Patents on NGT seeds:
technical processes cause legal differences

Article 53(b), EPC: the prohibitions

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, the EPO had stopped to grant patents on plants and animals, no matter if genetically engineered or not (Decision T 356/93), before the EU patent directive 98/44 was adapted.

Change in EPC after directive 98/44 was integrated

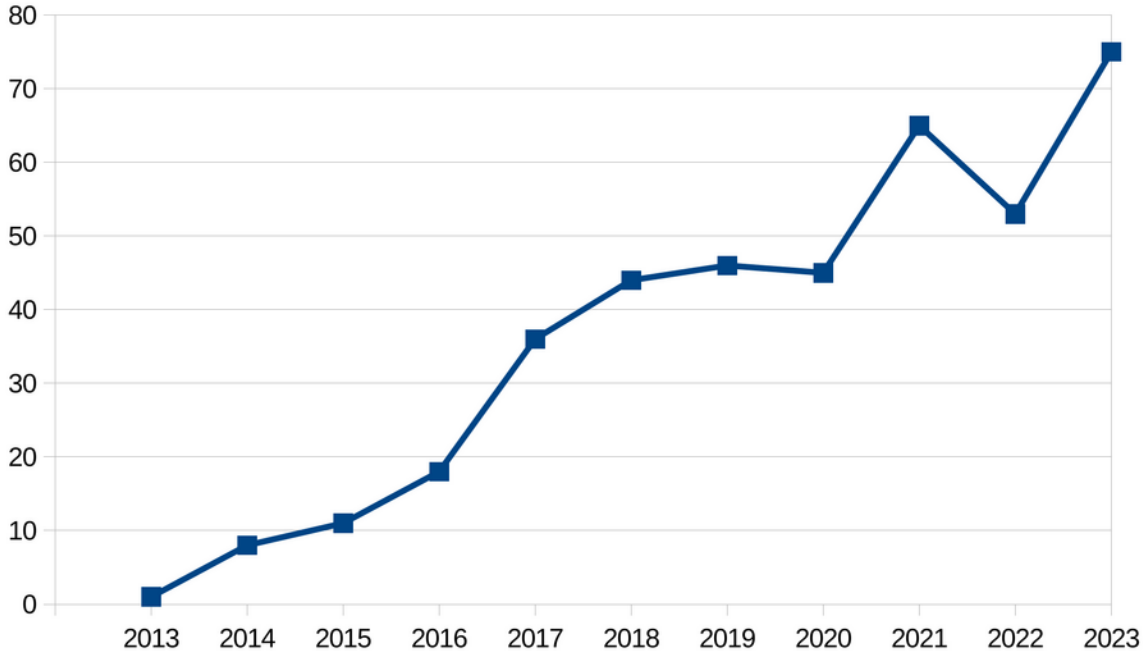
The EPO integrated the directive 98/44 into its rules for interpretation of the EPC and started to grant patents on genetically engineered plants as an exemption of the prohibitions of Art. 53 (b) (Decision G 1/98).

→ 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.

→ But 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 biodiversity / gene variants produced by technical processes: the resulting genetic resources can be patented, even if they before 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
phenotyping
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 prohibitions in regard to conventional breeding were strengthened, however loopholes remain: Plants derived from random mutagenesis (no matter if caused sunlight or other triggers) were declared to be patentable.

→ Meanwhile, more than 1000 conventionally bred varieties are concerned by patents!

→ The EU can change the interpretation of the definition of ‘essentially biological processes’ by changing its patent directive 98/44 and a vote in the Administrative Council of the EPO. Such a political initiative, to change the rules for interpretation of the EPC could close current loopholes.

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)

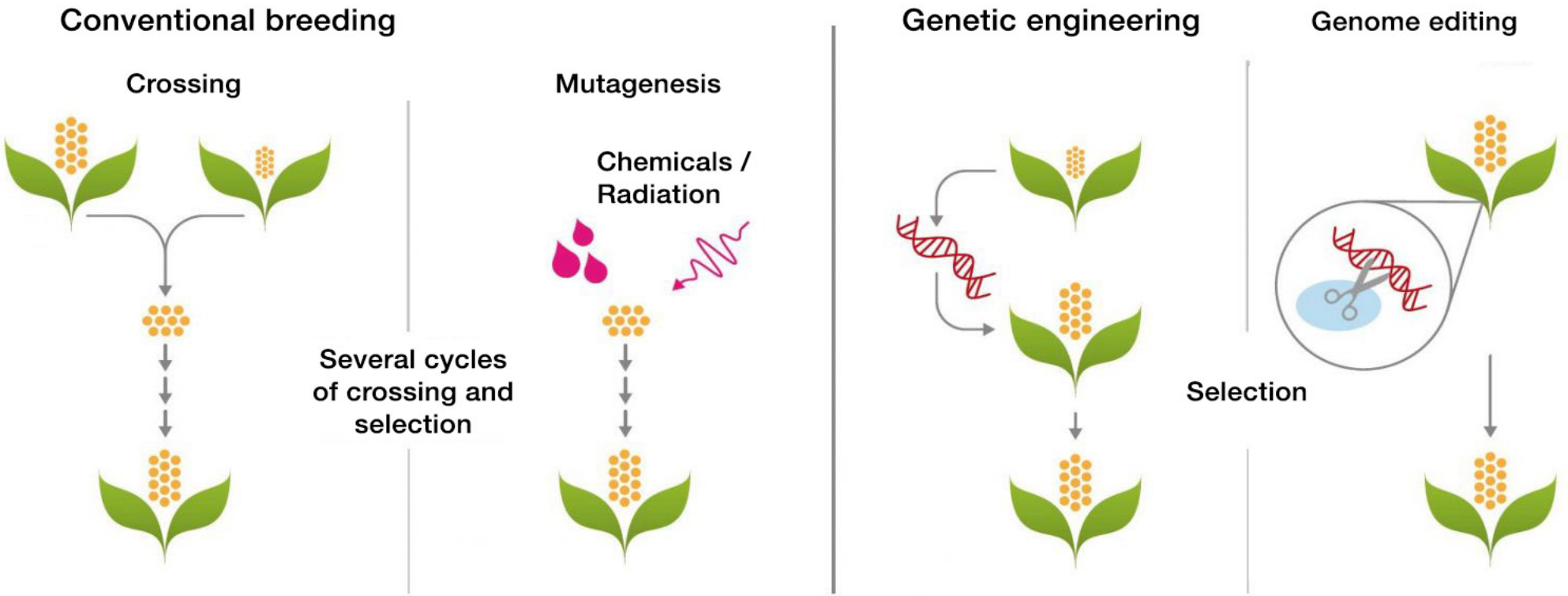


Figure 4: Differences between conventional breeding (including random mutagenesis) versus genetic engineering (including genome editing): conventional breeding always needs several cycles of crossing and selection to achieve to a desired trait, while GE can be used to directly insert new traits into 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 can not 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*).

→ Access to NGT plants may be eased by additional regulation (such as on licensing platforms). However, as long as the EPC is not changed, the introduction of NGT plants will go along with new dependencies.

* 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