What happened in the last two years?



IP Space: Brave new world?

- Patents:
  - EU: R28(2) & G3/19 – issue resolved?
  - BR, CN … light at the end of the tunnel?
- **PBR/PVP:** New breeding technology and EDV?



New Breeding Technologies: Light & Shadow

- **IP / FTO:** IP uncertainty
- **Regulatory:** Positive developments
- **ILP:** Initiative for ILP in field crops



Biodiversity Space: Digital

- Digital sequence information: Escalation?

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Patentability of plant with native traits

After 20 years: Issue settled ?

EP1069819 (Broccoli)
Priority: 09.04.1998
Filed: 21.10.1999

Opposition: 22.04.2003
Appeal: 20.01.2005
Referral: 22.05.2007

G2/07 – G1/08
Broccoli & Tomato I
09.12.2010

15.5 years

G 2/12 – G 2/13
Broccoli & Tomato II
25.03.2015

Commission Notice
on Directive 98/44/EC […]
08.11.2016

18 years

New Rule 28(2)
01.11.2017

19 years

T 1063/18
Filed: 5.4.2018
Decided: 5.12.2018

G 3/19
Decided: 14.05.2020

G 3/19

Taking into account developments after decisions G 2/12 and G 2/13 of the Enlarged Board of Appeal, the exception to patentability of essentially biological processes for the production of plants or animals in Article 53(b) EPC has a negative effect on the allowability of product claims and product-by-process claims directed to plants, plant material or animals, if the claimed product is exclusively obtained by means of an essentially biological process or if the claimed process features define an essentially biological process.

This negative effect does not apply to European patents granted before 1 July 2017 and European patent applications which were filed before that date and are still pending.

1. **Disclaimer** for applications filed after July 1, 2017
2. **Raising the bar 1:** Tighter clarity requirement for traits not described by sequences.
3. **Raising the bar 2:** Tighter deposits requirements for traits developed from non-Budapest accessions.

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Implementation of Rule 28(2) EOC
Disclaimer examples

A mutant of a plant carrying a heritable exchange in a nucleotide sequence effected by technical means, e.g. UV mutagenesis or CRISPR/Cas

A cultivated pepper plant expressing a mutated AHAS enzyme

With the proviso that the plant is not exclusively obtained by means of an EBP

A tomato carrying a mutation in gene X with extended shelf life as compared to a wild type plant

Progeny of a mutant plant which carries the mutation.

Issue with the Disclaimer

With the proviso that **the plant** is not exclusively obtained by means of an EBP

1. **The wording:** The disclaimer refers to **the plant** and not the trait:
   - Is a plant with a native trait and another technical trait (e.g., an off-patent man-made mutant) covered by the claim despite the disclaimer?
2. **The interpretation under national law:**
   - The definition for “essentially biological process” under EU national laws differs from G 2/07. Which definition will apply in national proceedings?
   - The disclaimer creates a product-by-process (PbP) claim. For interpretation of PbP claims process elements are to be ignored. What does this mean for the disclaimer in an enforcement action?
   - Burden of proof: With the patentee or with the defendant?

With the proviso that the [characteristic] is not exclusively obtained by the sexual crossing of whole genomes.

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EPO Guidelines - 5.4.2.1 Examples

The following subject-matter **is not excluded** from patentability under Art. 53(b):

- A mutant of a plant carrying a heritable exchange in a nucleotide sequence effected by technical means, e.g. UV mutagenesis or CRISPR/Cas with the proviso that the plant is not exclusively obtained by means of an essentially biological process (EBP).
- A transgenic plant carrying transgene X.
- Progeny of a mutant (wherein the mutant is not exclusively produced by EBP) or a transgenic plant which carries the mutation/the transgene.
- A seed of a wild-type plant covered with a chemical which inhibits fungal growth.
- Flour or oil produced from plant X (even if it is apparent from the description that said plant was exclusively obtained by means of an essentially biological method).

The issue of mutants.
Why do mutants need a disclaimer if the sequence has absolute novelty?
What about sequence claims?

Easy work-around as most seed is treated ?
→ Features which do not contribute to the technical character of the invention cannot support the presence of an inventive step (T 641/00).

Usually the flour / oil has to solve a different problem then the plant: A herbicide tolerance in flour has no use.

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Issue 1: The Patentability of Mutants

G-II, 5.2: *Both targeted mutation, e.g. with CRISPR/Cas, and random mutagenesis such as UV-induced mutation are such technical processes. When looking at the offspring of transgenic organisms or mutants, if the mutation or transgene is present in said offspring it is not produced exclusively by an essentially biological method and is thus patentable*.

So why is a disclaimer still required?

Patentable: Plant exposed to UV lamp. **Not-patentable:** Plants exposed to natural UV?

Proposal submitted by the President of the European Patent Office

to the Administrative Council / amendment of Rules 27(b) and 28 EPC." Doc CA/56/17 (6.6.2017)

41. [W]hether a specific mutation indeed would occur as the result of spontaneous mutagenesis is entirely speculative. […] The mere possibility that a claimed mutated plant might also result from a natural (i.e. non-technical) process thus does not permit to extend the envisaged exclusion to mutant plants which the patent application describes as being obtained and produced through the application of mutagenesis techniques resulting in the modification of the genome and the achievement of a technical effect.

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Plant Claims vs. Sequence Claims

A cultivated pepper plant expressing a mutated AHAS enzyme, with the proviso that the plant is not exclusively obtained by means of an EBP

Disclaimer required

A mutated AHAS enzyme encoded by the nucleotide sequence according to SEQ ID NO: 1.

No disclaimer required ?

Directive 98/44 - Article 9 The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in Article 5(1), in which the product **is incorporated** and in which the genetic information is contained and performs its function.

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Issue 1: Mutants & Sequence Claims

1. Nucleic acid molecule which encodes a polypeptide that is able to confer resistance to [redacted] in a plant in which the polypeptide is expressed, characterized in that the nucleic acid molecule comprises a nucleotide sequence which is selected from

   (a) a nucleotide sequence that encodes a polypeptide having an amino acid sequence according to SEQ ID No. 3;

   (b) a nucleotide sequence that comprises the DNA sequence according to SEQ ID No. 2;

   […]

   wherein the resistance to [redacted] is a resistance to [redacted] or the plant belongs to the subspecies [redacted]

- The sequence for the native trait cannot cover the wild-type source material.
- But can it cover other material (i.e., commercial varieties)?
- What is the meaning of “incorporated” (“Eingang findet”)?

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Plant Claims vs. Sequence Claims

A cultivated pepper plant expressing a mutated AHAS enzyme, with the proviso that the plant is not exclusively obtained by means of an EBP

Disclaimer required

A mutated AHAS enzyme encoded by the nucleotide sequence according to SEQ ID NO: 1.

No disclaimer required ?

Do we need a disclaimer for the entire patent and not for a specific claim?

Plants resembling or comprising any embodiment of this patent exclusively obtained by the sexual crossing of whole genomes are not covered by this patent.

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Issue 2: Technicall Treated Seed - Real Life Example

56. Seed ~~or descendant~~ of ~~the~~ a [redacted]-resistant plant, characterized in that the plant contains the nucleic acid molecule according to claim 1 as introgression or transgenically, wherein the plant which contains the nucleic acid molecule as introgression belongs to the subspecies [redacted] ~~endogenously or transgenically, wherein the plant which endogenously contains the nucleic acid molecule belongs to the subspecies~~ [redacted] ~~plant according to claim~~ 5, wherein the seed ~~or the descendant~~ comprises the nucleic acid molecule according to claim 1 transgenically or as introgression.

7. ~~Seed according to claim 6, which~~ and, wherein the seed has been technically treated, whereby the technical treatment is selected from the group consisting of:

(a) Polishing
(b) Pelleting
(c) Incrustation
(d) Colouring.

Guidelines GL G-II, 5.4: The technicality of a claimed plant or animal product may lie in a non-heritable physical feature imparted directly to the claimed organism, e.g. a seed coated with a beneficial chemical.

Technicality = Inventive Step ?

→ Features which do not contribute to the technical character of the invention cannot support the presence of an inventive step (T 641/00).

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