# Patents on NGT seeds:
# The technical processes are decisive

# The prohibtions of Article 53(b), EPC

European Patent Convention (EPC):

*“Exceptions to patentability*

*European patents shall not be granted in respect of:*

*(…)*

*(b) plant or animal varieties or essentially biological processes for the production of plants or animals; (...)”*

Based on these prohibitions, in 1995, the European Patent Office (EPO) had stopped to grant patents on plants and animals, no matter if genetically engineered or not (Decision T 356/93).

# Directive 98/44 was the starting point for patents on genetically engineered plants

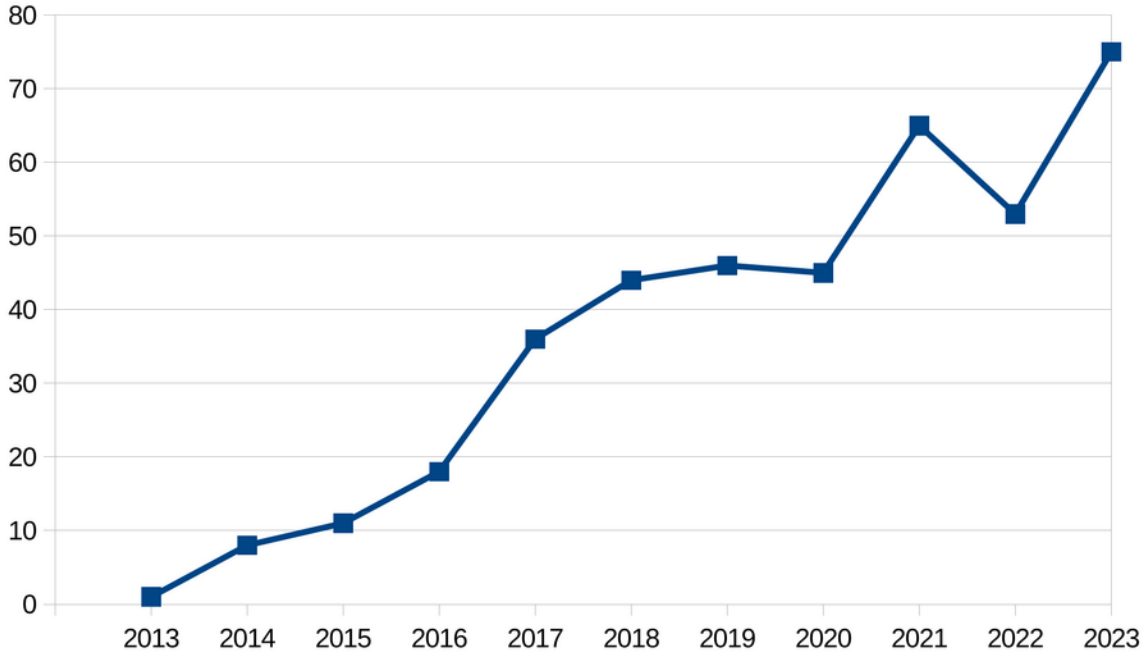
When the EU adopted its directive 98/44 on ‘the legal protection of biotechnological inventions’, the European Patent Office (EPO) changed its rules of interpretation of the EPC and started to grant patents on genetically engineered plants. This was an exemption of the prohibitions of Art. 53 (b) (Decision G 1/98).

→ Consequently, also the national patent laws of the 39 contracting states of the EPO were changed, to bring them in line with the EPC.

→ It is no longer in the power of the EU to prohibit patents on genetically engineered (NGT) plants, but would require unanimous vote of the 39 contracting states of the EPO to change the EPC and the national laws.

→ Patents on conventional bred plants (varieties) were never allowed.

https://www.no-patents-on-seeds.org/sites/default/files/news/Interpretation%20Art%2053%20(b)%20_NPoS_0.pdf




Number of international patent applications (WIPO/PCT) filed for genetically engineered plants per year which include the term ‘CRISPR’ in the claims. *Note: This research includes only patent applications filed in English language.* https://www.testbiotech.org/node/3181

# NGT patents are problematic for conventional breeding

NGT patents do not only concern technical processes, but also the gene variants produced by technical processes: the resulting genetic resources can be patented, even if they already existed in nature.

→ In result, the patents can cover genetic ressources also needed by conventional breeders.

# KWS maize patent EP 3560330



***The actual breeding process***

existing population → genotyping<br>phenotyping<br>new varieties

***Technical toppings***

marker genes

random mutagenesis

CRISPR/Cas

transgenesis

***The claims***

- Plants inheriting gene variants
- Use of plants for further breeding

# Patents on conventional breeding: a matter interpretation

In 2017, the EU, via the Administrative Council of the EPO tried to strengthen the prohibitions in regard to conventional breeding. However, loopholes remain: Plants derived from random mutagenesis (no matter if caused by sunlight or other triggers) are considered to be patentable.

→ Meanwhile, around 1200 conventionally bred varieties are concerned by patents!

→ A political initiative to clarify the rules of interpretation of the EPC could close current loopholes. The EU can change the interpretation of the definition of ‘essentialy biological processes’ by changing its patent directive 98/44 (Art 2.2.) followed by an initiative in the Administrative Council of the EPO.

# Examination guidelines of the EPO show the direction

„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 (see T 356/93). However, in such cases the claims must not, explicitly or implicitly, include the sexual crossing and selection process.“

Guidelines for the interpretation of Rule 26 (5)

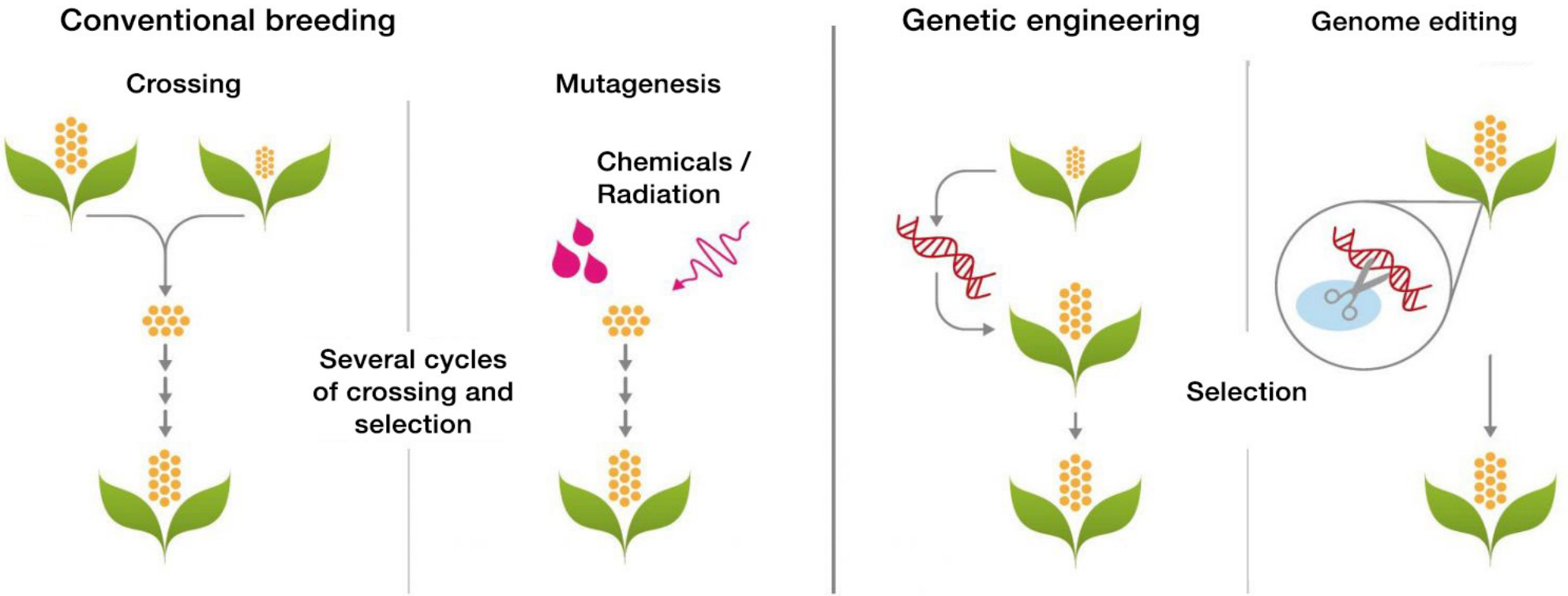



Figure 4: Differences between conventional breeding (including random mutagenesis) versus genetic engineering (including genome editing): conventional breeding always needs several cycles of crossing and selection to achieve to a desired trait, while GE can be used to directly insert new traits into a plant.

https://www.no-patents-on-seeds.org/en/report2023

# What the EU can do

To ensure freedom to operate for breeders, biodiversity should not be covered by patents.

→ As long as NGT patents cannot be prohibited, the interpretation of EPC should be changed, limit the scope of the patents to plants derived from targeted technical processes. The starting point would be a change in the definition of ‘essentially biological processes’ in directive 98/44. In result, all conventionally bred plants and plant varieties could be freely used for further breeding (see Austrian model law*).

→ There is no solution for NGT plants. Access may be eased by additional regulation (such as on licensing platforms). However, even if, for example, the costs for licenses are reduced, the introduction of NGT plants will go along with new dependencies.

* https://www.parlament.gv.at/gegenstand/XXVII/ME/229?selectedStage=100

# Proposal for improving directive 98/44

Currently, EU Dir. 98/44, Art 2.2 reads:

2. A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection.

Improved wording:

2. A process for breeding of plants or animals is essentially biological, if it is based on crossing, selection, non-targeted mutagenesis or random genetic variations that occur in nature.” (see also Austrian model law*)

* https://www.parlament.gv.at/gegenstand/XXVII/ME/229?selectedStage=100

# Thank you for your attention!

## Selected sources (with further references):

10 questions and answers: What do we really know about NGT plants?
https://www.testbiotech.org/node/3181

Future of plant breeding is under threat in Europe
https://www.no-patents-on-seeds.org/en/report2023

Interpretation of Article 53 (b)
https://www.no-patents-on-seeds.org/sites/default/files/news/Interpretation%20Art%2053%20(b)%20_NPoS_0.pdf