

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

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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 applications received at the EPO in cluster 223 (Biotech) relating to



Where do patents to plant related inventions come from?





And within Europe?



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



Development of plant biotech

- **Pre-1950:** conventional plant breeding to make new varieties
- **1980:** start of genetic engineering of plants: insertion of nonplant 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)

WYREALTRINE 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

- European Patent Convention EPC (1973, revised 2000)
 - 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
- Directive 98/44/EC of the European Parliament and the Council of the European Union of 6 July 1998 on the legal protection of biotechnological inventions
 - 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





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)



- 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)

- 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.

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