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INTELLECTUAL PROPERTY PROTECTION FOR PLANT-RELATED INNOVATIONS

Focus on
IP rights for plants in an evolving legal landscape in
Europe

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Intellectual property protection for plant-related innovations

Plant-related innovations are diverse:

Plants,

Methods for modifying plants,

Genetic material,

Tools for modifying plants,

Plant products (seeds),

etc.

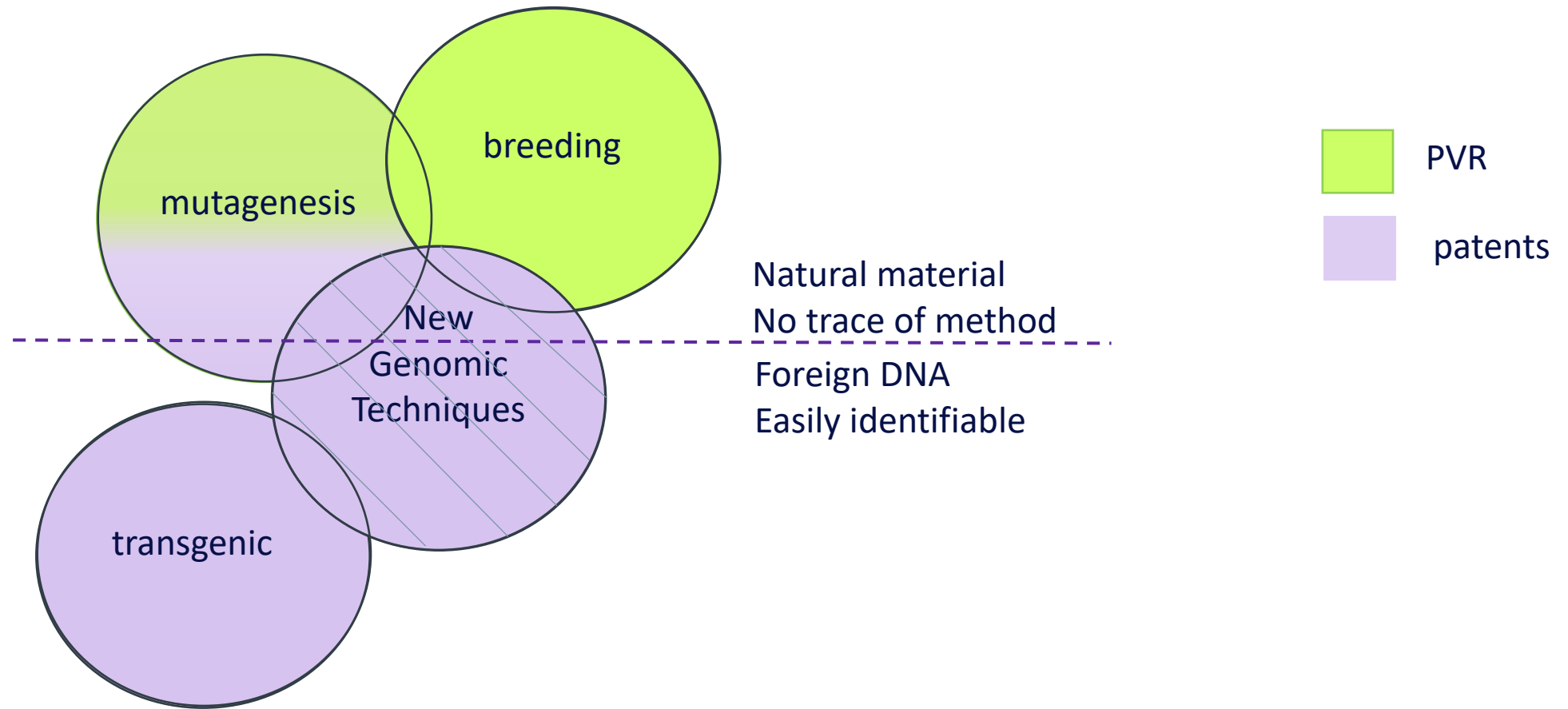


Intellectual property protection for plant-related innovations

IP protection: Rationale the same as in other fields

- Stimulation of innovation by providing temporary exclusivity
- Innovation necessary for
 - Advances for society – new products, services
 - Help to address problems – environment, climate change, health, food supply
 - Competitiveness of economy

Plants – produced by different methods



Different types of IP rights for plants

- **Plant variety rights**

- Protection of a given plant variety based on defined criteria

- **Patent rights**

- Technical contribution to the art which meets defined criteria
- Particular limitations with regard to plants and breeding methods
- May cover but not limited to a plant variety



Plant Variety Rights (PVR)

- Also referred to as “Plant Breeders rights” or “Plant Variety Protection Rights”
- Criteria: varieties which are
 - *New*
 - *D**istinct*
 - *U**niform*
 - *S**table*
- Time period: 25 y (30 y for trees and vines)
- Limited in territory
- Legal basis:
 - UPOV (International Convention (Union) for the Protection of new Varieties of plants)
- Implementation;
 - in national law (e.g. Belgian Plant breeder’s rights)
 - EC 2100/94: CPVR: Community Plant Variety right for EU member states, examined by the Community Plant Variety Office (CPVO) in Angers (FR)



Plant Variety Rights – SCOPE

- **Exclusive rights** to the owner of the variety right
- **Authorization** needed for:
 - Production or Reproduction (multiplication),
 - Conditioning for the purpose of propagation,
 - Offering for sale, Selling or other marketing,
 - Exporting , Importing,
 - Stocking for any of the previous purposes
- **Propagating** material and **Harvested** material
 - any plant or part, seeds, bulbs, tubers, material used for tissue grafting, flowers, leaves, fruits
 - products made from harvested material
- **Essentially derived varieties** (“EDVs”)
 - varieties which are not clearly distinguishable from the protected variety
 - varieties whose production requires the repeated use of the protected variety (e.g. inbred lines for the production of hybrids]

Plant Variety Rights – Limitations

- Breeder's exemption (determined by UPOV, but different levels)
 - Breeders may use a plant variety to **breed new varieties** without asking authorization from the owner of a PVR
- Farmer's privilege/Farm-saved seed (*optional*)
 - Farmers may produce on their own fields their own 'propagation material' from a variety covered by a PVR
 - EU State may fix the quantity of propagating material or the area on which farmer saved seed is grown

Plant Variety Rights – Considerations

- Plant Variety Rights are specific rights that can be enforced
 - restricted to varieties
 - do not protect traits
- Technological Evolutions in Breeding:
 - e.g. Precision breeding via genome-editing
 - Requires R&D Investments – identification of underlying genetic mechanism
 - Can often be applied to any variety within species or even in different species
 - Need for more generic protection to ensure return on investment
- Patents: provide tool for protecting the genetic modification(s) leading to given trait
 - Criteria to ensure there is technical innovation
 - Some limitations to avoid conflict with breeding activities

Patents

- Technical innovations relating to plants
 - e.g., drought tolerance, insect resistance, longer shelf life, etc.
- Criteria
 - Novelty, inventive step, industrial applicability, enablement (reproducibility)
- Time period: 20 y
- Legal basis:
 - Paris Convention, TRIPS
- Implementation:
 - National patent (e.g., BE patent)
 - European patent – to be validated in EPC member states
 - Unitary Patent



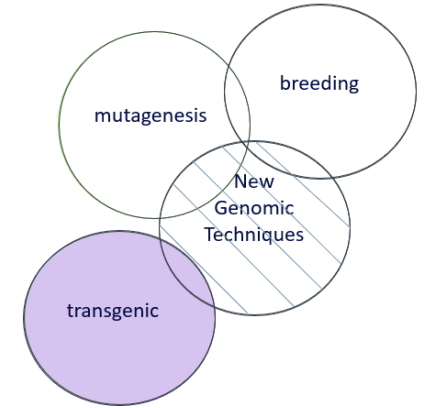
Patents – What can be protected (EU)?

- Plants
 - If not (limited to) plant variety (*Art. 53(b) EPC*)
 - If not exclusively obtainable by essentially biological process (*Rule 28(2) EPC*)^(*)
- Methods relating to production of plants
 - If not essentially biological processes for the production of plants (*Art. 53(b) EPC*)
 - Specifically: not methods reciting only crossing and selection
 - Methods based on classical transgenic approaches or on new genomic techniques (NGT)
- Genetic material and methods of modification
 - Isolated DNA sequences, markers, gene editing techniques

^(*) Since 1st July 2017

Plant claim

EP1127143



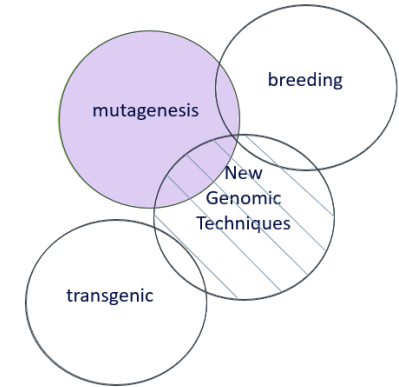
1. A **DNA molecule** comprising a **promoter sequence** and an **associated coding sequence** wherein the promoter sequence drives expression of the coding sequence specifically in the tapetum, endothecium and connective tissues of anthers but not in microspores or pollen, and wherein expression of the coding sequence starts at the tetrad stage and reaches a maximum level at the vacuolated pollen stage wherein said promoter sequence comprises a nucleotide sequence having 50 % of more sequence identity with the sequence shown in SEQ ID NO:3.

11. A transgenic **plant** and the sexual and/or asexual **progeny** thereof, which has been **transformed** with a DNA sequence according to any one of claims 1 to 9.

Plant generated by transgenic approach

Plant claim

EP944716B1

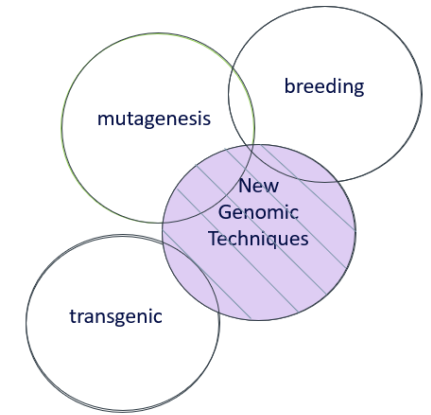


1. A **sugar beet plant material** consisting of mutated cells with a **mutated acetolactate synthase gene** encoding the synthase wherein a nucleotide is modified from guanine to adenine at position 337, wherein the mutated cells have a resistance to an imidazolinone herbicide and wherein the resistance is transmittable by conventional cross-breeding of plants produced from the cells and the cells are regenerable to a plant.

Plant generated by random mutagenesis approach

Plant claim

EP2934097B1



1. A *Solanum tuberosum* **plant, plant part, or plant cell** comprising a **deletion in** at least two **VInv alleles endogenous** to said plant, plant part, or plant cell,

wherein said deletion was induced **by introducing one or more rare-cutting endonucleases** into a *S. tuberosum* cell, such that said plant, plant part, or plant cell has reduced expression of vacuolar invertase as compared to a control *S. tuberosum* plant, plant part, or plant cell that lacks said deletion.

Plant generated by targeted genome editing

Patents – Limitations

- Research Exemption
 - Governed by **National Law** (but largely harmonized): *acts done for **experimental purposes** relating to the subject-matter of the patented invention allowed*
 - In the **Unitary Patent [Art. 27 (b) UPCA]**:
 - “The rights conferred by a patent shall not extend to [...]”
 - (b) acts done for **experimental purposes** relating to the subject-matter of the patented invention”.*
- Breeder’s exemption
 - In some **National Laws** (e.g., France, Germany, Switzerland): use of patented material for breeding allowed; commercialization only if patented trait is no longer present
 - In the **Unitary Patent [Art. 27 (c) UPCA]**:
 - “The rights conferred by a patent shall not extend to [...]”
 - (c) the use of biological material for the purpose of breeding, or discovering and developing other plant varieties, ..”*

Evolution in European patent law relating to plant-related innovations

- **Art. 53(b) EPC** : no patents on plant varieties, or essentially biological processes for the production of plants
- **2015: G2/12 - G2/13**: the exception does **not** apply to **products** (i.e. plants/plant material) obtained by an essentially biological process
- **2017: Rule 28(2) EPC**:
 - “European patents shall **not** be granted in respect of plants exclusively obtained by means of an essentially biological process”
 - Essentially biological = consisting entirely of natural phenomena (crossing & selection)
 - For patent applications filed after July 1st, 2017
 - Does not apply retro-actively
- **2020: G3/19**
 - Confirmed applicability of Rule 28(2) EPC
 - The exclusion also applies to plant **products** derived from plants exclusively obtained by means of an essentially biological process are also excluded from patentability

Intellectual property protection for plant-related innovations

Plant origin	IP protection	Regulatory: Deregulation EU GMO Directive (2001/18/EC)
Plants obtained by <i>conventional breeding</i>	PVR	NO
Plant obtained by <i>random mutagenesis/cell fusion</i>	PVR/patents	NO*
Plant obtained by <i>transgenic</i> approaches	Patents	YES
Plant obtained by <i>New Genomic Techniques/genome-editing</i> approaches	PVR/patents → <i>but see proposal for “NGT” Regulation</i>	YES

(*) *conventionally used / long safety record*

Proposal for NGT regulation

- **Aim: to allow easier market access for certain types of “NGT” plants**
 - Need to allow commercialization of plants that can contribute to food security
 - Specific limitations and procedures for information
 - Information provided through the labelling of seeds, in a public database and through the relevant catalogues on plant varieties.

() Committee on Environment, Public Health, and Food Safety*

Amendment to proposal by ENVI

- **Amendment to the proposal by ENVI (*)**
 - Further restriction in the definition of type of NGT plants receiving more lenient market access
 - Complete ban on patenting of all types of NGT plants

() ENVI = Committee on the Environment, Public Health and Food Safety*

“NGT plants”

Art. 3

Definitions

‘NGT plant’ means a genetically modified plant obtained by targeted mutagenesis or cisgenesis, or a combination thereof, on the condition that it does not contain any genetic material originating from outside the breeders’ gene pool that temporarily may have been inserted during the development of the NGT plant;

‘category 1 NGT plant’ means a NGT plant that:

- (a) fulfils the criteria of equivalence to conventional plants, set out in Annex I, or

ANNEX I

Criteria of equivalence of NGT plants to conventional plants

A NGT plant is considered equivalent to conventional plants when it differs from the recipient/parental plant by no more than 20 genetic modifications of the types referred to in points 1 to 5, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools.

- (1) substitution or insertion of no more than 20 nucleotides;
- (2) deletion of any number of nucleotides;
- (3) on the condition that the genetic modification does not interrupt an endogenous gene:
 - (a) targeted insertion of a contiguous DNA sequence existing in the breeder’s gene pool;
 - (b) targeted substitution of an endogenous DNA sequence with a contiguous DNA sequence existing in the breeder’s gene pool;
- (4) targeted inversion of a sequence of any number of nucleotides;
- (5) any other targeted modification of any size, on the condition that the resulting DNA sequences already occur (possibly with modifications as accepted under points (1) and/or (2)) in a species from the breeders’ gene pool.

IP clause introduced with the Amended NGT Proposal

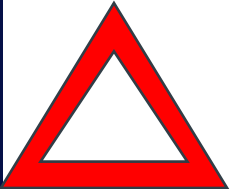
- New Art. 4a and Art. 33a

Amendment

Article 4a

Exclusion from patentability

NGT plants, plant material, parts thereof, genetic information and process features they contain shall not be patentable.



- Not limited to NGT-I
- “genetic information” they contain
- “process features” they contain”

Amendment

Article 33a

Amendments to Directive 98/44/EC

1. Article 4 of Directive 98/44/EC on the legal protection of biotechnological inventions is amended as follows:

In paragraph 1, points (c) and (d) are added:

'(c) NGT plants, plant material, parts thereof, genetic information and process features they contain, as defined in Regulation (EU) .../... [insert reference to this Regulation];

(d) plants, plant material, parts thereof, genetic information and process features they contain that can be yielded by techniques excluded from the scope of Directive 2001/18/EC as listed in Annex

I B to that directive.'

Art.4 §1: shall not be patentable...

- Classical mutagenesis
- Cell fusion

Further attempt to limit IP for plants

Draft regulation for plant reproductive materials (PRM regulation)

- Draft regulation proposed by the EU commission on the production and marketing of plant reproductive material in the Union (2023/0227 COD)
- ENVI suggested several compromise amendments with following provisions:
 - **Redefinition of essentially biological process** as breeding processes implying conventional breeding techniques such as crossing, selection, non-targeted mutagenesis or naturally occurring random genetic variations
 - **Redefinition of patentability of biological material isolated from its natural environment** by means of a technical process. Now it would read “Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention *except where it previously occurred in nature*” (instead of “even if it previously occurred in nature”)
 - Statement relating to **enforceability** of claims to plants: inventions relating to plants and animals are patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety **but the patent shall not have any effect when the invention applies to a variety.....**
 - Broadening of the **compulsory license** (Biotech Directive Art. 12) for developers of a new variety with environmental interest
- Final ENVI proposal (12/03/2024) limited to
 - proposed introduction of amendments 77 and 78, trying to introduce into the Biotech Directive Art. 4 the exclusion from patentability of NGT plants, as well as plants obtained by random mutagenesis or protoplast fusion, including the genetic information they contain.
- Final list of compromise amendments to proposal (15/3/2024)
 - No longer contains provisions to amend Biotech Directive

Next steps and consequences (1)

- Status of NGT proposal
 - Amendment of the proposal: Voted on February 7, 2024 by EU Parliament
 - Trilogue negotiations : EU Commission, EU member states, EU Council before NGT regulation could be finally adopted – regulation could still be amended/maintained as is
 - Whether this will be possible before the European elections in June 2024 is uncertain.
- Danger of confusion of regulatory and IP requirements
 - Criteria should be independent
 - Regulation provisions should focus on health and safety not driven by commercial interest
 - Patentability criteria relate to technical innovation and should be independent of political views
 - Measures to ensure accessibility can be taken – based on public interest
- Risk of overflow of “anti-patenting” effort to other technologies
 - E.g. proposal by ENVI on PRM regulation to limit patentability of all isolated biological material

Next steps and consequences (2)

- Potential impact of reduced IP protection for plants ?
 - Could stifle innovation – leading to slower development of interesting traits
 - Companies revert to trade secret – less information made public, only through new varieties
 - Could affect competitiveness, particularly EU vs rest of the world
- Does it really solve the problem?
 - One of the main concerns: Breeders would be at risk of being sued for infringement without knowing it
 - Notification issue rather than patenting issue
 - Risk of protection of native traits
 - Provisions exist in patent law to exclude protection for products obtained by EBP
 - What about claims to DNA, NGT method of production?

Conclusion


- PVP rights and Patent: different focus; both afford valuable and necessary protection for actors in the field
- IP landscape for plants has become more complex with introduction of new genome-editing techniques
- Exclusion from patentability not the answer in view of potential impact on innovation
- Need to ensure balance of IP rights which ensures stimulation of innovation while ensuring equitable access for farmers and consumers


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Thank you!