

Opposition against the KWS patent on maize with cold tolerance



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1.

Patent EP3380618 claims maize
for cultivation in Nordic regions

(19)



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(54) **KÜHLETOLERANTE PFLANZE**

PLANT WITH TOLERANCE OF THE COLD

PLANTE RUSTIQUE

(84) Benannte Vertragsstaaten:
**AL AT BE BG CH CY CZ DE DK EE ES FI FR GB
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(73) Patentinhaber: **KWS SAAT SE & Co. KGaA
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(56) Entgegenhaltungen:
**WO-A1-2008/034648 WO-A1-2014/160304
US-A1- 2007 044 171**

- Nino Baliashvili: "Feinkartierung eines QTL (Quantitative Trait Locus) für Kühletoleranz auf Chromosom 4 in Mais und dessen molekularbiologische und phänotypische Charakterisierung. Inaugural-Dissertation zur Erlangung des Doktorgrades der Mathematisch-Naturwissenschaftlichen Fakultät der Heinrich-Heine-Universität", , Januar 2011 (2011-01), Seiten I-V, 1-96, XP55273945.

The 'invention': conventional breeding

KWS produced the maize from pre-existing maize lines that were already known to have cold tolerance and could be cultivated in climate conditions such as those in Northern Europe.

The company analysed the genomes of the pre-existing plants and identified so-called marker genes (gene variants) for use in screening and selecting the desired traits.

The 'invention' already existed

According to the patent description, these were pre-existing plants:

the analysis of existing breeding populations showed that 86% of the plants inherited the described genetic trait.

Fake technical elements of the 'invention'

The patent includes a number of additional elements 'on top' to create the impression of a technical invention:

Random mutagenesis, i.e. the use of chemicals, was applied in addition to the breeding process.

Tools such as CRISPR/Cas are also mentioned in the patent. However, new genetic engineering methods were not applied.

None of these processes are necessary to produce the desired plants.

The claims of the 'invention'

The scope of the claims includes:

Plants inheriting the identified mutations, regardless of whether they were induced randomly, e.g. via random mutagenesis or with a targeted intervention (new genetic engineering) or just by crossing and selection.

Also included is the use of the marker genes to screen natural / pre-existing populations.

The claims thus create a broad range of 'monopoly' rights, providing the patent holder with extensive and comprehensive control of biological resources needed in conventional plant breeding.

2.

Grounds for opposition

General legal background (EPC)

Article 53 (b) of the European Patent Convention (EPC) prohibits patents

- on plant varieties and
- processes used in conventional breeding (‘essentially biological processes’).

In 1995, this provision was confirmed as a general exclusion of plants from patentability (T356/93).

EU patent directive: Exemption from the prohibitions

In 1998, the EU adopted Directive 98/44 on the legal protection of biotechnological inventions (EU patent directive).

This directive allowed patents to be granted on inventions in regard to plants and animals for the first time.

While the prohibitions in Article 53 (b) are still valid, an exemption to the prohibition was introduced for genetically engineered plants and animals.

These exemptions were integrated into the 'rules for interpretation' of the European Patent Convention (legal basis of the EPO).

EPO examination guidelines: Conventional breeding vrs genetic engineering

“Genetic engineering techniques applied to plants which techniques differ profoundly from conventional breeding techniques as they work primarily through the purposeful insertion and/or modification of one or more genes in a plant are patentable (...). However, in such cases the claims must not, explicitly or implicitly, include the sexual crossing and selection process.”

Comparison: Conventional breeding vrs genetic engineering

Criteria	Conventional breeding	Genetic engineering
Insertion of traits	Traits can only be established ex-post, from pre-existing genetic diversity by selection (crossing and selection).	Traits can be predicted (ex-ante) and directly inserted.
Transfer of traits	Traits (genetic information) can only be exchanged between the plants (crossing and selection) or by protoplast fusion.	Traits (genetic conditions) can be isolated and transferred or inserted via technical means.
Species borders	Traits can only be exchanged within species borders (closely related species, breeders' gene-pool).	Traits can be transferred or introduced without being limited by borders between the species.
Genetic diversity	The natural or induced genetic diversity limits the potential selection of desired genetic conditions (traits).	The traits are not limited by pre-existing genetic diversity.
Genetic background	The impact of the genetic background differs from case to case and can be influenced by further crossing and selection.	The impact of the genetic background can be reduced or silenced via technical means (such as additional promoters).

3. Outlook

The EPO is likely to reject the opposition.

One reason: the patent was filed before 1 July 2017, when a new Rule 28 (2) came into force.

However, the opposition is not based on Rule 28 (2), but on the general prohibitions in Article 53 (b).

If the opposition is rejected, we can file an appeal.

Ultimately, the EU needs to make a political decision to stop patents on conventionally-bred seeds.

Thank you very much for your attention!



<https://www.no-patents-on-seeds.org/en/maize-cold-resistance>