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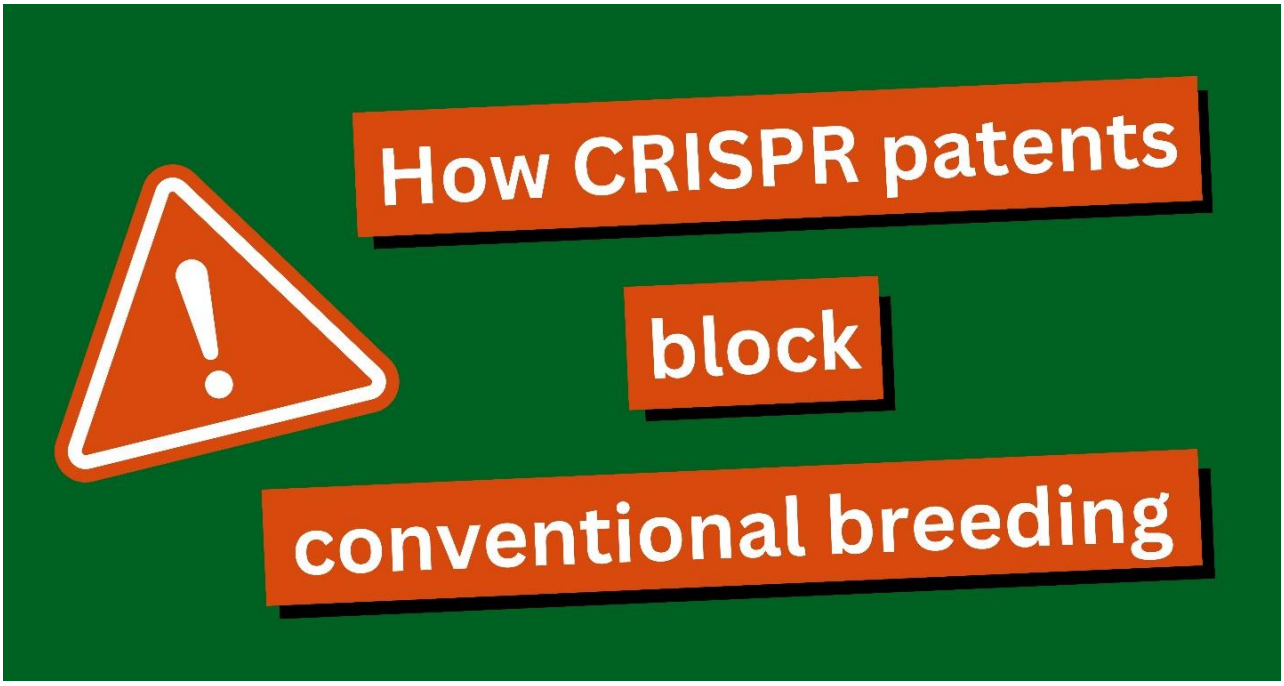

Table of contents

Summary

New *No Patents on Seeds!* research into international patent applications published in 2023 shows how CRISPR/Cas technology and new genetic engineering (NGTs) are being used to extend patent protection to conventionally-bred plants.

In many cases, gene variants and traits found in existing plant populations are being 're-invented' with NGTs to create the impression of a technical invention, which can subsequently be used as a basis to file patent applications.

To 're-invent' the plants, traits found in existing plant populations are reproduced by using tools like the gene scissors CRISPR/Cas. Also, random mutagenesis is used to create the same or similar gene variants. From a plant breeders' perspective, these processes are not necessary to derive to the desired traits. Only for a company that wants to get a patent these processes for 're-inventing' make sense: They can claim the traits as their invention.

Consequently, these patents are not restricted to genetic engineering processes, but are also a problem for conventional breeders: The patents claiming these 're-invented' plants not only cover plants obtained from (targeted) NGTs, but also plants obtained from (non-targeted) random mutagenesis. Previously, plant varieties inheriting random mutations were placed on the market without patents and could be used freely by other breeders to develop and market further plant varieties.

Breeding companies are filing these patent applications and, with 'support' by the European Patent Office (EPO), are attempting to blur the distinctions between technical inventions and random processes. If granted, the patent holders could control access to plants, regardless of whether genetic engineering is used or not.

The analysis of current EPO practice shows that patents on randomly mutated plants are indeed being granted, thus expanding patent monopolies beyond the processes of genetic engineering. As a result, conventional breeders' freedom to operate is being eroded. Even though European patent law prohibits patents on plant varieties and conventional breeding, more than 1000 European plant varieties are already affected by patents. The existing data shows that a single patent can impact dozens of varieties and that several varieties are affected by several patents already.

This backgrounder provides an overview of recent examples of patent applications, and also provides an insight into current EPO practice. Plant species affected by recent patent applications include tomatoes, carrots, cucumber, lettuce, broccoli, pepper, spinach, maize, wheat, barley and soybeans. Many of the patent applications also claim the food products derived from these plants.

In addition, the backgrounder explains the differences between conventional breeding and genetic engineering from the perspective of patent law. The EU needs to clarify that if patents are granted on plants, they must be restricted to the technical processes of genetic engineering and not include other methods of breeding.

Background

European breeders currently should have free access to all conventionally-bred varieties or native plants for use in producing new varieties. This is known as the breeders' privilege and is guaranteed by the plant variety protection (PVP) system - which is designed to provide freedom to operate and is known to promote innovation in European plant breeding. It also ensures 'open access' to biodiversity necessary to produce 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 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: 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.[1]

Plants obtained from random mutations could until now be used freely by all European breeders under the plant variety protection (PVP) law, and were not previously covered by patents. At present, there are several thousand varieties on the global market[2] that were originally obtained from random mutagenesis, and can, therefore, be used freely for 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 expanding the patent law beyond the realm of genetic engineering (see Table 1).

Current EPO practice is in conflict with the EPC

Rule 28 (2) for the interpretation of Article 53(b) was introduced into the EPC in 2017. This rule strengthens the prohibitions in Article 53(b) in regard to conventional breeding, and excludes patents on plants and animals obtained from crossing and selection. At the same time, an unusual explanatory note introduced by the President of the EPO explicitly allowed patents on plants obtained from random mutagenesis.

Random mutagenesis processes using chemical compounds or physical stressors (radiation) to increase genetic diversity can be patented as technical processes. However, the genetic variations and plants obtained from these processes were not previously considered to be inventions. Earlier EPO decisions (G2/07 and G1/08) confirmed this difference, clarifying that only traits obtained from direct insertion can be regarded as technical invention. It is obvious that random mutagenesis is different to genetic engineering in this regard since physical and chemical stressors only allow to randomly increase genetic diversity. These processes do not enable targeted insertion of a desired

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

trait. Table 1 lists some general differences between random mutagenesis (and conventional breeding in general) and genetic engineering in regard to patent law.

Table 1: 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).

Also, the examination guidelines of the EPO 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.*"[3]

However, it is apparent in some patents recently granted by the EPO that the fundamental differences between genetic engineering and random processes are being blurred. The most recent decisions are listed in Table 2, and show that the EPO considers genetic variations and plants obtained by random mutagenesis to be technical inventions. These cases, although limited in numbers, are especially relevant, as the EPO has for the first time begun to apply Rule 28 (2) to the examination of patent applications.

[3] https://www.epo.org/en/legal/guidelines-epc

Table 2: Patents granted by the EPO under Rule 28 (2)

EP Number	Company	Plant species, traits and claims	Comment
EP 3560330	KWS	Maize with higher digestibility. Claims: methods for selection and production of plants, including the plants and harvest.	Plants were originally derived from existing varieties, random mutagenesis. New GE was used to 're-invent' the trait.
EP3447134	KWS	Maize with increased fungal resistance, preferably against Northern Corn Leaf Blight. Claims: plant production method	Method of producing plants based on random mutagenesis or New GE
EP3747263	Klemm	Euphorbia pulcherrima (Poinsettia, also known as Christmas Star) with white foliage phenotype Claims: method of selecting and producing plants, including the plants that are grown	Random mutagenesis, i.e. UV, radiation, chemicals and CRISPR
EP3984355	Klemm	Double flowering dwarf Calibrachoa Claims: markers and methods for identification.	The EPO made a distinction between spontaneous mutations and induced mutations (both using sunlight).

How CRISPR/Cas gene scissors are being used to undermine the freedom of conventional plant breeders

New patent application research carried out by *No Patents on Seeds!* shows how CRISPR/Cas technology is being used in the most recently filed applications to undermine the freedom to operate in conventional breeding.

The starting point for nearly all of these patent applications is the detection of already existing gene variants in the plant populations. CRISPR/Cas (new genetic engineering, NGTs) is then subsequently used to 're-invent' (or imitate) the plants: The gene variants and traits (like resistance to plant pathogens) found in existing plant populations, are reproduced by using tools like the gene scissors CRISPR/Cas. In these cases, it appears that NGTs were simply used to create the impression of a technical invention, while in reality, the plants are actually obtained from non-technical processes. NGTs are simply used as technical topping without actually being necessary.

Also, random mutagenesis is used to create the same or similar gene variants. Careful reading of the patents revealed that not only are NGTs simply added as a top-up; in most cases, also random mutagenesis actually appears to be superfluous. In these cases, random mutagenesis is apparently being used in the patents to extend the claims beyond genetic engineering.

Consequently, if the patents are granted, the companies can claim the genetically engineered (NGT) plants as well as characteristics of randomly mutated (conventionally-bred) varieties. The gene variants obtained from the technical processes and processes routinely used in conventional breeding will thus be subjected to 'monopoly' patent claims.

It appears that the companies are filing these patent applications in order to systematically and intentionally blur the distinction between technical inventions and random processes. This would ultimately put an end to the freedom to operate for conventional breeders. In many cases, they cannot be sure if they might infringe patents even if they only use conventional varieties.

Table 3: Patent applications published in 2023. The relevant gene variants were found in existing plants, new genetic engineering was added as technical topping, but is not absolutely necessary. In addition, random mutagenesis was introduced to extend the claims beyond genetically engineered plants.

	Patent application	Company	Plant species, traits
1.	WO2022234584	Tomatech	Tomato with resistance to Tomato Brown Rugose Fruit Virus
2.	WO2023095144	Volcano Institute / Israel	Tomato with resistance to Tomato Brown Rugose Fruit Virus
3.	WO2023135335	Rijk Zwaan	Tomato with resistance to Tomato Brown Rugose Fruit Virus
4.	WO2023156569	Syngenta	Tomato with resistance to Tomato Brown Rugose Fruit Virus
5.	WO2023144828	Philoseed	Tomato with resistance to Tomato Brown Rugose Fruit Virus
6.	WO2023194291	Syngenta / Nunhems/ Rijk Zwaan / Takii	Tomato with resistance to Tomato Brown Rugose Fruit Virus
7.	WO2023020938	BASF/Nunhems	Lactuca plants with delayed bolting (start of flowering) to increase their size at harvest.
8.	WO2023051902	Bejo Zaden	Lactuca plants that are resistant to a fungal pathogen (downy mildew or Bremia lactucae).
9.	WO2024002949	Enza Zaden	Lactuca plants that are resistant to a fungal pathogen (Fusarium wilt or F. oxysporum).
10.	WO2023232265 WO2023117154	Enza Zaden	Lactuca plants that are resistant to a fungal pathogen (downy mildew or oomycetes).
11.	WO2023275048	BASF/Nunhems	Watermelon with dwarf phenotype (higher branching)
12.	WO2023004429	BASF	Brassicaceae with resistance to blackleg
13.	WO2023012342	KWS	Spinach with resistance to downy mildew
14.	WO2023006933	KWS	Maize with higher digestibility
15.	WO2023012325	Vilmorin	Capsicum with resistance to powdery mildew
16.	WO2023019172	Pioneer	Pearl millet with lower rancidity (longer shelf life)
17.	WO2023019314	CSIRO	Wheat with changes in starch composition
18.	WO2023046288	Bejo Zaden	Carrots with resistance to tropical root knot
19.	WO2023052561	BASF	Wheat with higher yield
20.	WO2023131639	KWS	Several species with higher level in fructose, higher yield, improved stress resistance
21.	WO2023151004	Syngenta	Soybean with changed oil and protein content
22.	WO2023151007	Syngenta	Soybean with changed oil and protein content
23.	WO2023165711	Enza Zaden	Tomatoes with resistance to wilt virus
24.	WO2023170272	Carlsberg	Barley and yeast with reduction of specific enzymes
25.	WO2023187757	Benson Hill	Soybean with reduction in saponins
26.	WO2023232429	Bejo Zaden	Broccoli with reduction in anthocyanins

As shown in the list of patent applications, random mutagenesis is the 'Trojan Horse' being used to introduce patents covering conventionally-bred varieties. In the past, genetic variations obtained from random mutagenesis were used in plant breeding for decades without patents being filed to claim the plants. Indeed, according to European patent law, these non-predictable and non-targeted processes cannot be regarded as technical inventions. However, the patent holder can now control further breeding, regardless of whether genetic engineering is used or not.

These patents will have detrimental effects on European plant breeders even before they are granted, as they lead to legal uncertainty, and thus act as a deterrent in the production of new varieties: conventional breeders who want to develop and market improved varieties and, at the same time, avoid any patent infringement would, in many cases, need to analyse dozens of patent applications. Alternatively, breeders may try to get licenses with several companies.

In summary, these circumstances are extremely problematic for conventional breeders or also for farmers that are breeding actively, as they would create new dependencies and major legal uncertainties, and are thus likely to extensively hamper future plant breeding. In many cases, it will not be possible to find out if the traits inherited in the plants are derived from random mutagenesis. This is different from seeds being labeled as genetically engineered.

Consequences

Hundreds of patents on conventionally-bred tomatoes, lettuce, broccoli, maize and barley have already been granted, even though patents on plant varieties and conventional breeding are prohibited in Europe. The patents affect more than 1200 conventionally-bred varieties. The existing data show that a single patent can impact dozens of varieties and that several varieties are affected by several patents already.[4] Most of these patents were granted before Rule 28 (2) came into force. However, as shown above, the introduction of Rule 28 (2) will not stop patents being granted on conventionally-bred plants even though this was the intention.

These patents are detrimental to European plant breeders even before they are granted, as they lead to legal uncertainties, and thus have a deterrent effect on the production of new varieties:

- the claims are not restricted to genetically engineered plants, but extend to characteristics present in conventional plants;
- one single variety may need several licenses before marketing can commence;
- it is unclear which patents will ultimately be the most relevant and, therefore, unclear which patent holder should be approached for a license;
- the costs for some of the licenses are reportedly very high, especially for smaller breeders;
- 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, Syngenta and KWS.

In addition, the license platforms proposed by industry as a solution cannot solve the problems: several license contracts may be needed with several companies to produce the desired traits, thus again strongly increasing dependencies on larger companies. As a result, legal uncertainty and the threat of incurring high costs are likely to prevent them from breeding the desired varieties.

[4] https://euroseeds.eu/pinto-patent-information-and-transparency-on-line/

This situation is likely to put an end to diversity in European plant breeding. It will cause further market concentration and hand the future of our food to a few large international agrochemical companies.

The consequences will impact all sectors in future breeding, e. g. adaptation to climate change as well as sustainability and food security. Therefore, this is a major problem both for the general public and the future of our food. It can and must be solved by political decision-making.

How the EU can stop patents on seeds

The independence of traditional breeders in Europe must be maintained. The necessary access to biological diversity, which is also essential to meet the challenges of climate change and future food security, must not be controlled, hindered or blocked by patents. Not only patents on plants obtained by processes such as crossing, selection and the use of natural genetic variations must be prohibited, but also those on plants derived from random mutagenesis. Similarly, patents on food products derived from such plants, must be stopped. This includes for example, patents on barley and beer or tomatoes.

Therefore, the EU needs to clarify that (if at all) only genetically modified plants can be patented, but conventionally-bred plants and the free use of conventionally-bred plants cannot be obstructed by granting patents on technical processes or on genetically engineered plants.

Resolutions passed in 2012, 2015 and 2019 in the European Parliament were an attempt to enforce the current prohibitions in patent law in regard to conventionally-bred plant varieties, and thus stop the European Patent Office (EPO) from granting these patents.[5]

The legislator in Austria has already successfully amended national patent law and limited patents to cover 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*"[6]

The EU now has the chance to adopt similar wording in EU Patent Directive 98/44 (Art. 2.2 or Art. 4.1), and thus put an end to the abuse of patent law as well as stop large corporations from taking extensive control of the genetic resources needed for our future food production. These legal provisions could be integrated into the EU Patent Directive 98/44 by using e. g. the wording in the box below.

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5 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

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

Box: Proposed wording for changes to EU Patent Directive 98/44 to exclude patents 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 from 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."

Further information can be found on the website of *No Patents on Seeds!*:
https://www.no-patents-on-seeds.org/en/background/publications