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A huge challenge for the European Union

Analysis of the problem, case studies and potential solutions

Authors: Ruth Tippe, Anne-Charlotte Moy, Johanna Eckhardt, Andreas Bauer-Panskus & Christoph Then
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1. Summary

Patents are exclusive rights to commercially exploit a technical invention. In Europe, there is currently an ongoing controversial debate in regard to patents on seeds. The EU parliament and the EU member states are trying to find a solution to stop patents being issued on biological resources needed for breeding. There is strong political consensus in the EU to not allow patents on conventional seeds. Nevertheless, the European Patent Office (EPO) continues to grant them.

The EU, therefore, needs to find solutions to secure the freedom to operate for conventional breeders and, at the same time, restrict the scope of patents granted on genetically engineered plants, including seeds obtained from new genetic engineering (NGTs). This is an urgent problem which must be solved in order to safeguard the future of European plant breeding, agriculture and food production.

Findings from recent patent research

In 2023, *No Patents on Seeds!* conducted comprehensive research into patents on plants and seeds. The researchers used the WIPO (World Intellectual Property Organisation)[1] and the European Patent Office (EPO)[2] databases for this purpose. The aim was to identify patents and filed patent applications relevant to conventional breeding.

Our research identified around 80 patents on plants granted in 2023. Of these more than 20 concerned conventional breeding. Among the plant species covered were cucumber, maize, melon, oilseed rape, pepper, spinach, tomato and wheat. Patent holders include companies such as Nunhems/BASF, Enza Zaaden, KWS, Rijk Zwaan, Seminis/Bayer and ChemChina/Syngenta.

A more detailed analysis found that, in particular, processes used in random mutagenesis were used to circumvent the prohibitions in the European Patent Convention (EPC), Article 53 (b), which prohibits patents on plant varieties and conventional plant breeding.

In 2023, more than 70 new international patent applications included conventional breeding (out of around 300 patent applications filed for plants). Around one third out of these claim plants obtained from random mutagenesis.

In addition, further research using the PINTO database[3], which was established by the European Seed Association (ESA), identified 115 relevant European patents affecting 1365 plant varieties and more than 40 plant species. More than 400 varieties are affected by more than just one patent, and up to six patents can apply to a single variety. The number of plant varieties covered by patents doubled between 2020 and 2024. The companies holding the highest numbers of patents are Bayer (Seminis/ Monsanto), BASF (Nunhems) and Rijk Zwaan. They are followed by ChemChina/Syngenta and KWS.

The history of plant patents in Europe

Article 53 (b) of the European Patent Convention (EPC) prohibits patents on plant varieties and processes used in conventional breeding. In 1995, the rationale behind this provision in the EPC was interpreted as a general exclusion of plant varieties from patentability (Decision T356/93). However, in 1998, the EU patent Directive 98/44/EC allowed patents to be granted on genetically engineered plants.[4] Directive 98/44/EC was subsequently integrated into the EPC and into the national laws of all its 39 contracting states.

1 www.wipo.int/patentscope/en/
2 www.epo.org/en/searching-for-patents/legal/register
3 www.euroseeds.eu/pinto-patent-information-and-transparency-on-line/
4 https://www.no-patents-on-seeds.org/en/interpretation

In the meantime, the European Patent office (EPO) has granted thousands of patents on genetically engineered plants, including plants obtained from new genetic engineering (also called new genomic techniques, NGTs).[5] Genetically engineered plants covered by patents cannot be used by any other breeders unless they have licensing agreements.

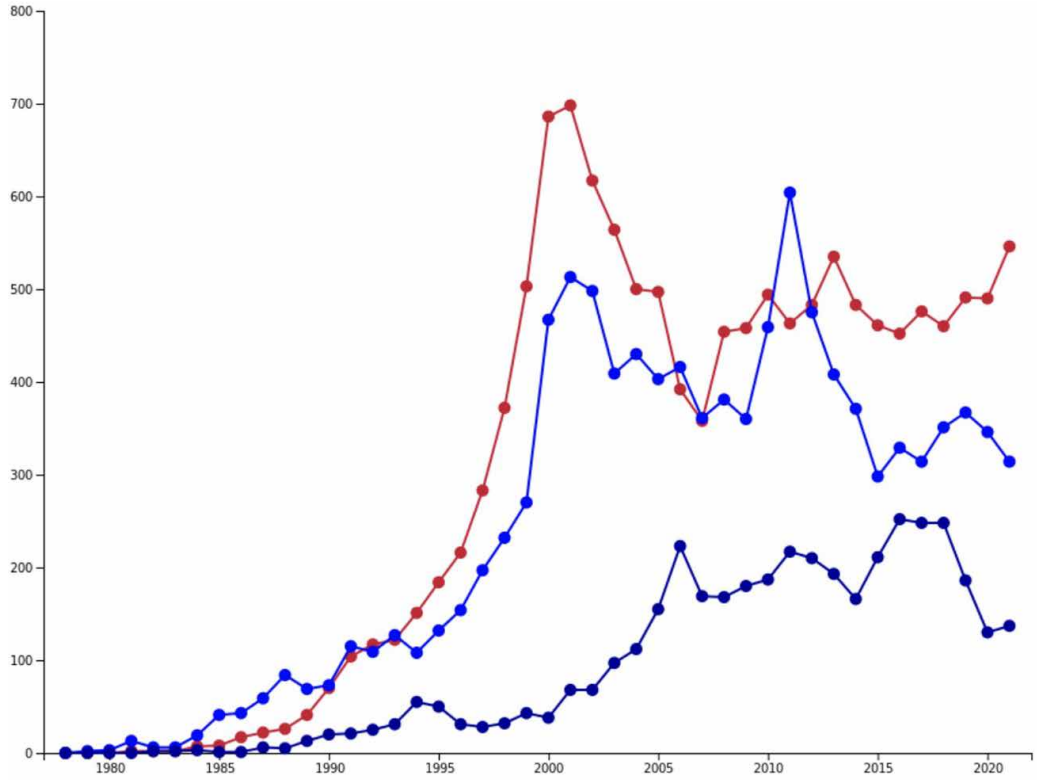

Figure 1: Number of all patent applications filed for plants under the PCT/WIPO (upper /red line) and at the EPO (middle / light blue line), including patents on plants granted by the EPO (lower / dark blue line) per year. Research according to official classifications (IPC A01H or C12N15/82). Source: www.kein-patent-auf-leben.de/patentdatenbank/

Europe has never actually adopted any regulation that would allow patents to be granted on conventionally-bred plants, as this would circumvent the prohibitions in Article 53 (b). Therefore, in accordance with the legislation, breeders should still be able to freely use conventionally-bred plant varieties to produce and market new, improved varieties. The freedom to operate for conventional breeders is also guaranteed in the breeders' privilege set out in the Plant Variety Protection (PVP) law. This legal framework is intended to ensure and maintain diversity in the European seed market. Currently, however, the freedom guaranteed to European breeders is under serious threat.

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

Patents impact conventional plant breeding

Patents on plants obtained by NGTs are routinely granted in Europe and the US, and large international corporations, such as Corteva (formerly DowDupont) and Bayer, are currently spearheading this development.[6] As a result, medium-sized European breeders that want to use the new technology are often forced into signing contracts with larger corporations, and thus into dependencies.

NGT plants are obtained from so-called 'targeted mutagenesis', which was developed to enable the direct introduction of a trait into the plant genome. These techniques are considered to be different (and therefore patentable) in patent law to methods used in conventional plant breeding. In contrast to the targeted introduction of a new trait, conventional breeding is always dependent on greater genetic diversity, which is the basis for selection and further crossings.

However, in many cases, the scope of NGT patents is not limited to the genetically engineered plants. For example, a patent (EP3560330) was granted to Kleinwanzlebener Saatzucht (KWS) for maize with higher digestibility. The trait was identified in naturally existing plants and then ‚re-invented' with CRISPR/Cas. The patent covers both the plants obtained from targeted mutagenesis (NGT) and from random mutagenesis (conventional breeding).[7] Patents covering plants obtained from random mutagenesis, which frequently also include claims on the selection of traits by using natural gene variants, give the patent holder comprehensive, exclusive rights to control biological resources needed for conventional breeding.

The KWS patent is not the only one of its kind: the EPO has already granted several hundred patents on conventionally-bred plants, covering more than 1300 conventionally-bred European varieties. Large companies, such as Bayer, BASF and ChemChina (Syngenta), hold the highest number of relevant patents.

Our research shows that random mutagenesis is the main 'point of entry' allowing the EPO to issue patents which impact conventionally-bred varieties. Plants obtained from random mutagenesis were introduced into the European markets without ever being patented, and have been used freely for decades in conventional breeding. Now, however, such plants are claimed as technical inventions.The EPO has extended the limits of patentability to conventionally-bred plants, thus going beyond what was intended in the EU patent directive 98/44.

The consequences and legal uncertainties brought about by these patents are a major threat to the freedom of those breeders who simply want to use conventionally-bred varieties for the production and marketing of new and improved varieties. Their freedom to operate has always been considered one of the main factors in innovative plant breeding. This may now be replaced by a system of new dependencies, costs and 'patent thickets'. The consequences of this development include increasing concentration in the seed market, loss of agricultural biodiversity and limited choice for farmers, gardeners, food producers and consumers.

6 https://www.testbiotech.org/wp-content/uploads/2021/06/Patents_on-new-GE.pdf
7 https://www.no-patents-on-seeds.org/en/report2023

Political initiatives to stop patents on conventionally-bred seeds

The legislator in Austria responded to this development in 2023, when the national patent law was limited to patents to genetically engineered seeds. According to the Austrian Patent Act, patents are not permitted if they are „based on natural phenomena such as crossing, selection, non-targeted mutagenesis or random genetic modifications occurring in nature."[8] For these regulations to become effective at the European level, the EU in particular would now have to clarify that, as long as patents on plants are not completely prohibited, only genetically engineered plants can be patented.

If the initiatives to ban patents on conventional breeding fail, the situation in Europe will become more or less the same as in the US: large corporations, such as Bayer and Corteva, BASF and ChemChina, will soon be able to control all seeds in Europe - with or without genetic engineering. According to a report from the US Agricultural Services, the top four companies (Bayer, Corteva, ChemChina and BASF) in the US, own the intellectual property rights for 97% of canola, 95% of corn, 84% of soybean, 51% of wheat and 74% of cotton.[9]

8 https://www.parlament.gv.at/gegenstand/XXVII/ME/229?selectedStage=100
9 https://www.ams.usda.gov/sites/default/files/media/SeedsReport.pdf

2. Patents on conventionally-bred plants granted in 2023

Our research identified around 80 plant patents that had been granted in 2023. Of these, more than 20 cover conventional breeding. Plant species include, for example, cucumber, maize, melon, oilseed rape, pepper, spinach, tomato and wheat, while major corporations among the patent holders are Nunhems/BASF, Enza Zaaden, KWS, Rijk Zwaan, Seminis/Bayer and ChemChina/Syngenta. Some selected examples are summarized in Table 1.

Table 1: Examples for patents involving conventional plant breeding, granted by the EPO in 2023

Patent number, patent holder	Plant species	Content
EP 3016505 Rijk Zwaan	Sweet pepper	Plants with new flavor
EP 3016504 Rijk Zwaan	Sweet pepper	Fruits with increased sugar content
EP 3368677 KWS	*Beta vulgaris*	Inhibition of bolting and flowering
EP 2635683 Arista	Wheat	High amylose kernels
EP 2825024 Nunhems (BASF)	Tomato	Virus resistance to tomato yellow leaf curl virus
EP 3250694 Rijk Zwaan	Melon (*Cucumis melo*)	Fruits without seeds
EP 2773185 Rijk Zwaan	Spinach	Resistance to downy mildew
EP 2330886 Enza Zaaden	Melon (*Cucumis melo*)	Virus resistance to cucumber vein yellowing virus
EP 2966988 Rijk Zwaan	Cucumber	Dark green color
EP 2708115 Seminis (Bayer)	Broccoli (*Brassica oleracea*)	Improved nutritional value after crossing with wild relative species
EP 3447134 KWS	Maize	Resistance to fungal disease (*Helminthosporium turcicum*)
EP 3742892 Nunhems (BASF)	Spinach	Resistance to downy mildew
EP 3556203 Syngenta	*Brassica oleracea*	Resistance to fungal disease (*Albugo candida*)
EP 3302035 Klemm	Poinsettia (*Euphorbia pulcherrima*)	White foliage
EP 2912940 Seminis (Bayer)	Spinach	Resistance to downy mildew
EP 3539372 Arcadia	Wheat	Increased starch levels

One specific group of granted patents is highly relevant to current and future EPO practice: in these cases, granting the patent was based on an Enlarged Board of Appeal decision (G3/19), that requests the EPO to apply the new the Rule 28 (2), EPC, to patent applications filed after 1 July 2017.

The background: the new rule was introduced on the initiative of the EU and is intended to strengthen the prohibitions in Article 53 (b). For this purpose, the Administrative Council of the EPO decided in June 2017 that patents on conventionally-bred plants and animals would no longer be granted, and the new Rule 28(2) was subsequently introduced into the Implementing Regulations of the European Patent Convention (EPC).

However, the problems were not solved by the introduction of the new rule and new loopholes opened up, in particular because a preparatory document, which is relevant to the interpretation of the new Rule 28(2), equated random mutagenesis to genetic engineering techniques.[10]

Furthermore, it is highly problematic that the G3/19 decision introduced a key date for the application of the new rule. Even before that date, hundreds of patent applications were filed for conventional breeding. 18 out of the 20 patents granted in 2023 for conventionally-bred plants were filed before this key date.

2.1 Patents granted after Rule 28 (2), EPC came into force

For the purposes of this report, we were interested to see whether the EPO decided on any patent applications covering conventionally-bred plants filed after the key date 1 July 2017. We examined the patents that were granted to see if the claims covered plants not obtained from methods of genetic engineering, and whether random mutagenesis played a role in this context.

So far, such cases are limited in number. One patent on maize with improved digestibility (EP3560330, company KWS) was already identified in research conducted in 2022:[11] The KWS patent claims the maize plants, regardless of whether they are derived from random mutations or genetic engineering. As indicated in the patent description, the respective gene variants were originally detected in existing maize plants obtained from conventional breeding.

In addition, we found one patent claiming flowers that was granted to a company called Klemm, in 2023 (EP3747263). The patent claims poinsettia plants, also known as Christmas Star, with white foliage. Similar to the KWS patent on maize, this patent also included claims on plants obtained from random mutagenesis (also including UV-light) and from NGTs.

In both cases, the use of natural genes used to select the required traits is included in the claims, thus undermining the processes of crossing and selection. These claims create broad 'monopoly' rights, as they include both the use of natural genes for selection and breeding and the plants obtained from random mutagenesis. This gives the patent holder extensive, comprehensive control over biological resources needed in conventional plant breeding.

As the EPO examination files show, both patents were granted after discussions on the prohibitions in Article 53 (b) and Rule 28 (2). The fact that the EPO granted these patents must be considered to be evidence of current EPO practice.

Another patent granted under Rule 28 (2) to KWS (EP 3447134) in 2023, confirms this: While broader claims directed to the plants were rejected, claims on the processes for the production of plants via random mutagenesis were allowed.

10 https://www.no-patents-on-seeds.org/sites/default/files/news/proposal_admin_council_epo_june_2017.pdf
11 https://www.no-patents-on-seeds.org/en/report2022

It cannot be excluded that other processes used in conventional plant breeding, are still regarded as patentable. For example, in July 2024, the EPO announced that patent EP3720272 (WO2019110821) would be granted to Rijk Zwaan. The patent claims tomatoes with resistance to the Tomato Brown Rugose Fruit Virus. In this case, the EPO accepted claims on a naturally occurring quantitative trait locus (a combination of genes) that is supposed to confer resistance to the virus. Furthermore, they granted a claim on a process for the production of the plants. This decision seems to contradict other EPO case law (such as G3/19, G2/07 and G1/08): it is evident that the plants are simply obtained from crossing and selection. Therefore, the patent is unlikely to survive under current EPO practice if it is opposed.

We concluded that even patent applications filed after the key date 1 July 2017 can still cover plants obtained from random mutagenesis and trait selection methods used in conventional plant breeding. In other words, these patents are not restricted to plants derived from genetic engineering, but allow control of biological resources needed for conventional breeding. Conventional plant breeders are, therefore, put at risk of infringing patent rights. This finding is especially relevant in regard to the large number of patent applications filed in 2023 claiming plants obtained from random mutagenesis (see below).

In summary, current EPO practice is extremely problematic for conventional breeders and also for farmers or participatory initiatives engaged in breeding activities, as they can create new dependencies and major legal uncertainty, and are thus likely to extensively hamper future plant breeding.

3. Patent applications filed in 2023 for plants obtained from conventional breeding

We identified more than 70 international patent applications filed in 2023 that included conventional plant breeding. The filed patent applications were analyzed to investigate whether the processes involved in the production of these plants included random mutagenesis.

In order to assess the impact on the breeding of specific plant species, this report includes an overview of patent applications for a specific pathogenic virus (Tomato Brown Rugose Fruit Virus) found in tomatoes and pepper. In order to highlight the implications of 'patent thickets', we investigated the relevant patent applications filed in 2023 and other relevant applications filed in previous years.

Finally, we include a case study on a new KWS patent application claiming maize with higher digestibility.

3.1 Patent applications filed for conventionally-bred plants that include random mutagenesis

In our analysis of current EPO legal practice (see above), we investigated which patent applications filed for conventionally-bred plants included random mutagenesis (or NGTs), as these patent applications have a good chance of being granted, despite the new Rule 28 (2). If granted, they are likely to undermine the freedom of conventional breeders to operate, as they claim specific biological resources and gene variants.

We identified at least 22 patent applications with the relevant profile. The patent applications (listed in Table 3) start with the use of existing gene variants in plant populations. This means that the gene variants and traits, e.g. resistance to plant pathogens, were originally simply detected in plants obtained from crossing and selection.

In addition, we found that random mutagenesis and NGTs were used to reproduce these traits. However, careful reading of the patents revealed that random mutagenesis (as well as NGTs) was actually superfluous in the development of the plants. It appears that the additional steps were only introduced to create the impression of a 'technical invention', and thus comply with current EPO practice. Therefore, such applications can be considered to be 'fake inventions'.

In conclusion, these patent applications follow the current pattern of EPO practice when examining and granting patents. If the patents are actually granted, the companies can claim both the genetically engineered (NGTs) and randomly mutated (conventionally-bred) plants as their invention.

Furthermore, similarly to the previously described patents, even the filed patent applications can be detrimental to crossing and selection processes, as the genes used to select the relevant traits are covered in the claims. Thus, if granted, these patents will enable comprehensive control of biological resources needed for conventional plant breeding. This is due to the way in which they combine the claims on the use of natural genes for the selection and breeding processes with plants obtained from random mutagenesis.

3. Patent applications filed in 2023 for plants obtained from conventional breeding

Table 2: Patent applications published in 2023. The relevant gene variants were found in existing plant populations. Random mutagenesis and new genetic engineering (NGT) were added as technical toppings, but are non-essential.

	Patent application	Company	Plant species, traits
1.	WO2023095144	Volcano Institute / Israel	Tomato with resistance to Tomato Brown Rugose Fruit Virus
2.	WO2023020938	BASF/Nunhems	Lactuca plants with delayed bolting (start of flowering) to increase their size at harvest
3.	WO2023051902	Bejo Zaden	Lactuca plants that are resistant to a fungal pathogen (downy mildew or Bremia lactucae).
4.	WO2024002949	Enza Zaden	Lactuca plants that are resistant to a fungal pathogen (Fusarium wilt or F. oxysporum)
5.	WO2023232265	Enza Zaden	Lactuca plants that are resistant to a fungal pathogen (downy mildew or oomycetes)
6.	WO2023117154	Enza Zaden	Lactuca plants that are resistant to a fungal pathogen (downy mildew or oomycetes)
7.	WO2023275048	BASF/Nunhems	Watermelon with dwarf phenotype (higher branching)
8.	WO2023004429	BASF	Brassicaceae with resistance to blackleg
9.	WO2023012342	KWS	Spinach with resistance to downy mildew
10.	WO2023006933	KWS	Maize with higher digestibility
11.	WO2023012325	Vilmorin	Capsicum with resistance to powdery mildew
12.	WO2023019172	Pioneer	Pearl millet with lower rancidity (longer shelf life)
13.	WO2023019314	CSIRO	Wheat with changes in starch composition
14.	WO2023046288	Bejo Zaden	Carrots with resistance to tropical root knot
15.	WO2023052561	BASF	Wheat with higher yield
16.	WO2023131639	KWS	Several species with higher level in fructose, higher yield, improved stress resistance
17.	WO2023151004	Syngenta	Soybean with changed oil and protein content
18.	WO2023151007	Syngenta	Soybean with changed oil and protein content
19.	WO2023165711	Enza Zaden	Tomatoes with resistance to wilt virus
20.	WO2023170272	Carlsberg	Barley and yeast with reduction of specific enzymes
21.	WO2023187757	Benson Hill	Soybean with reduction in saponins
22.	WO2023232429	Bejo Zaden	Broccoli with reduction in anthocyanins

The above list of patent applications shows that random mutagenesis is becoming the 'Trojan Horse' for introducing patents covering conventionally-bred seeds and plants. Random mutations can be triggered by sunlight, radiation or chemical compounds. Genetic variations obtained from random mutagenesis have been used in plant breeding for decades without patents being filed to claim the plants. Indeed, according to European patent law, these non-targeted processes cannot be regarded as technical inventions (see below).

3.2 Case study: Patent applications filed for tomatoes

In order to analyze the impact of recently filed patent applications on a specific plant species, we compiled a list of patent applications filed for tomatoes resistant to the Tomato Brown Rugose Fruit Virus (TBRFV). The virus, which is also known as the 'Jordan-Virus', was first found in the region of the river Jordan in 2014. It poses a serious threat to tomato and pepper crops.

Many of the gene variants known from existing tomato plant populations may confer tolerance or resistance to Tomato Brown Rugose Fruit Virus. Nevertheless, a 'patent thicket' has built up around these genetic resources. The first patent applications were filed in 2018 and 2019. Meanwhile, at least 20 international patent applications filed by ten different companies, e. g. BASF, Bayer, Rijk Zwaan and ChemChina/Syngenta, have been published (see Table 3). The patent applications cover dozens of gene variants. In several cases, the claims of the different companies seem to overlap for some of the targeted genetic regions within the respective chromosomes. At least one patent (EP3629711, filed as WO2018219941) was granted already. Another patent (EP3720272, filed as WO2019110821) seems to be just about to be granted.

Table 3: Patent applications for resistance to Tomato Brown Rugose Fruit Virus (ToBRFV or TBRFV) claiming genetic resources (gene, plants, seeds), with and without genetic engineering (2018-2023).

Company	Number of patent application	Number of chromosomes with specific gene variants	Technical toppings in addition to crossing & selection
Vilmorin	WO2018219941	Chromosomes 6,9,11	Random mutagenesis
Rijk Zwaan	WO2019110130	Chromosomes 6, 11, 12	-
Rijk Zwaan	WO2019110821	Chromosome 11	-
Seminis	WO2020018783	Chromosome 11	-
Enza Zaden	WO2020148021	Chromosome 8	-
Vilmorin	WO2020249996	Chromosome 11	Random mutagenesis
Vilmorin	WO2020249798	Chromosomes 6,9,11	Random mutagenesis
Rijk Zwaan	WO2021110855	Chromosome 11	Random mutagenesis and NGT
Rijk Zwaan	WO2021170868	Chromosome 11	Random mutagenesis and NGT
BASF/Nunhems	WO2021213892	Chromosomes 2 and 11	-
Vilmorin	WO2021245282	Chromosome 9 or 11	Random mutagenesis and NGT
Rijk Zwaan	WO2022013452	Chromosome 8	-
Philoseed	WO2022018734	Chromosomes 2 and 11	-
Tomatech	WO2022234584	Chromosome 1,2,3,4,6,9,11	-
Vilmorin	WO2022117884	Chromosome 9	Random mutagenesis and NGTs
Volcano Institute / Israel	WO2022091104	Chromosome 9	Random mutagenesis and NGTs
Volcano Institute / Israel	WO2023095144	Chromosome 9, 11	Random mutagenesis and NGT
Rijk Zwaan	WO2023135335	Chromosome 8	Random mutagenesis and NGTs
Syngenta	WO2023156569	Chromosome 1	-
Philoseed	WO2023144828	Chromosome 2	-

3. Patent applications filed in 2023 for plants obtained from conventional breeding

The starting point for these patent applications was the detection of gene variants in existing plant populations. In several cases, both NGTs and random mutagenesis were subsequently used to 're-invent' (imitate) the plants, or to trigger further mutations, and thereby achieve 'patentable mutations'. Again, such processes can be regarded as technical toppings without actually being essential to develop the desired resistance.

Furthermore, as described above, such patent applications can seriously hinder crossing and selection processes since the use of the genes to select the relevant traits is also part of the claims.

Which of these patents will actually be granted remains to be seen. Whatever the case, there are major legal uncertainties attached to these applications: as mentioned, in July 2024, the EPO announced that patent EP3720272 (WO2019110821) will be granted to Rijk Zwaan. It is evident that the patent is completely based on crossing and selection. Therefore, the patent is unlikely to survive if opposed under current EPO practice. Nevertheless, this case is a good example of how the legal chaos at the EPO traps conventional breeders.

In some instances, companies may seek to control further breeding even before a patent is granted. Indeed, as shown below, Rijk Zwaan is already claiming exclusive rights in the case of patent application WO2022013452 (EP4181663), despite the application still being at the examination stage. The PINTO database lists 32 plant varieties affected by this patent.

This only adds to the overall confusion, as the company has applied for several patents for the same trait; at the same time, it is still completely unclear which of these patents is really relevant to plant breeding.

The above problems have also been confirmed by active breeders. For example, Frans Carree, who works for organic breeder 'De Bolster', is mentioned in an article in Euronews, in which he describes how his efforts to develop a tomato resistant to the brown rugose fruit virus are being hampered by more than a dozen patent applications on this particular trait. He speaks out about the fact that these patents create huge legal uncertainty, even though the patents have not yet been granted. As stated in the article: "In order to develop his own virus-resistant tomato, Carree would need to read all patent applications to understand which traits the companies have filed a patent application for. The patent applications are written in such complicated language, however, that he sometimes struggles to understand them.

He would then need to ask a laboratory to sequence all of his plants to make sure that the patented trait is not included in his varieties – a time and cost intensive task." [12]

In conclusion, these patents are detrimental to European plant breeders even before they are granted, as they cause major legal uncertainty, and have a deterrent effect on to the production of new varieties:

- the sheer number of patent applications filed for the desired trait and the various companies involved may cause a buildup of 'patent thickets'. These may prove to be impenetrable for SME breeders wanting to produce new plant varieties with improved resistance to Tomato Brown Rugose Fruit Virus;
- the claims are not restricted to genetically engineered plants, but extend to traits present in conventional plants;
- one single variety may need several licenses before marketing could commence;
- it is unclear which patents will in the end be the most relevant and, therefore, which patent holder should be approached for a license;
- the costs for some of the licenses are reported to be very high;
- even if no costs were to be incurred, smaller plant breeders would need contracts with patent holders, thus creating new dependencies on big corporations, such as Bayer, BASF and ChemChina/Syngenta.

12 www.euronews.com/green/2024/08/18/europes-seeds-are-being-privatised-by-patents-and-it-could-threaten-food-security

These problems are very likely to systematically hinder future plant breeding. In addition, the license platforms proposed by industry as a solution cannot solve the problems: several license contracts may be needed to produce a single variety with the desired trait, thus strongly increasing costs and dependencies on larger companies.

3.3. Case study: New patent application filed for maize with higher digestibility

As mentioned, a patent was granted to the company KWS in June 2022 for maize with improved digestibility. EP3560330 was the first plant patent granted for an application filed after July 2017. It was, therefore, the first case to which the new Rule 28(2) was applied in accordance with the G3/19 decision (see above). As mentioned, the KWS patent EP3560330 claims maize plants, regardless of whether they were derived from random mutations or genetic engineering. In addition, it claims the usage of naturally-occurring gene variations for screening and selecting the plants within the process of conventional plant breeding.

In 2023, KWS filed another international patent application for the same trait (WO2023006933). However, this time, the patent application covered different (marker) genes to select and breed the plants.

This new patent application has revealed that the plants claimed in the previously granted patent are associated with genetic instability. As explained in the new patent application: *"The present inventors have found that the invention in the allele previously described (…) can get lost, and excision might result in the loss of the (…) the improved digestibility trait."* An analysis of 1720 breeding lines of 42 populations showed that in 2% the relevant gene variants got lost. KWS concluded that *"this shows an unacceptable high risk to loss [sic] the trait." (Page 2)* And further: *"Surprisingly, a high number of lines was identified, where these markers showed contradictory data."* (Page 92)

These statements not only show that the original data in the patent that was granted are not adequate to identify the plants with the desired traits. It also indicates that the trait was already present in many breeding lines and plant populations before the company applied for the patent. It appears that KWS is trying to use its patents to control access to genetic resources that were simply detected, and might have already been present in many varieties.

No Patents on Seeds! has filed an opposition against patent EP3560330 and is demanding that KWS withdraws both its new patent application and the previously granted patent.

4. Legal analysis

As the analysis above shows, attempts to control conventional breeding processes start with patent claims on the use of naturally occurring genes to select desired traits within a given plant population. In addition, random mutagenesis is being used as a 'Trojan Horse' to obtain patents on plants, seeds and harvest.

However, as shown below, there is no legal basis in Article 53 (b), EPC, for granting these kind of patents.

4.1 Are randomly mutated plants eligible for patent protection?

European breeders should in practice currently have free access to all conventionally-bred varieties or native plants for use in producing and marketing of new varieties. This is known as the breeders' privilege and is guaranteed by the plant variety protection (PVP) system. The PVP system is designed to provide breeders with the freedom to operate and is known to promote innovation in European plant breeding. It also ensures 'open access' to the biodiversity necessary to produce and market new varieties. Ultimately, if patents are granted on genetic resources, access to biodiversity needed by all breeders for future plant breeding can be hampered or blocked.

Article 53 (b) was introduced into the European Patent convention (EPC) in order to avoid the overlap of PVP law and patent law. It prohibits patents on plant varieties and conventional plant breeding. There is only one exemption to these prohibitions, i.e. genetically engineered plants (regardless of whether they are obtained from old or new genetic engineering techniques) are regarded as technical inventions. This exemption from the prohibitions in Article 53 (b) was introduced by the European Union in 1998, and subsequently integrated into the national laws of the 39 Contracting States of the EPO.[13]

Europe never adopted regulations allowing patents to be granted on conventionally-bred plants, as it would circumvent the prohibitions in Article 53 (b). Therefore, European breeders should be able to freely use all plants obtained from random mutagenesis, as guaranteed in the plant variety protection (PVP) law. Indeed, these plants were never previously covered by patents. There are currently several thousand varieties on the global market[14], all of which were originally obtained from random mutagenesis. They can all be used freely in the further breeding and marketing of improved varieties.

However, analysis of current European Patent Office practice shows that these plants are now being regarded as technical inventions, thus extending patent law beyond the realm of genetic engineering (see above).

This means that the EPO is ignoring the fundamental differences between genetic engineering and previously established plant breeding methods, e.g. random mutagenesis processes which use specific chemical compounds or physical stressors (sun light, radiation) to increase genetic diversity. However, these processes cannot be used to avoid a longer breeding process, or to directly introduce a new trait into the genome. The desired gene variants can only be selected ex-post from a sufficiently broad range of genetic diversity. Therefore, these methods are radically different from genetic engineering.

Earlier EPO decisions (G2/07 and G1/08) confirmed this difference, clarifying that only traits obtained from direct insertion (genetic engineering) can be regarded as technical inventions. Table 4 lists some crucial differences between random mutagenesis (and conventional breeding) and genetic engineering in regard to patent law.

13 https://www.no-patents-on-seeds.org/en/interpretation
14 https://nucleus.iaea.org/sites/mvd/SitePages/Home.aspx

Table 4: Differences between conventional breeding (including random mutagenesis) and genetic engineering relevant to the interpretation of Article 53 (b), EPC.

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 promotors).

Our analysis is in accordance with the EPO examination guidelines that state: *"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."* [15]

However, it is apparent that the EPO is currently ignoring the fundamental differences between genetic engineering and random processes (see above).

4.2 Can patents be granted on plant selection?

Officially, the EPO does not grant patents on breeding processes consisting of crossing and selection. However, a patent can be granted if it only covers methods of selection. This differentiation between the patentability of 'processes for selection' and 'processes for crossing and selection' is not supported in the EPC and is undermining the purpose of Article 53 (b).

It is also evident that the selection stage in conventional plant breeding is covered by the prohibitions in Article 53 (b). For example, the Rule 26 (5) of the EPC reads: *"A process for the production of plants or animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection."* (emphasis added)

Therefore, when the EPO is examining a patent application, it should decide whether a process for the production of the plant is technical or non-technical. The relevant criteria are set out in the G2/7 and G1/08 decisions, i.e. if the process does not aim to insert a trait directly into the genome, it has to be regarded as non-technical; it also has to be considered to be 'essentially biological' and is therefore excluded from patentability. This prohibition has to be applied to both steps of 'crossing' and 'selection'.

As shown above, if patents are granted on plants obtained by random mutagenesis and, at the same time, methods for the selection of plants via natural gene variants are claimed, this allows companies to take far-reaching, comprehensive control of biological resources needed by conventional breeders. It can be assumed that if these kinds of patents are granted, this will significantly undermine the intention of Article 53 (b).

15 https://www.epo.org/en/legal/guidelines-epc

5. Consequences for European plant breeders

Even though patents on plant varieties and conventional plant breeding are prohibited in Europe, hundreds of patents on conventionally-bred tomatoes, lettuce, broccoli, maize and barley have already been granted, thus impacting more than 1300 conventionally-bred varieties. This is described in more detail below.

It also has to be taken into account that patent applications take several years to be decided. In addition, oppositions filed thereafter may again take several years. This legal uncertainty lasting over many years can significantly influence decisions made by breeders about which varieties and traits they will work on.

If patents on conventional plant breeding are not stopped, the situation in Europe will become more or less similar to the situation in the US, and larger companies will soon be able to control all the seeds in Europe, with or without genetic engineering. According to a report from the US Agricultural Services, the top four (Bayer, Corteva, ChemChina and BASF) own 97% of canola, 95% of corn, 84% of soybean, 51% of wheat, and 74% of cotton intellectual property rights.[16]

More than 1300 conventionally-bred varieties are impacted by patents

The PINTO database[17] established by European Seed Association (ESA), lists 115 European patents as of June 2024; the number of varieties affected by these patents was 1365, comprising more than 40 plant species. More than 400 varieties are currently affected by more than just one patent, and just one single variety can be affected by up to six patents. The number of plant varieties covered by patents doubled between 2020 and 2024 (see Figure 2).

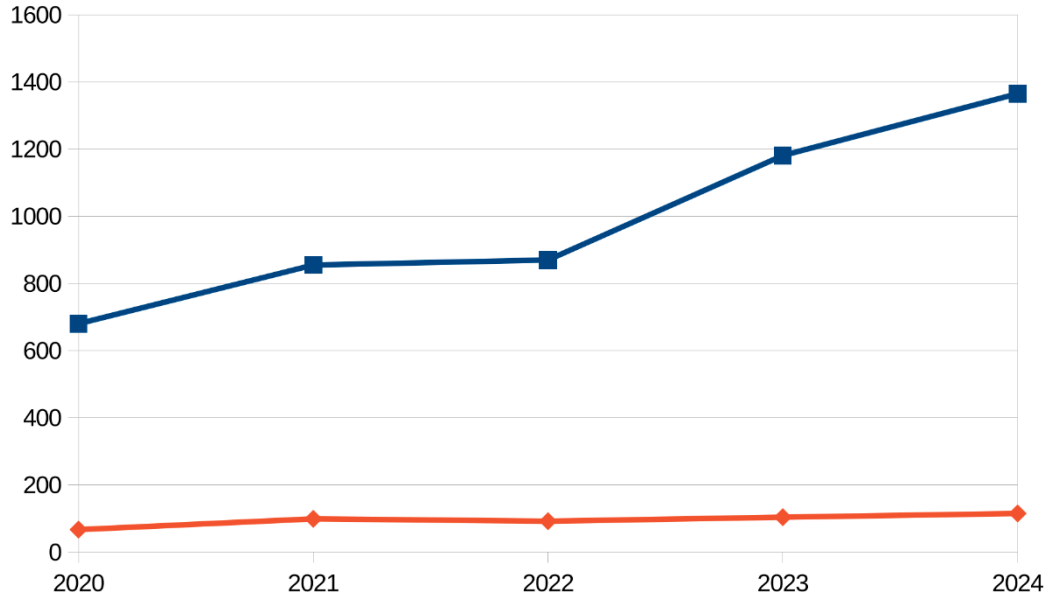

Figure 2: Number of European patents (red line) and of conventionally-bred varieties (blue line) affected by patents from mid-2020 until mid-2024 (data collected by *No Patents on Seeds!* from the PINTO database).

16 https://www.ams.usda.gov/sites/default/files/media/SeedsReport.pdf
17 www.euroseeds.eu/pinto-patent-information-and-transparency-on-line

The companies holding the highest numbers of patents are Bayer (Seminis/Monsanto), BASF (Nunhems) and Rijk Zwaan, with each holding 20 patents. They are followed by ChemChina/Syngenta (19) and KWS (8). Table 5 gives an overview of patents affecting numerous plant varieties.

Table 5: Overview of some patents which affect numerous plant varieties (data collected by *No Patents on Seeds!* from the PINTO database)

Patent number	Content	Company	Number of varieties concerned
EP3282016	Resistance to Rhizomania in sugar beet	KWS	175
EP2464215	Enhanced production and quality in maize	Syngenta	126
EP2464213	Enhanced production and quality in maize	Syngenta	125
EP3011037	Resistance to Rhizomania in sugar beet	KWS	122
EP2961263	Lettuce with resistance to downey mildew	Bejo Zaden	121
EP2515630	Drought tolerance in maize	Syngenta	93
EP3567111	Resistance to nematodes in sugar beet	KWS	65
EP2451269	Resistance to pathogen in lettuce	Syngenta	56
EP1804571	Virus resistance in sweet pepper	Monsanto	47
EP2773185	Spinach with resistance to downey mildew	Rijk Zwaan	39
EP1973396	Reduced browning in lettuce	Rijk Zwaan	38
EP0921720	Aphid resistance in lettuce	Rijk Zwaan	37
EP1525317	Clubroot (fungal disease) resistant *Brassica oleracea* plants (Broccoli, Brussels sprouts, Cauliflower, Cabbage)	Syngenta	37
EP3041345	Maize resistant to *Helminthosporium turcicum* (fungal disease)	KWS	36
EP4181663 (WO2022013452)	Tomato with resistance to TBRFV	Rijk Zwaan	32

While the database does provide a degree of transparency, the information it contains is not wholly reliable: input to the database is voluntary, making it very likely that several patents covering conventional breeding are not listed. Furthermore, the patents that are listed have not always been granted, but may be still at the examining stage, or may never come into force, for example, EP4181663 for tomatoes with resistance to the Tomato Brown Rugose Fruit Virus (equivalent to WO2022013452, see Table 3) is still being examined by the EPO. Furthermore, it remains unclear which patents claim selection methods and which cover plants and seeds. It might be in the interests of the company to create the impression of patent protection whilst, in reality, the seeds could be used without license agreements.

License platforms such as the Agricultural Crop Licensing Platform (ACLP)[18] proposed by industry as a solution cannot solve the problems: for example, several license contracts might be needed to produce a single trait, e.g. resistance to the Tomato Brown Rugose Fruit Virus. In addition, simply crossing even two conventionally-bred varieties may already involve more than 10 patents. Whatever the case, dependencies on large companies will increase strongly in future.

This situation could very well end diversity in European plant breeding, thus leading to even further market concentration and enabling a few large international agrochemical companies to take charge of our food. The consequences will impact all sectors in future breeding, e. g. adaptation to climate change, sustainability and food security. Therefore, this is a major problem for the general public and the future of our food, which can and must be solved by political decision-making.

6. How the EU can stop patents on biodiversity

Essentially, the access to biological diversity, which is necessary to meet the challenges of climate change and food security, must not be controlled, hindered or blocked by patents. Patents on processes based on crossing, selection, the use of natural genetic variations or the results from random mutagenesis must be prohibited.

The EU, therefore needs to clarify that (if at all) only genetically modified plants can be patented. Resolutions passed in 2012, 2015 and 2019 by the European Parliament tried to enforce the current prohibitions in patent law regarding conventionally-bred plants varieties, and thus to stop the European Patent Office (EPO) from granting such patents.[19]

The EU tried to enforce these prohibitions in 2017 by initiating the decision of the Administrative Council of the EPO on Rule 28 (2), but with only partial success. Meanwhile, more than 1300 conventionally-bred varieties are affected by patents.

The EU Parliament adopted a proposal in 2024 on the future regulation of NGT plants. This proposal aims to exclude patents on NGT plants, and may also exclude patents on conventionally-bred plants, including random mutagenesis.[20] However, the EU cannot force the 39 contracting states of the European Patent Convention (EPC) to exclude genetically engineered plants (including NGT plants) from patentability, as these patents are explicitly allowed by EPC, and also in the national patent laws of its contracting states.

When the Council of EU Member States discussed the future regulation of NGT plants, it tried to avoid a clash of legal norms. Instead, the Belgium Presidency proposed a regulation that would leave the initiative up to industry. In short, if companies want fast track market access, they need to restrict their patent claims to NGT processes and not claim comprehensive patent protection ('absolute product protection') for the plants and their seeds. However, also this proposal raises complicated legal questions. For example, it is unclear whether patent law and risk assessment can be linked in this way: why should a non-patented NGT plant undergo a less rigorous risk assessment than a plant that is patented? And how does this plan avoid patents on randomly mutated plants? It is no surprise that this proposal did not find any majority.

18 https://aclp.eu/

19 2012: https://www.europarl.europa.eu/doceo/document/TA-7-2012-0202_EN.html?redirect;
2015: https://www.europarl.europa.eu/doceo/document/TA-8-2015-0473_EN.html?redirect;
2019: https://www.europarl.europa.eu/doceo/document/TA-9-2019-0020_EN.html.

20 https://oeil.secure.europarl.europa.eu/oeil/popups/printsummary.pdf?id=1775085&l=en&t=E

Against this backdrop, it appears that a two-step approach will be needed to solve the most pressing problems:

1. Strengthening the existing prohibitions in respect to conventional breeding. This could be resolved simply by correcting the interpretation of the EPC. This could be achieved by the Administrative Council of the EPO and/or by amending EU patent directive 98/44, as the latter is used as a guideline for interpretation of the EPC. At the same time, there is also the option of amending national patent laws.

2. Change the EPC to exclude all patents on plants (and animals) even if they are obtained from genetic engineering. The necessary steps can only be taken by a diplomatic conference of the contracting states of the EPC. It would need to be followed by mandatory changes in the national patent laws. This would mean that the EU patent directive would no longer be applicable.

These approaches are different not only in their aims and the institutions involved, but also in regard to the speed with which these goals can be achieved, as measures to correct the interpretation of existing patent law can be taken at any time by the Administrative Council of the EPO (it meets four times a year), but changes to the EPC require a diplomatic conference that typically needs several years preparation. In the follow up to the diplomatic conference, the changes would have to be ratified by the legislators of the contracting states. This ratification process will itself also take several years.

Therefore, while patents on NGT plants will remain an unresolved issue for the coming years, the EU could easily close the gaps to at least maintain freedom to operate for conventional breeders.

Austria is leading the way: No patents on conventionally-bred seeds!

The legislator in Austria has already successfully amended national patent law and limited patents to genetically engineered seeds. According to the Austrian Patent Act, patents are not permitted if they are "based on natural phenomena such as crossing, selection, non-targeted mutagenesis or random genetic modifications occurring in nature." Furthermore, the effect of patents "does not extend to plants or animals with the same specified properties which are produced independently of the patented biological material and by essentially biological processes".[21]

These legal provisions could be integrated into the EU patent directive 98/44 by using, e. g. the wording as presented in the box below.

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

Proposed wording for changes to the EU patent directive 98/44 to exclude patent on conventionally bred plants

Article 2 (2) is replaced by
"2. A process for breeding of plants or animals is essentially biological, if it consists entirely of conventional breeding techniques such as crossing, selection, or the use of random or naturally occurring genetic variations."
Article 4 (1) is replaced by:
"1. The following shall not be patentable:
(a) plant and animal varieties,
(b) plant material and parts thereof, as well as genetic information contained therein, which have been obtained by plant material and parts thereof, as well as genetic information contained therein, which have been obtained by non-targeted mutagenesis.
(c) essentially biological processes for the production of plants or animals as well as plants or animals exclusively obtained by means of an essentially biological process and the genetic information contained therein."
At article 8, paragraph 3 is inserted:
"3. By derogation to paragraphs 1 and 2, the protection conferred by a patent on biological material, or extending to the use of the biological material, possessing specific characteristics as a result of the invention, shall not extend to biological material possessing these specific characteristics when these have been obtained independently from the patented invention."

If these regulations came into force, the EU could clarify that only genetically engineered plants can be patented, as intended by the EU Patent Directive 98/44. In this context, the EU patent directive 98/44 could be used as a binding guideline for the interpretation of the EPC.

However, if the initiatives to ban patents on conventional breeding fail, the situation in Europe will be more or less the same as in the US. The freedom to operate for conventional breeders will be ended, smaller European plant breeders will vanish from the market, agrobiodiversity may be severely reduced and choice for farmers, food producers and consumers severely restricted.

7. Free the seeds!

As long as patents on plants are not completely prohibited in Europe, *No Patents on Seeds!* will campaign to at least safeguard the 'freedom to operate' for all European conventional breeders. Access to biological diversity needed for further breeding must not be controlled, hampered or blocked by patents.

This 'freedom to operate' is the precondition for the future of:

- Diversity in the fields,
- Farmers' rights,
- Choice for consumers and
- Food security and food sovereignty.

According to our analysis, there are three crucial areas that need to be changed to make current prohibitions regarding patents on conventionally-bred plant and animals effective:

1. Definition of "essentially biological processes"

It has to be made clear that the term "essentially biological processes" covers all conventional breeding processes, including random mutagenesis as well as all individual steps in the process, such as selection and / or propagation. As far as conventional breeding is concerned, any use of genetic resources that occur naturally must be excluded from patent law.

2. Definition of 'products' used or derived from breeding

It has to be made clear that all 'products' used in or emanating from 'essentially biological processes' are captured by the exclusion from patentability, including all plant and animal varieties, plant/animal parts, cells and genetic information.

3. Limiting the scope of protection

In the context of plant and animal breeding, the EPO must not grant unrestricted product protection that enables a patent on a plant or animal derived from a technical process to be extended to all conventionally-bred plants with the same traits.

Consequently, patents on processes including crossing and selection, or the use of naturally occurring or randomly generated genetic variations, have to be prohibited, as does the extension of patents on genetically engineered processes to plants and plant varieties obtained from conventional breeding.

The correct interpretation of the EPC should be implemented as soon as possible by vote in the Administrative Council of the EPO, which meets four times a year. A three-quarter majority would be sufficient. The EU would already have about 27 of the 30 votes needed for a majority. The necessary clarifications should also be introduced into the EU patent directive 98/44. In addition, national legislation of the contracting states of the EPO should be amended to include the correct interpretation of patent laws.

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