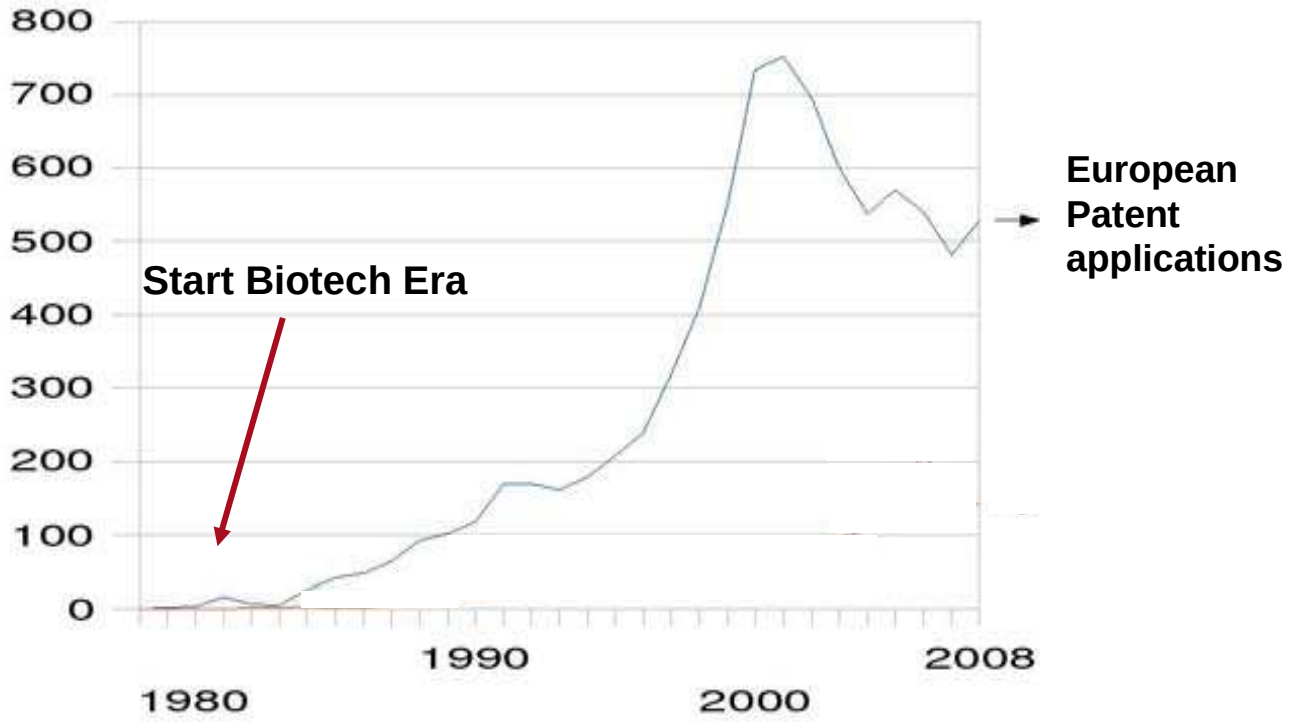
  Benefit Patent Holder:
  - Return on investments possible due to time-limited exclusivity

➔ Incentives for investments boost technological innovation, progress

⇒ **Property rights support plant innovations**

Agro-Biotech Patent Landscape

- Broadened property rights in biotechnology (genes) and plant-related inventions helped create new biotech industry



- **Upward trend in agro-biotech (~ 10% of biotech patents) at European Patent Office 1980–2008** (source: Espace Access Vol. 2009/001, Vol. 2009/00)

Biotechnology - Patenting

Principal criteria:

♦ New ♦ Inventive ♦ Industrial applicable

1980 – US Supreme Court: 'Anything under the sun made by man – thus living being'

1998 -- EU Directive 98/44/EC:

'Biological material **isolated** from its natural environment or **produced** by means of a technical process shall be patentable even if it **previously occurred in nature**'

'A sequence of a gene **may be patentable**, even if the structure is **identical** to that of a natural element'

⇒ **Inventions in the genetic field are patentable**

Exceptions to Patentability in Europe

European Patent Convention (EPC 1973/2000):

- Exploitation of invention would be contrary to public order or morality
- Medical treatment on human or animal body (surgery, therapy, diagnostics)
- Plant/Animal varieties or essentially biological processes for the production of plants/animals

Types of Protection in Agro-Biotech

Obligation by Trade Agreement on Intellectual Property Rights
(WTO 1994)

WTO OMC

⇨ Defines minimum standard for protection

❖ 'Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by a combination thereof...'

⇨ **Plant Breeders Right (PBR)**

⇨ **Patent System**

Plant Breeders Rights (PBR)

Plants of traditional breeding are not reproducible ⇒ not patentable

Plant Variety Protection under Union for Protection of New Varieties of Plants (1961)

US Plant Variety Protection Act (1970)

EU Community Plant Variety Right (1995)

Criteria: ♦ Novel ♦ Distinct/ Uniform/ Stable ♦ Denomination

- **Breeders Right: Exclusive right to re/produce; covers plant with all its characteristics and 'Essentially Derived Varieties' (EDVs)**
- **Breeders Exemption: Allows breeding of other varieties, EDVs excluded (GM-plants, Mutants)**
- **Farmers Rights: Allows reuse of 'product of harvest' on their own holdings (in USA also limited sale possible)**

Plant Patenting in USA

- 1930 -- Plant Patent Act

  Protects novel, asexually reproduced but not tuber-propagated plants; the entire plant (not parts thereof)

US Patent and Trademark Office

- 1980 -- Utility Patent

  Protects inventions involving 'living' organisms; since 1985 plants are patentable, including that created by conventional breeding !
  No breeders-, farmers-, research -exemption

- 2001 -- Double protection allowed

Plant Patenting in Europe

Legal Framework

- Directive 98/44/EC (EU Parliament):

  Plants/ Animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant/animal variety

- Case Laws of Boards of Appeal (European Patent Office):

  e.g. Decisions G1/98, T320/87, G2/07

Case Law Milestones

❖ **Decision G1/98** – Transgenic Plants/Novartis:

❖ Transgenic plant and seeds with anti-pathogenically effective lytic and hydrolytic peptides

⇨ Claims relating to transgenic plants are allowable even if they may cover plant varieties

⇨ Claims relating to plant varieties, irrespective of the way they are produced, i.e. genetic engineering, are not patentable

⇒ **GM Plants can be patented**

Case Law Milestones

- **Decision T320/87** – Hybrid Plant/ Lubrizol:
- Process combining several steps of crossing and cloning for rapidly developing hybrid plants/ seeds

⇨ The process was not found to be 'essential biological' as the modifications (cloning) are of important technological character.

⇨ The totality of human intervention and its impact on the results is decisive.

⇒ **Hybrid Plants can be patented**

Case Law Milestones

- **Pending Decision G2/07** - Broccoli/ Plant Biosciences
- A method for production of '*Brassica…'* having elevated levels of anti-cancerogenic glucosinolates combining crossing with selection by screening for marker genes ('Marker Assisted Selection', MAS)

⇨ It is questioned if a process like MAS is 'essentially biological', if it consists 'entirely' of a natural phenomena

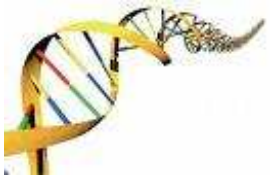
⇨ The degree/ nature of human intervention has to be assessed

♦ **Judgement** hand down December 2010

Decisive impact of a technical step is required (would question MAS) ⟷ **G2/07** ⟷ **Every human intervention is an essential technical step (may include traditional breeding)**

Scope of Protection

❖ Example: A plant produced by inserting a gene which leads to a pathogen resistance



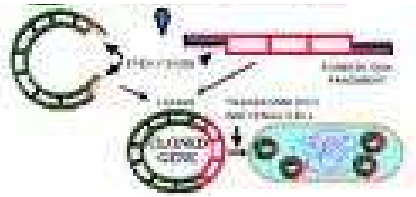
⇨ **Compounds** :

Sequences of Genes, Promotors, Enhancers, Vectors, Mutations, Polymorphisms, Amino acid sequences (Proteins), Antibodies

Provided plant and plants produced by the same method, parts of the plant, plant cells, cell cultures, propagation material

⇨ **Methods** :

Breeding or genetic engineering methods for producing the plant, methods for obtaining compounds from the plant



⇨ **Uses** :

Use of the plant (e.g. for making tobacco products)

Current Trends of Plant Protection

- Products of genetic engineering are generally protected by patents (broad-ranging protection)
- Since 1995 increase of patents for plants, whereas applications for 'Plant Variety Protection' decrease
- Use of non-legal self-enforcing protection:

  ⇨ Hybrid Plants

  ⇨ Genetic Use Restriction Technologies: Regulation of gene expression

  e.g. 'Terminator-technology'- expression of a plant-specific toxin-gene in the seed at very late stage kills the embryo which leads to a full-sized but sterile seed (US Patent: 'Control of Plant Gene Expression')

Thank You !

Appendix

Imperial Tobacco

	Patent Protection	Breeder's right based on the UPOV Convention
I. Object of protection	invention	plant variety
II. Requirements for protection		
1. documentary examination	required	required
2. field examination	not required	required
3. plant material for testing	deposit of material may be required only in certain cases	required
4. conditions for protection	(a) novelty (b) industrial applicability (c) unobviousness (inventive step) (d) an enabling disclosure	(a) commercial novelty (b) distinctness (c) uniformity (d) stability (e) an appropriate denomination
III. Scope of Protection		
1. determination of scope of protection	determined by the claims of the patent	fixed by the national legislation in accordance with the UPOV Convention
2. use of a protected variety for breeding further varieties	may require the authorization of the patentee	does not require authorization of the right holder (breeder's exemption)
3. use of propagating material of the protected variety grown by a farmer for subsequent planting on the same farm	may require the authority of the patentee	often does not require authorization of the right holder
IV. Variety Denomination	not required	required
V. Term of Protection	20 years from date of application	18 years for trees and vines, 15 years for other species, from date of grant (increased respectively to 25 years and 20 years in the 1991 Act)

Source: WIPO-UPOV Symposium 2002/02

Changes to the PVP law

Act 1991:

efforts to strengthen 'Plant Variety Protection' (PVP), to provide better possibility of return on investment

Key Changes:

- ➔ Extension of Protection to all plant species
- ➔ Duration of protection increased up to 20 years (vine, trees -25 years)
- ➔ Extension of breeders right to all production/ reproduction (previously commercial marketing only) and to harvested material
- ➔ Restricted farmers privilege – only 'product of harvest' on own holdings
- ➔ Introduction of 'EDV' clause to prevent 'cosmetic breeding' (minor modifications) – shall reduce return for follow-on developments
- ➔ Dual protection allowed (e.g. patent in parallel)

Patent Protection

- Covers as well plant varieties (indirectly), plants with the claimed feature
- Broader protection: Technique extentable to other varieties; covers whole production (i.e. seeds), processes, uses, genes, vectors…
- Stronger protection: Research exemption only; limited farmers rights (some listed plants in Europe) (none in US)

Plant Variety Protection

- Covers varieties derived from conventional breeding
- Easier to get (no inventive step, enablement, utility), cheaper
- Weak right (Breeders/ Farmers Exemption)

Different but Supplementary Protection Rights

The Patent 'Thicket'

- Research tools (promotors, enhancer…) and lab techniques may be covered by sometimes numerous patents
- Crucial for making GM Plants ⇒ need of licences
- Free access after patent run out or if it was previously published

Example Plant Promotors:

- ⇨ 35S Promotor: Monsanto, US patents will expire 2011 and 13, EP patent expired
- ⇨ Double 35S Enhancer: Monsanto, several patents valid (latest expiry 2013)
- ⇨ Opine Promotors itself (Nos, Ocs, Mas): publ. before 1990 - free
- ⇨ Ubiquitin-1, -2 Promotors (maize): Mycogen and Monsanto, US and EP patents valid
- ⇨ Figwort MV: Monsanto US patent exp. 2012, EP patent exp. 2010

For a detailed analysis of promotor patents: See ⇨ www.patentlens.net/daisy/promotors.768.html

! Be aware - patents may exist to individual constructs with combinations of various promotors and upstream activating sequences !