Latest Developments in Patenting Plant Inventions in Europe

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The European Patent Convention

- The European Patent Convention (EPC)
  - provides the legal framework for the granting of European patents via a centralised procedure
  - establishes the European Patent Organisation

- The EPO will grant and administer the EU unitary patent once the relevant legislation enters into force

- 1973 – Diplomatic Conference in Munich ► signature of the EPC by 16 countries

- 1977 – Entry into force of the EPC in 7 countries - marked as follows
38 EPO contracting states, including all EU states

Albania • Austria • Belgium • Bulgaria • Croatia • Cyprus • Czech Republic • Denmark • Estonia • Finland • France • Germany • Greece • Hungary • Iceland • Ireland • Italy • Latvia • Liechtenstein • Lithuania • Luxembourg • Former Yugoslav • Republic of Macedonia • Malta • Monaco • Netherlands • Norway • Poland • Portugal • Romania • San Marino • Serbia • Slovakia • Slovenia • Spain • Sweden • Switzerland • Turkey • United Kingdom

European patent applications and patents can also be extended at the applicant's request to the following states:

Bosnia-Herzegovina • Montenegro

A validation agreement with Morocco is ready to enter into force
Biotech patent applications at the EPO

• Biotechnology is one of the ten most active fields for applications
  – around 4.9% of all applications in 2010

• EPO's task is to apply law handed down by European legislator
  – does not create its own laws

• Strict quality standards
  – average grant rate for all technical fields is 43%
  – only about 28% of biotech applications lead to a patent

• 1.5 million patents granted by the EPO since 1977
  – 2.8% of these concern biotech-related inventions
Total no. (11,624 incl. pre-1990) of plant related applications in the patent applications database (EPODOC) per year of priority.
Nr. of new applications received at the EPO in cluster 223 (Biotech) per technical field

- Other
- Peptides and their genes
- Plants
- Cells
- Immunology
- Genetic Engineering and Microbiology
- Diagnostics

Year:
- 2006
- 2007
- 2008
- 2009
- 2010
- Sep 2010-Aug 2011

Numbers of applications:

- Other: 1.048, 1.244, 1.205, 1.260, 2.331, 2.344
- Peptides and their genes: 1.747, 1.958, 1.889, 1.705, 2.316, 2.122
- Plants: 581, 508, 538, 612, 726, 717
- Cells: 1.070, 1.077, 1.276, 1.509, 2.041, 1.626
- Immunology: 1.224, 1.117, 1.221, 1.097, 1.560, 1.626
- Genetic Engineering and Microbiology: 2.495, 2.730, 2.909, 3.018, 3.299, 3.460
- Diagnostics: 0, 2.000, 4.000, 6.000, 8.000, 10.000

Graph shows the trend of applications from 2006 to Sep 2010-Aug 2011.
Nr. of applications received at the EPO in cluster 223 (Biotech) relating to Plants

Year | Nr. of Applications
--- | ---
2006 | 593
2007 | 522
2008 | 571
2009 | 626
2010 | 732
Sep2010-Aug2011 | 732

2006 2007 2008 2009 2010 Sep2010-Aug2011
Where do patents to plant related inventions come from?

Countries of origin of European patents relating to plants

- Unites States of America: 39%
- EPC States: 42%
- Japan: 4%
- Australia: 4%
- Canada: 1%
- Korea: 3%
- Others: 3%

Data from Sept 2011
And within Europe?

![Diagram showing European countries of origin of European patents relating to plants]

- DE: 29%
- GB: 17%
- BE: 12%
- NL: 10%
- CH: 10%
- FR: 11%
- Others: 11%

Data from Sept 2011
What are the granted plant patents related to?

- inventions not related to genetically modified plant
- inventions related to genetically modified plant

Data from Feb 2011
Development of plant biotech

• **Pre-1950**: conventional plant breeding to make new varieties

• **1980**: start of genetic engineering of plants: insertion of non-plant genes into plant genomes
  – **Monsanto**: glyphosate (Roundup Ready) - resistant plants
  – **Ciba-Geigy**: BT (Bacillus toxin) - containing corn

• Early patents all for transgenic plants

• **From 2000**: rapid development of gene technology: possible to work on plant genomes to improve classical plant breeding
  – marker-assisted breeding
  – characterisation of native plant traits (natural genes encoding resistance to herbicides, pests, drought)
Types of plant inventions

• Better processing
  – herbicide resistance
  – pest resistance (viruses, nematodes)
• Improved plants
  – functional food
    (broccoli, sunflower, "golden rice")
  – drought resistance
  – high yield
• New ornamental plants
  – flowers with novel colours
  – dwarf plants
• Plants as a biofactory (vaccines, antibodies)
• Methods for making new plants
  – expression systems
  – transformation methods
Legal basis for patenting biotechnological inventions

  - Implementing Regulations to the EPC
  - Guidelines for Examination in the EPO
- **Case Law of the Boards of Appeal** of the European Patent Office
  - establish practice
  - rule on how to interpret the law
  - implemented into the EPC in 1999
  - Directive shall be used as supplementary means of interpretation
- **National law** to implement EPC and Directive
Patentable are (EU Directive, EPC)

- Biological material (e.g. a (plant) gene sequence) which is isolated from its natural environment or technically produced, even if it previously occurred in nature

- **Plants** or animals if invention can be used to make more than a specific variety

- Microbiological processes and their products
Plant patentability (EPC, EU Directive)

- **Plant varieties** and **essentially biological processes for the production of plants** are not patentable
  - technical processes, e.g. irradiation of seeds, are patentable
- **Plants** are patentable when the technical feasibility of the invention is not confined to a particular plant variety (EU Directive, EPC)
- A patent claim in which specific plant varieties are not individually claimed is not excluded from patentability, even though it may embrace plant varieties (EPO Enlarged Board of Appeal Decision **G1/98**)
- Directive provides for cross-licensing between patent and plant variety owners in case of overlap
Reasons for exceptions in 1973

• Plant varieties to be protected under UPOV
  – legislator did not want double protection (possible since 1991)

• Classical plant breeding processes relying on sexual crossing and the resulting varieties are not reproducible
  – every variety is a random event defined by its entire genome
  – no general technical teaching
  – biological, not technical processes

• Some indication that legislator wanted to exclude breeding processes used by plant breeders for making new plant varieties from patentability *(G 2/07)*
Definition of plant variety (Rule 26(4) EPC = UPOV Convention)- DUS

Any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:

(a) defined by the expression of the characteristics that results from a given genotype or combination of genotypes (distinct),

(b) distinguished from any other plant grouping by the expression of at least one of the said characteristics (uniform), and

(c) considered as a unit with regard to its suitability for being propagated unchanged (stable).
Tomato varieties: distinct, uniform, stable
Plants versus varieties

Plants containing gene X for increasing Vitamin C content: 
**patentable**

Golden Delicious: 
**not patentable** (variety)

Variety A containing gene X: 
**not patentable** (variety)
Plant patentability

- Plants are patentable
  - if the plant grouping is not a variety
  - if the invention can be used to make more than a particular plant variety
  - no matter how they are prepared
  - as long as no individual plant varieties are mentioned in the claim

- Conventional, non-transgenic plants obtained by breeding are also patentable as long as they are not varieties by DUS criteria
  - EPO Technical Board of Appeal Decision T 1854/07, sunflower
Patent versus plant variety rights

PATENT

• Plant defined by one or more inventive characteristics, not by whole genome
• All plants with the inventive feature protected, however obtained
  – foreign genes, e.g. from related species (broccoli, tomato) or bacteria (glyphosate resistance)
  – gene mutation (e.g. sunflower)
• Teaching must be novel and inventive
• Plant protected for all uses
  – no EU-wide breeders' exemption

PLANT VARIETY RIGHT

• Variety defined by whole genome or gene complex (DUS criteria)
• Only single variety and varieties essentially derived from it protected
  – entire phenotype as defined by the genome
• Variety must be distinct (novel)
  – no inventive step requirement
• Breeders' exemption
  – free use of protected variety for further breeding
  – free commercialisation of new varieties (except for essentially derived ones)
What is an “essentially biological process“ for producing plants?

• In 1973, only traditional plant breeding processes possible
  – crossing and selection
  – no controlled genetic engineering
• Modern gene technology made generic plant inventions possible and revolutionised breeding
  – mapping of plant genes and native traits by markers
  – moving genes between plants in a controlled way
• Where is the line to be drawn between patentable and non-patentable processes?
  – is marker-assisted breeding patentable?
  – is a breeding process patentable if it includes further steps as well as crossing and selection?
Essentially biological processes?

**EP 1 069 819 (G 2/07, broccoli):**

Method for production of *Brassica oleracea*, comprising steps of crossing and selection, wherein **molecular markers** are used to identify desired hybrids.

**EP 1 211 926 (G 1/08, wrinkled tomato)**

Method for breeding tomato plants that produce tomatoes with reduced fruit water content, comprising crossing and selection steps, **followed by** allowing fruit to remain on the vine until it is partially dried, and screening the fruit for reduced water content.
Broccoli/tomato rulings on breeding methods for plants (G 2/07, G 1/08)

- Classical methods for producing new plants by sexual crossing of *whole genomes* and subsequent selection of desired plants are not patentable even if there is an additional technical step before or after the breeding steps
  - marker-assisted breeding not patentable

- Transfer of a gene (or group of genes) encoding a *single trait* into a plant by genetic engineering is patentable

G 2/07 does not address the patentability of plants *per se*
  - this was dealt with by G 1/98 (1999)
Conclusions

• Plant varieties are not patentable
  – they can be protected under the UPOV Treaty

• Plants are patentable whether or not they are genetically modified

• Plants produced by classical breeding are patentable
  – provided they are not a plant variety

• Breeding methods for producing plants based on the sexual crossing of whole genomes and subsequent selection are not patentable
Thank you for your attention.