NO PATENTS ON SEEDS!

The future of plant breeding is under threat in Europe

Current interpretation of patent law is insufficient to stop patents on conventional breeding

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

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Summary

This report provides an overview of granted patents and patent applications with claims covering conventional plant breeding in Europe. The past decade has seen a growing number of patent applications filed for conventionally-bred plants used in food production. These include broccoli, tomatoes, melons, spinach, lettuce, maize, wheat and barley. It is mostly international companies from the agrochemical sector that are filing these patents, e. g. Bayer, BASF, Syngenta and Corteva, but also some traditional breeders such as Rijk Zwaan and KWS.

These patents are a violation of European patent law which prohibits patents on plant varieties and conventional breeding. According to Article 53 (b) of the European Patent Convention (EPC), plant and animal varieties as well as conventional breeding are excluded from patentability. However, in 1998 the EU adopted Directive 98/44 on the legal protection of biotechnological inventions (EU patent directive). Adoption of this directive allowed patents to be granted for the first time (only) on inventions related to the genetic engineering of plants and animals. However, the prohibitions in Article 53 (b) remained effective for plants and animals derived from conventional breeding.

The strategy of the companies

In order to obtain patents on conventionally-bred plants, companies, therefore, frequently introduce specific wording into patent applications, which appears to suggest the use of genetic engineering processes. However, a closer look at the patents included in this report shows that, in most cases, these technical methods were not applied and were simply not necessary to develop the desired plants.

Most patent applications attempting to claim exclusive rights to conventional breeding are for plants which inherit specific gene variants. A typical patent application starts with a claim covering a plant trait and a specific genotype, regardless of the method used in the process. In addition, the patent claims cover the seeds, progeny, harvest and the usage of marker genes that are necessary for the selection and successful crossing of the plants.

It is obvious from the patent descriptions that methods, such as selecting gene variants from existing plant populations or screening for random mutations, are decisive for the production of the claimed plants. These methods are typical for processes of conventional breeding. Technical processes are also frequently mentioned, e. g. transgenesis or new genomic techniques, even though, in reality, the plants have been obtained through conventional breeding.

Ultimately, the strategy behind these patents is designed to enable companies escape the prohibitions in Article 53 (b), and thus establish claims on the biological resources (gene variants) needed by all breeders. As a further consequence, this also allows to claim plants resulting from further breeding as an invention that inherit the relevant gene variants.

Patent applications claiming thousands of gene variants

In 2022, there were around 100 patent applications with claims covering conventional plant breeding. The patent applications frequently claim genetic variations known as ‘single nucleic polymorphisms’ (SNPs). Polymorphisms may be associated with favorable biological effects and can be found in most genes within each species. SNPs can confer desired plant characteristics such as greater tolerance to plant diseases. The relevant genetic variations are often found in native populations that are crossed with the commercial varieties. For example, the publication of a patent application filed by Syngenta/ChemChina shows that the company is trying to claim around 45.000 SNPs in wild relatives of soybeans as their invention (WO2022173659).

Patent granted to KWS for cold-tolerant maize (EP 3380618)

In 2022, more than 20 patents were granted for conventional plant breeding. One of those patents is EP 3380618 owned by KWS. The maize claimed in the patent was produced by using existing maize lines that were already known to tolerate colder climate conditions such as those in northern Europe. The genome of the plants was analyzed and so-called marker genes (gene variants) were identified that could be used for screening and selecting the desired traits.

Interestingly, tools such as CRISPR/Cas are mentioned in the description of the patent. However, new genomic techniques were not applied and are also not necessary to obtain plants which already exist in nature. This case and others highlight how CRISPR/Cas is frequently abused as a tool within the patent system to take over the genetic resources of biological diversity needed for traditional plant breeding.

It has to be assumed that plants with the described genotype and phenotype are present in several plant varieties already on the market. This patent creates a monopoly for the patent holder for further usage of all of these plants. The patent holder can thus try to stop all other breeders from using these varieties for producing and marketing of new varieties with the claimed characteristics, which is otherwise guaranteed by the breeders' privilege.

Such patents can hamper future breeding and even go as far as creating difficulties for breeders who own varieties where any of the plant material described in the patent was used in an earlier breeding process. License contracts with the patent holder would be the only way out of this problem – but this typically would create new dependencies, additional costs and in result end the breeders' freedom to operate.

In general, such patents can be used to hamper or even block access to the biological resources needed by other breeders to develop new maize varieties that, for example, are cold tolerant. These kinds of patents are, therefore, a threat to all breeders active in the field, who rely on the freedom to breed using existing varieties to produce new varieties, and thus adapt to present and future challenges. Beyond that, there is a risk that farmers and our future food security as well as food sovereignty may be severely impacted. In many cases, the patents also cover the use of the harvested plants for food production. As a result, breeders, farmers and consumers are all at risk of becoming more and more dependent on big companies that can control access to biological resources needed for further breeding.

The global impact of patents on seeds

Patents granted on genes, seeds and food represent one of the biggest risks to both global food security and regional food sovereignty. Patents on genes can block the usage of biological diversity for all kinds of breeding, for all plants and animals. Patents on variants of important genes can, in particular, result in a patent thicket for all medium sized and smaller breeders. The breeder's exemption, which under the plant variety protection system, provides breeders with free access to use the existing plant varieties and freedom to operate in Europe could, very soon, become a thing of the past.

If this development is not stopped, plant breeding as we know it will end: there will be no way for a traditional breeder to use the existing varieties or native populations for breeding without risking patent infringement Consequently, many breeders will either have to stop breeding or become dependent on bigger companies through having to take out license contracts with patent holders.

All this will also have consequences for the Global South, where many countries have adopted legislation to allow patents on seeds. Previous findings[1] indicate that 75 of the 126 countries in the Global South for which data were available, are ready to allow the patenting of plants, or parts thereof. Many such patents have already been identified. This could threaten food sovereignty in these countries as well as traditional regional production, propagation and seed exchange.

The political demands

No Patents on Seeds! wants to safeguard 'freedom to operate' for all European breeders, market gardeners and farmers involved in conventional breeding, growing and propagation of food plants and farm animals. Access to biological diversity needed for conventional breeding must not be controlled, hampered or blocked by patents. Global food security and food sovereignty must not be endangered by exclusive property claims on biological diversity needed for plant breeding.

Consequently, patents on breeding processes, including crossing or selection as well as the use of naturally occurring or randomly generated genetic variations, have to be prohibited, as any extension of patents to genetically engineered plants and animals to the respective varieties generated by conventional breeding.

The correct interpretation of the EPC should be implemented as soon as possible by a simple majority vote in the Administrative Council of the EPO, which meets four times a year. In addition, national legislation of the contracting states of the EPO should be adopted with the correct interpretation of patent laws. A first model law was established in Austria in 2023. Article 2, para 2.3. reads (own translation): "*A process for breeding of plants or animals is essentially biological, if it is exclusively based on natural phenomena such as crossing, selection, non-targeted mutagenesis or random genetic variations that occur in nature.*"[2]

1 https://onlinelibrary.wiley.com/doi/full/10.1111/jwip.12143
2 https://www.parlament.gv.at/gegenstand/XXVII/ME/229?selectedStage=100

1. Introduction

'Patents on life' with claims covering plants and animals as 'inventions' first emerged in Europe in the 1980s when companies such as Monsanto started to produce genetically engineered plants. Patents on plant and animal varieties are explicitly prohibited in Europe.[3] Nevertheless, with the support of patent attorneys and the European Patent Office (EPO), the biotech industry succeeded in making patents on seeds a reality. These developments were driven by vested interests, as the agrochemical companies, patent attorneys and the EPO all profit from the patent business. Meanwhile, according to official classifications, more than 4000 patents on plants and 2000 patents on animals have been granted in Europe, mostly for genetic engineering.

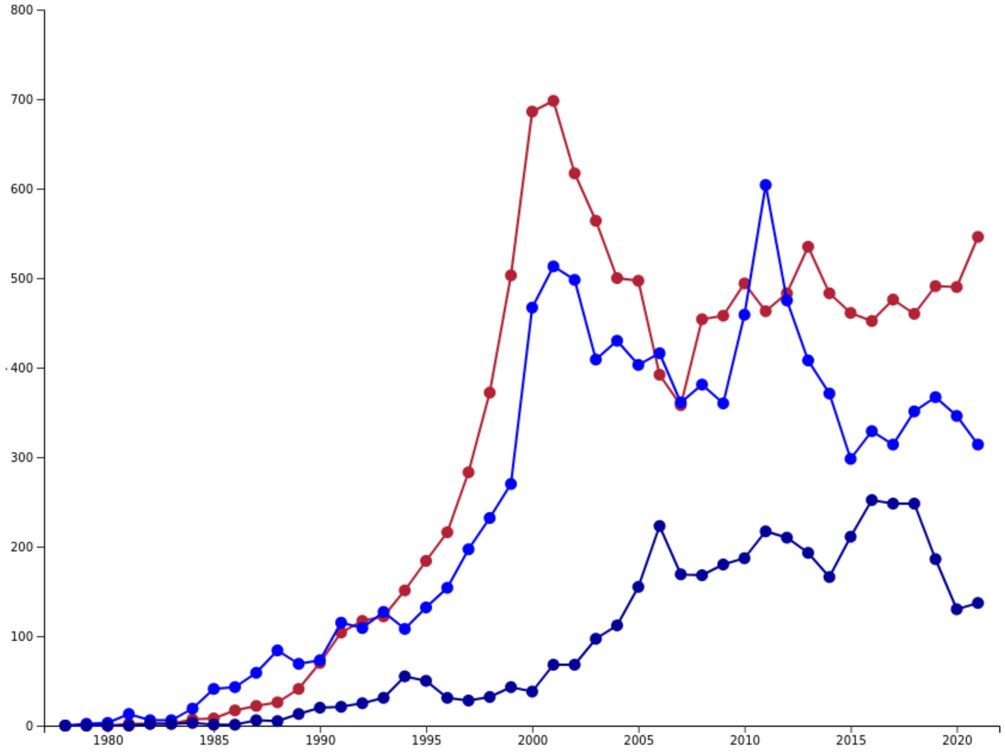


Figure 1: Patents on plants – the number of all patent applications filed for plants under the PCT/WIPO (upper /red line) and at the EPO (middle / lighter blue line), including patents on plants granted by the EPO (lower / darker blue line) per year. Research according to official classifications (IPC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

At the present time, there is an alarming trend in patents being extended to conventional breeding: around 100 new patent applications per year were filed in Europe for conventional plant breeding (via EPO or WIPO) over the last ten years. More than 1500 patent applications have been filed altogether, and around 700 are currently pending. More than 300 patents have already been granted, even though patents on 'essentially biological' (non-technical) plant and animal breeding are prohibited in European patent law (Article 53(b), European Patent Convention, EPC; EU Directive 98/44, Article 4.2). These patents are frequently an abuse of patent law, as they are mostly based on trivial technical features, i. e. they use patent law as a tool to misappropriate biological resources needed for our daily food production. *No Patents on Seeds!* aims to stop these patents.

[3] https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar53.html

Every patent on conventionally derived traits can affect dozens or possibly even more than a hundred plant varieties on the market.[4] Depending on the business strategy of the patent holder, breeders may be required to sign license contracts, or patent holders may completely block access to the necessary biological material to strengthen their market position.

It should be noted that these patents are not just limited to plants and seeds, they can also cover the harvest and any food produced thereof. For example, patents covering conventionally-bred barley and the beer made with the barley were granted to Carlsberg and Heineken in 2016 and 2022.

A global perspective

Corporations, such as Bayer (Monsanto), Corteva (previously DowDupont/Pioneer), BASF and ChemChina/Syngenta, will become even more dominant if patents on plants and animals are not stopped. They already own more than 50 percent of the international seed market through acquisition of breeding companies all over the world.[5] Moreover, they could shut down free access to biological diversity needed by other breeders if they own patents on seeds.

As a result, a handful of big corporations will acquire far-reaching control over our daily food production - they will decide what we eat, what farmers produce, what retailers sell and how much we all have to pay for it.

Experience shows that the dynamics within the patent regimes mostly favour the larger companies, such as Corteva, Bayer, BASF and ChemChina (Syngenta), which were all originally agrochemical companies (see Figures 2 and 3). Traditional plant breeding companies, such as Rijk Zwaan and KWS (also Bejo Zaden, Enza Zaden and Vilmorin), have also shown some interest in filing patents. The patent applications are presented as a response to overall developments to counteract the predominant position of the agrochemical companies. However, it remains to be seen which of these latter companies will actually survive if the freedom to operate and the breeders' exemption guaranteed under plant variety protection (PVP) law were to be seriously undermined by patent law. Experience from the US breeding sector shows that diversity among plant breeding companies is likely to vanish if the patent system gains ascendance over the PVP system.

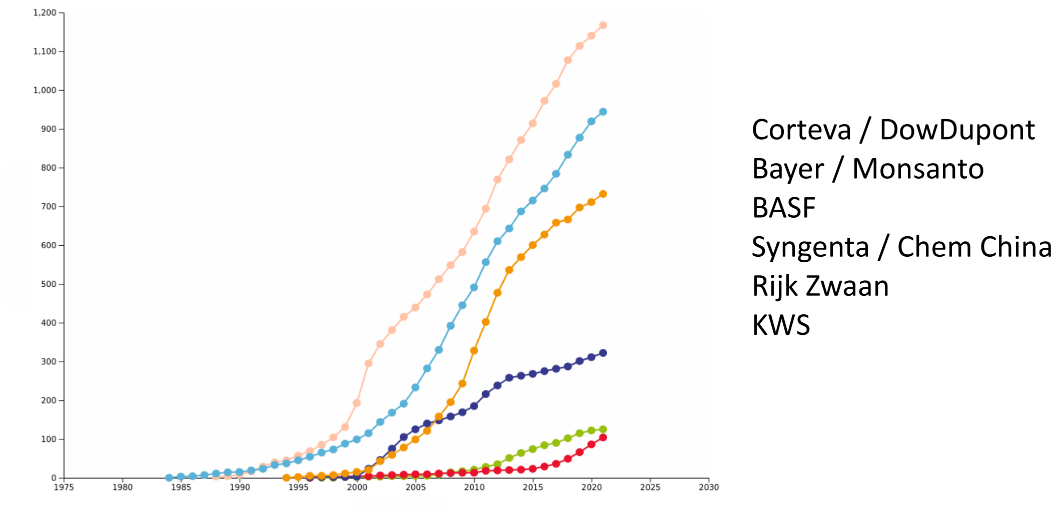


Figure 2: Patents on plants - number of all patent applications filed for plants under the PCT/WIPO, categorized by individual companies and accumulated since 1990. Research according to official classifications (IPC A01H or C12N15/82). Source: www.kein-patent-auf-leben.de/patentdatenbank/

[4] Report from *No patents on seeds!* (2022): https://www.no-patents-on-seeds.org/en/report2022

[5] See also: https://etcgroup.org/sites/www.etcgroup.org/files/files/etc_platetechtonics_a4_nov2019_web.pdf

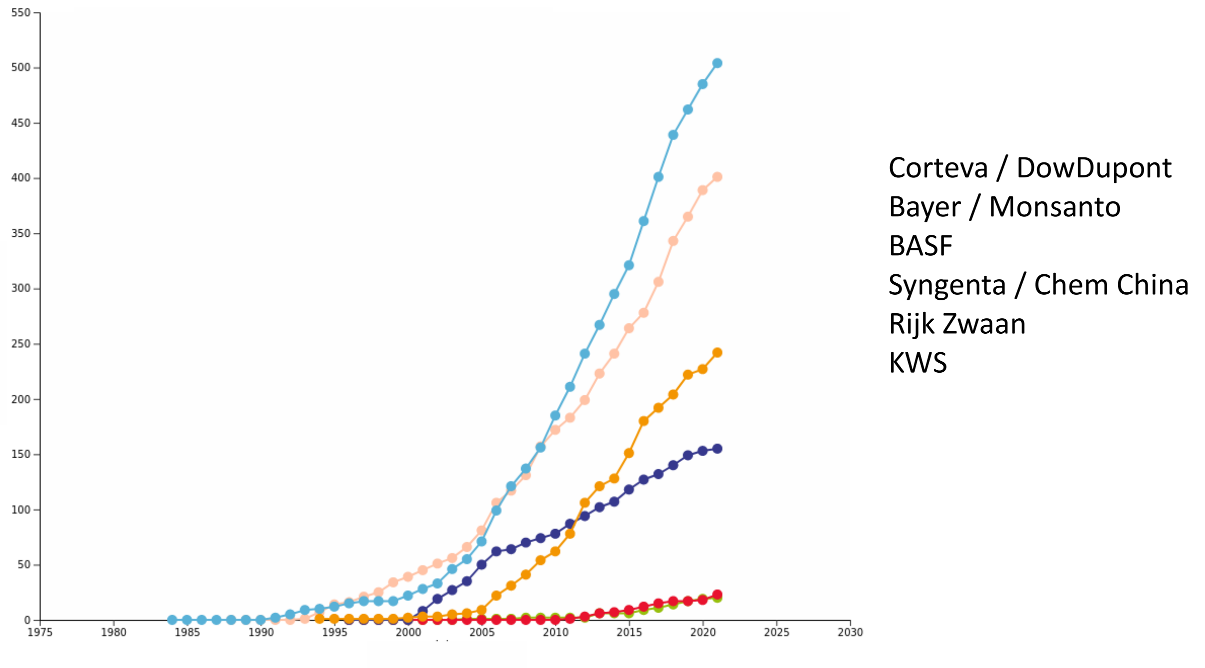


Figure 3: All EPO patents granted on plants, categorized by individual companies and accumulated since 1990. Research according to official classifications (IPC A01H or C12N15/82).
Source: www.kein-patent-auf-leben.de/patentdatenbank/

The above-described developments will also have consequences for the Global South, where many countries have adopted legislation to allow patents on seeds. Previous findings[6] indicated that 75 of the 126 countries in the Global South for which data were available are ready to allow the patenting of plants, or parts thereof. Many such patents have already been identified. This could threaten food sovereignty in these countries as well as traditional regional production, propagation and seed exchange.

From a global perspective, agro-biodiversity is one of the most important pre-conditions for the future of breeding, as well as for environmentally-friendly agriculture and adaptability of our food production to changing conditions, e. g. climate change. In this context, patents on seeds must be seen as one of the biggest risks to global food security and regional food sovereignty.

2. Research on patent applications published in 2022 covering conventional breeding

2.1 Overview

No Patents on Seeds! carried out extensive in-depth research on international patent applications in order to compile a comprehensive overview of the most recent international patents filed through the Patent Cooperation Treaty (PCT) at the WIPO (World Intellectual Property Organisation). Patent applications filed at the WIPO include more than 150 countries where patent protection could be issued. The WIPO itself does not grant any patents, but for many companies it is a first step in filing patent applications in multiple countries around the world. Looking at recent figures, estimates indicate that two thirds of patents filed for plants at the WIPO will also become European patent

[6] https://onlinelibrary.wiley.com/doi/full/10.1111/jwip.12143

applications. On average, around one third of the European patent applications in this field will be granted (for comparison see Figure 1).

The research is based on searches in several databases with specific International Classifications (IPC = A01H or C12N15/82) and names of relevant companies, as well as on the analysis of several hundred patent applications. During 2022 (and similarly to preceding years), around 300 patent applications were published covering plants and plant breeding, of which more than 100 applications cover conventional breeding.

Patent applications for plants with specific genetic variations

Most patent applications for conventional breeding claim plants which inherit specific gene variants. A typical patent application starts with a claim on plants described by a trait and a specific genotype, regardless of the method used to generate the plants. In addition, other claims cover seeds, progeny and harvest. The examples given in the patent descriptions clearly provide evidence that non-inventive methods, such as screening for gene variants and beneficial characteristics within existing plant populations, random mutagenesis, selection or crossing and selection, are decisive for the production of the plants claimed in the application. In many cases, specific language is used to disguise the differences between technical and non-technical processes simply by adding terms such as ‘mutations’, ‘gene modification’, ‘introgression of genes’ or ‘recombination of genes’. These terms all can be used to refer to genetically engineered plants as well as plants that are, for example, crossed or obtained from random mutagenesis. In many cases, the claims refer to technical processes, such as transgenesis and new genomic techniques, whilst in reality the claimed plants have actually been obtained from conventional breeding.

Simply put, in order to circumvent the prohibition of patenting ‘plant varieties’ and ‘essentially biological processes’ (Article 53 (b), EPC, see Chapter 5), the companies are now trying to establish claims on the biological resources (gene variants) needed by all breeders. Therefore, in most cases, their patent strategy is to describe a specific DNA sequence (which may be used as a marker for the selection of the plants) as their invention. If the gene sequence is regarded as a ‘technical invention’, the following steps of crossing and selection involving the gene sequence are no longer considered to be ‘essentially biological’, but deemed to involve a ‘technical step’.

In many cases, these patent applications claim genetic variations known as ‘single nucleic polymorphisms’ (SNPs). Such polymorphisms may be associated with favourable biological effects and can be found in most genes within each species. SNPs can confer desired plant characteristics such as higher tolerance to plant diseases. The relevant genetic variations are frequently found in native populations that are crossed with the commercial varieties. For example, in 2022, a Syngenta/ChemChina patent application was published - it claims around 45.000 SNPs in wild relatives of soybeans as their invention.

In summary, these patent applications represent a new strategy for circumventing the prohibitions under Article 53 (b): instead of claiming plant varieties, or plants derived from specific techniques, or methods, the usage of all plants which inherit the desired genetic traits are claimed as an invention. Consequently, the genes (their variations and all plants (inheriting them) resulting from further breeding are claimed as invention.

Table 1: Examples of international patent applications published in 2022. Most claim plant genes, the usage of the genes for breeding and the resulting plants

Company	Number	Species	Goal
Arcadia	WO2022051702	wheat	increased fiber
BASF/ Nunhems	WO2022078792	watermelon	parthenocarpic plants
	WO2022200149	watermelon	high number of male flowers
	WO2022096451	watermelon	parthenocarpic plants
	WO2022223550	cucumber	resistance to Tomato Leaf Curl New Dehli Virus
Bayer / Seminis	WO2022046455	tomato	resistance to tomato chlorosis virus (ToCV) in combination with resistance to Fusarium
Bejo Zaden	WO2022111797	spinach	resistance to peronospora and stemphylium
	WO2022136652	celery	resistance to Fusarium
	WO2022179682	*Brassica oleracea* (such as broccoli)	resistance to *Albugo candida*
	WO2022248060	*Beta vulgaris*	resistance to Cercospora
Better Seeds	WO2022185312	cocoa	yield
Consejo Superior Investigacion & Abiopep	WO2022263602	Solanum, Capsicum etc.	resistance to Pepino Mosaic Virus
CSIRO (Commonwealth Scientific and Industrial Research Organisation)	WO2022115902	cereals	nutritional value
	WO2022053866	wheat / triticale	resistance to stem rust
ELO Life Systems & University of California	WO2022087527	vanilla	improved flavor and less dehiscence
Enza	WO2022048726	squash	resistance to downy mildew
	WO2022058624	lettuce	resistance to oomycetes
	WO2022122164	brassica	resistance to chlorosis
	WO2022128132	lettuce	resistance to downy mildew
	WO2022199812	tomato	insect resistance to whitefly
	WO2022248025	melons	increased sugar content
Equi-Nom	WO2022038615	pea	high protein

Company	Number	Species	Goal
KWS	WO2022013268	maize	resistance to northern corn leaf blight
	WO2022037967	beet and spinach	resistance to cercospora
	WO2022090264	oilseed rape	resistance to fungal pathogen
	WO2022268862	maize	resistance to northern corn leaf blight
Origene	WO2022049571	watermelon	resistance to powdery mildew
	WO2022149122	watermelon	drought tolerance
Philoseed	WO2022018734	tomato	resistance to TOBRF virus
Rijk Zwaan	WO2022013452	tomato	resistance to TOBRF virus
	WO2022018030	watermelon	compact growth
	WO2022034149	cucumber	resistance to begomovirus
	WO2022090543	spinach	resistance to peronospora
	WO2022189674	honey melon	Resistance to chlorotic leaf curl virus
	WO2022234045	lettuce	shade tolerant
	EP4026424	spinach	red leaves
	EP4029370	lettuce	resistance to virus
Syngenta/ ChemChina	WO2022002795	honey melon	resistance to fusarium
	WO2022008422	lettuce	resistance to Bremia
	WO2022035648	soybean, brassica, etc.	crosses between domestic varieties and wild relative species
	WO2022046487	watermelon	resistance to fungal pathogen
	WO2022090188	honey melon	longer shelf life
	WO2022173659	soybean	resistance to pathogens like Asian soy rust
Tomatech	WO2022234584	tomato	resistance to TOBRF virus
University Adelaide & Shanghai University	WO2022251904	barley	yield
University Montana	WO2022150489	wheat	increased biomass and semi-dwarfing
Vilmorin	WO2022117884	tomato	resistance to TOBRF virus
	WO2022069693	honey melon	extended shelf life
	WO2022208489	Cucurbita	growth habit
Volcano Institute	WO2022091104	tomato	resistance to TOBRF virus

2.2 Examples

The strategy underpinning patent applications has fundamentally changed in recent years. Even just a short time ago it was, in many cases, the method of producing the plants that was decisive for the wording of the claims. At present, claims now mostly refer to gene variants and the plants that inherit them. The gene variants are commonly found in plant populations that are tested in the field, the greenhouse or the lab (exposure to pathogens, climate stress or specific growth conditions). Quite often random mutagenesis is applied to enhance genetic diversity prior to screening. The selected plants are then used for further crossing and selection, as well as to establish the desired characteristics in the offspring. All these steps are commonly applied in conventional breeding to obtain plants that are grown for food production.

Companies filing the patents seem to be well aware that genetic engineering (transgenesis, genome editing) is not necessary to derive the claimed traits. In order to obtain patents that allow them to control the use of the plants for further breeding they add ‘technical toppings’ to the breeding process described in the application, and thus disguise these as technical inventions.

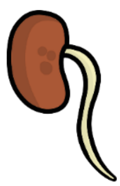
In many cases, randomly triggered mutations are the door-opener needed to expand the patents from genetic engineering to non-technical breeding methods. The mutations can occur after exposing plant material to sunlight, chemicals or other physico-chemical stimulation. Unlike the targeted methods of genetic engineering (genome editing), these mutations are not predictable. Indeed, random mutagenesis is not a method that can be used to introduce a trait in a targeted way, it is a way of enhancing genetic diversity. Often the companies that file the patents use these processes to generate gene variants already present in existing plant populations.

Despite the underlying technical and biological mechanisms of random processes being fundamentally different to genetic engineering processes, current EPO decision-making throws them all into one basket labelled ‘technical invention’. This has huge implications: if patents claiming randomly occurring mutations and gene variants are granted, all further usages of the plants inheriting these mutations will be controlled by the patent holder. In these circumstances, the freedom to operate as guaranteed by the breeders’ exemption in the plant variety protection (PVP) law can no longer be exercised.

The underlying patent strategy is exemplified by the following five examples:

a) Syngenta / ChemChina patent application for soy plants with resistance to Asian soybean rust, WO2022173659

The patent description shows how the gene variants were detected in populations of wild relatives of soybeans (*glycine tomentella*), i. e. by screening for their natural resistance. It is shown that crossing and selection is sufficient to generate new varieties with improved resistance to Asian soy rust.



The wording in the claims references six gene variants and plants inheriting the genes, regardless of whether these are obtained from genetic engineering processes or conventional breeding. In addition, the claims cover all plants inheriting any of the genetic markers listed in two tables included on around 200 pages in the patent. The tables comprise around 45.000 gene variants (SNPs). Furthermore, the patent claims soybean plant production methods which involve selecting plants by using the marker genes. Previous research revealed similar Syngenta patent applications[7].

[7] Report from No patents on seeds! (2022): https://www.no-patents-on-seeds.org/en/report2022

b) KWS patent application for maize with resistance to northern corn leaf blight, WO2022268862

It is evident from the patent description that the gene variants conferring resistance to the above disease were detected in existing maize populations via screening for natural resistance. It is shown that crossing and selection are sufficient to generate new varieties with improved resistance to northern corn leaf blight.

The wording of the claims describes the selection of maize plants by using one or more of around 70 gene variants (markers). The patent claims all plants inheriting these gene variants, regardless of whether they are derived from genetic engineering or random mutagenesis. Furthermore, if the genes are isolated, they are claimed as a technical invention.

KWS already holds several patents on maize and other plants derived from conventional breeding, see also the list of patents granted in 2022 (Table 2).

c) Rijk Zwaan patent application for tomatoes with resistance to Tomato Brown Rugose Fruit Virus (TOBRFV), WO2022013452

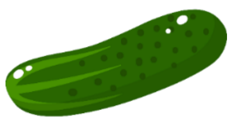
The patent description explains how the gene variants were detected in populations of wild relatives of domesticated tomatoes (*Solanum pimpinellifolium*), i. e. by screening for natural resistance. It is shown that crossing and selection are sufficient to generate new varieties with improved resistance to TOBRFV.

The wording of the claims describes gene variants (and markers) detected in the wild species and the domesticated tomato plants that were obtained from further breeding. In addition, it claims the marker genes and breeding method if the gene variants are used in the selection process.

The 2022 *No Patents on Seeds!* report[8] revealed several patent applications for tomatoes with resistance to TOBRFV. At that time, it was found that around a dozen international patent applications covering conventionally-bred TOBRFV resistant tomato plants had been filed. Companies that are filing these patents include, e. g. BASF (Nunhems), Bayer (Seminis), Enza Zaden, Philoseed, Rijk Zwaan and Vilmorin. Our recent research shows that five further patent applications were published, thus increasing the legal uncertainties for all interested breeders.

d) Nunhems / BASF patent application for cucumber with resistance to Tomato Leaf Curl New Dehli Virus (TOLCNDV), WO2022223550

From the patent description and the patent claims, it is evident that screening for natural resistance was used to detect the gene variants in wild cucumber plants. It is shown that crossing and selection are sufficient to generate new varieties with improved resistance to the virus.



The wording of the claims describes cultivated cucumber with gene variants from wild cucumber, comprising at least 5 or 10 gene variants (out of around 60 marker genes). Furthermore, it also claims seeds, fruits and the selection method.

Nunhems / BASF is known to be especially active in filing patents on melons, cucumber and tomatoes. A previous *No Patents on Seeds!* report revealed some similar patents[8].

[8] https://www.no-patents-on-seeds.org/en/report2022

e) CSIRO patent application for cereals with enhanced nutritional value, WO2022115902

It is evident from the patent description that the beneficial trait was first detected by screening a population of plants. Random mutagenesis was used to obtain similar plants which were subsequently genotyped. It is shown that crossing and selection are sufficient to generate new varieties with the desired plants.

The wording of the claims describes grains (rice, wheat, barley, maize) that inherit gene variants associated with the desired phenotype. Furthermore, it claims the gene variants and their usage in plant breeding. It also seeks patent protection for food, such as bread, pasta, breakfast cereals, snack foods, cakes and more.

CSIRO (Commonwealth Scientific and Industrial Research Organisation) is known for its various patents filed on barley (see background on 'New applications for patents on barley'[9]).

3. Research into European patents granted in 2022 covering conventional breeding

3.1 A precedent case: EP 3560330

The EPO set a significant and worrying precedent in 2022; it provides clear evidence that the current legal situation is insufficient to prevent patents from being granted on conventional breeding. In June 2022, a patent was granted to the German company, KWS, (Kleinwanzlebener Saatzucht), covering maize with improved digestibility (EP3560330). The KWS patent claims patent protection for the maize plants, regardless of whether they are 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. As indicated in the patent description, the respective gene variants were originally detected in existing maize plants obtained from conventional breeding. The KWS can now control the future production of plants derived from randomly mutated genes, and thus prevent other breeders from using the naturally-occurring genes in conventional plant breeding. *No Patents on Seeds!* filed an opposition against the patent in 2023[10].

EP3560330 is the first patent to be granted for which an application was filed after July 2017, it was the first case to which the new rule 28(2) was applied in accordance with the G3/19 decision. The background: 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 introduced into the Implementing Regulations of the European Patent Convention (EPC). However, new loopholes were also opened up, as a preparatory document for the interpretation of the new rule equated random mutations to those achieved with genetic engineering.

The highest legal body of the EPO, i. e. the Enlarged Board of Appeal, confirmed the new rule in 2020 (decision G3/19). It was also decided that the new rule should only be applied to patents filed from July 2017 onwards.

[9] https://www.no-patents-on-seeds.org/en/patents_barley
[10] https://www.no-patents-on-seeds.org/en/patents/maize

Patent applications filed after July 2017 must be examined under the new rule, and the EPO examination guidelines request that a so-called 'disclaimer' is inserted to prevent plants derived from 'essentially biological processes' from falling within the scope of the patent. In the case of EP3560330, the disclaimer was introduced (in Claim 3), but it has only a limited effect: the patent still covers randomly mutated plants and the usage of genetic variations for the screening and detection of plants within the process of conventional plant breeding. Thus, the patent as granted is not confined to genetic engineering, but also impacts the conventional breeding of the respective plants.

3.2 Overview on patents granted on conventionally bred plants

Besides EP3560330, all other patents granted in 2022 were filed before July 2017. However, as shown in Table 2, it is likely that the majority of patents would have been granted even if Rule 28 (2) had been applied. Ultimately, the patents granted in 2022 show that the current interpretation of Rule 28 (2) does not prevent the EPO from granting patents on conventionally-bred plants.

Table 2: Examples of European patents granted on conventionally-bred plants in 2022

Number / Company / Date of grant	Content, methods, claims	Could the patent have been granted if Rule 28 (2) had been applied?
EP 3064586 Dümmen Group 4.5.2022	Content: mildew resistance gene in kalanchoe (flower / medical plant) Methods: phenotyping / genotyping Claims: on gene variants for mildew resistance	Yes
EP 2966994 Rijk Zwaan 4.5.2022	Content: red spinach Methods: random mutagenesis, phenotypical selection Claims: on plants, seeds, progeny, tissue, harvest	Yes
EP 3560330 KWS 15.6. 2022	Content: maize with higher digestibility Methods: random mutagenesis (or GE), Selection Claims: on plants, seeds, feed, selection	The patent was granted under Rule 28 (2)
EP 2961263 Bejo Zaden 3.8.2022	Content: lettuce (lactuaceae) with resistance to downy mildew Methods: selection after bio-assay, identification of marker genes, Claims: on plants, seeds, marker genes and method for selection	Yes
EP 2512217 Nunhems 3.8.2022	Content: Tetraploid lettuce (*Valeriana locusta*) Methods: two varieties were subjected to chemical treatment to obtain polyploidy. Claims: on plants, seeds, cell, methods	Yes

Number / Company / Date of grant	Content, methods, claims	Could the patent have been granted if Rule 28 (2) had been applied?
EP 3380618 KWS 24.8. 2022	Content: Maize with cold tolerance Methods: crossing and selection, phenotyping, genotyping, random mutagenesis Claims: on plants, methods for selection	No
EP 2302061 Syngenta 21.9.2022	Content: Brassica plants (broccoli, white cabbage, cauliflower …) with resistance to clubroot disease Methods: crossing and selecting between two brassica species, one of them being resistant (Chinese white cabbage) Claims: on plants, kit for selection	No
EP 2247751 Hazera Seeds Ltd.; Volcani Center 5.10.2022	Content: Pepper with resistance to potyviruses and powdery mildew disease Methods: selection after bio-assay, crossing and selection Claims: on plants, seeds, fruit, tissue, selection	No
EP 3182820 Rijk Zwaan 5.10.2022	Content: Tomato, inheriting gene variants (SNPs) which allow the fruits to develop a hairy phenotype and, at the same time, a reduction in secondary metabolites. In consequence, beneficial mites may be established on these plants. Methods: EMS or selection or (new) genetic engineering can be used to achieve these plants. Claims: on genes, plants, seeds, parts of plants used for propagation.	Yes
EP 2753168 Syngenta 19.10.2022	Content: Pepper (block type) with dark green color at immature state and higher content in some beneficial secondary metabolites. Methods: Crossing and phenotyping, genotyping Claims: on plants.	No
EP 3242944 Alsia 2.11.2022	Content: Tomatoes with resistance to broomrape Methods: Tilling, gene sequencing, phenotyping Claims: on usage of gene variants for selecting and screening	Yes
EP 3344033 Lion-Flex 14.12. 2022	Content: Taraxum hybrid plants used for rubber production Methods: crossing European with Asian taraxum Claims: on methods for selection (genotype) and plants	No
EP 1727905 Carlsberg 28.12.2022	Content: Barley with reduction of undesirable compounds for brewing Methods: random mutagenesis, phenotyping, genotyping Claims: on barley, malt, beverage, food	Yes

Number / Company / Date of grant	Content, methods, claims	Could the patent have been granted if Rule 28 (2) had been applied?
EP 3405024 Volcani Center 28.12.2022	Content: Tomatoes which produce fruits without being pollinated (parthenocarpic) Methods: random mutagenesis Claims: on plants, fruits	Yes
EP 3116301 Volcani Center 28.12.2022	Content: Melons without seeds, smaller fruits Methods: Random mutagenesis Claims: on plants, melons, gene variants and usage for further breeding	Yes

3.3 Case study: Cold-tolerant maize (EP 3380618)

The KWS patent for cold-resistant maize (EP 3380618) is a good example of the way in which the EPO undermines the legal prohibitions in Article 53 (b) (see Chapter 5): KWS produced the maize by using existing maize lines that were already known to have tolerance to growing conditions, such as those in northern Europe. They analyzed the genome of the plants and identified so-called marker genes (gene variants) that can be used for screening and selecting the desired traits. Further crossing and selection was performed to see if the marker genes and the intended trait (cold resistance) were inherited together.

In addition, random mutagenesis was applied to see if these gene variants can also be achieved with this method (which is not surprising). Random mutagenesis was introduced 'on top' to create the impression that this was a technical invention. However, the outcomes of the random mutagenesis processes are largely impacted by the biological mechanisms in the cells, they are neither predictable nor targeted. Therefore, from the perspective of patent law, random mutagenesis is fundamentally different to the technical processes used in genetic engineering (genome editing).

Interestingly, tools such as CRISPR/Cas are mentioned in the patent description. However, these new genomic techniques were not applied, and they are not necessary to achieve the plants which already exist in nature. This case has some similarities with other patents and patent applications (see last report[11]) showing that CRISPR/Cas is being abused within the patent system as a tool to appropriate the genetic resources of biological diversity needed for traditional plant breeding.

Ultimately, targeted technical methods were not applied and they are also not necessary to breed maize with cold-tolerance. The patent explicitly states conventional breeding and usage of the existing biological diversity is the real source of this 'invention': on page 27, a short summary of the examples shows that further crossing and selection are sufficient to achieve the desired plants. It also explains that the majority of plants (86 % of the plants used as female part in hybrid breeding) in the existing breeders' gene pool already inherit the gene variants that are responsible for cold

[11] https://www.no-patents-on-seeds.org/en/report2022

tolerance. The patent as granted by the EPO comprises the future usage of these gene variants as well as of the maize plants inheriting the gene variants.

In summary, the patent is not only a violation of Article 53 (b) (prohibition on granting patents covering plant varieties and non-technical methods for breeding) it is also not inventive. This example shows how the EPO is intentionally ignoring the differences between conventional breeding and genetic engineering. This undermines and exempts the existing prohibitions in patent law, which only allows the patenting of technical inventions.

The example of the patent for cold-resistant maize (EP 3380618) shows that the detrimental effects of these patents can seriously impact the activities of traditional breeders, as they can no longer use the existing varieties to produce new and even better plant varieties. The impact of this patent is also relevant for organic maize breeders: KWS seeds are widely used for breeding maize varieties used in conventional and organic agriculture, it is thus also likely that future breeding with several of these varieties will fall within the scope of the patent.

It may become very difficult for other breeders to resolve these legal uncertainties, as identification methods described in the patent can hardly be applied in practice. Furthermore, the patent also covers detection methods which cannot, therefore, be used without the permission of the patent holder.

4. Overview: patents and patent applications 2012-2022

4.1 Patent applications

We used the *No Patents on Seeds!* database to investigate patent applications filed for conventional breeding over the last ten years. The aim was to give an overview of the plant species primarily targeted in these patent applications, and identify which companies are most active in this respect. The results are more specific for the sector of conventional breeding than the statistics presented in Figure 2 that comprise all patent applications for plants.

According to the figures, around 700 patent applications are currently pending. Bayer (& Monsanto, Seminis) filed the highest number of patent applications closely followed by Rijk Zwaan and BASF (Nunhems) (Figure 4).

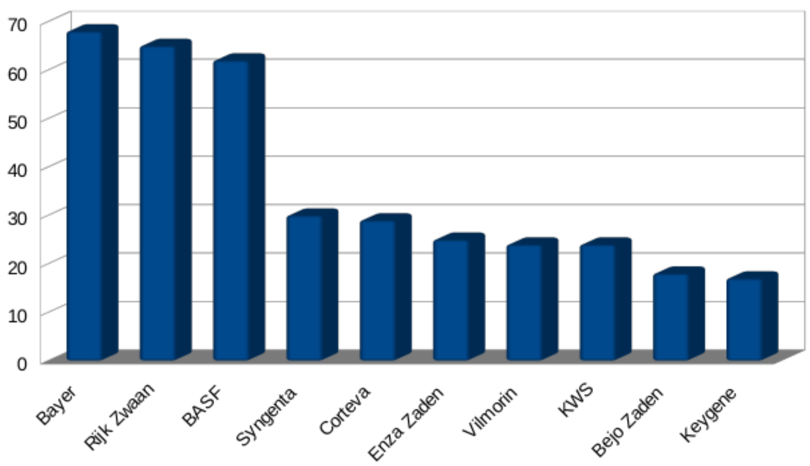


Figure 4: Patent applications covering conventional plant breeding – the number of patent applications filed between 2012 and 2022, published via the PCT/WIPO (international classifications IPC A01H or C12N15/82) and categorized by individual companies. Source: database of *No Patents on Seeds!*

Tomatoes, brassica and maize (Figure 5) are among the most targeted species. There are some limitations to these findings: the numbers only include the patent applications which explicitly refer to tomatoes (and not, for example, more generally to, *Solanaceae*, which also include tomato species). For brassica, only the vegetables were included in the statistics, leaving aside crops such as oilseed rape (which also belongs to the *Brassicaceae*).

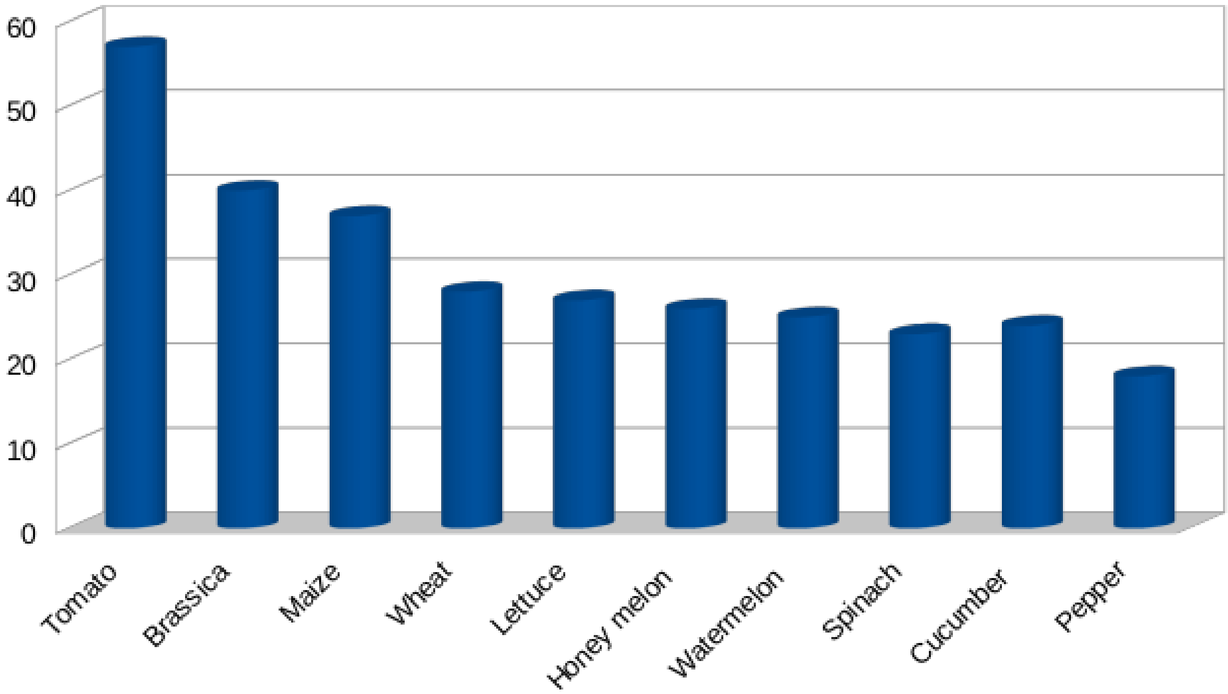


Figure 5: Patent applications filed for conventional plant breeding – the number of patent applications filed between 2012 and 2022, published via the PCT/WIPO (international classifications IPC A01H or C12N15/82) and categorized by plant species. Source: database of *No Patents on Seeds!*

4.2 Patents granted

The *No Patents on Seeds!* database was used to research patents granted on conventional breeding over the last ten years. The aim was to give an overview of the plant species most commonly targeted in the patent applications, and which companies were the most actively filing respective patent applications. The results are more specific for the conventional breeding sector than the statistics presented in Figure 2, which comprises all patents granted on plants.

According to these figures, more than 300 patents have already been granted. Most patents are owned by Bayer (& Monsanto, Seminis), BASF (Nunhems) and Corteva (DowAgro Sciences, DowDuPont, Pioneer) with Riik Zwaan having nearly the same number of granted patents as Corteva (Figure 6).

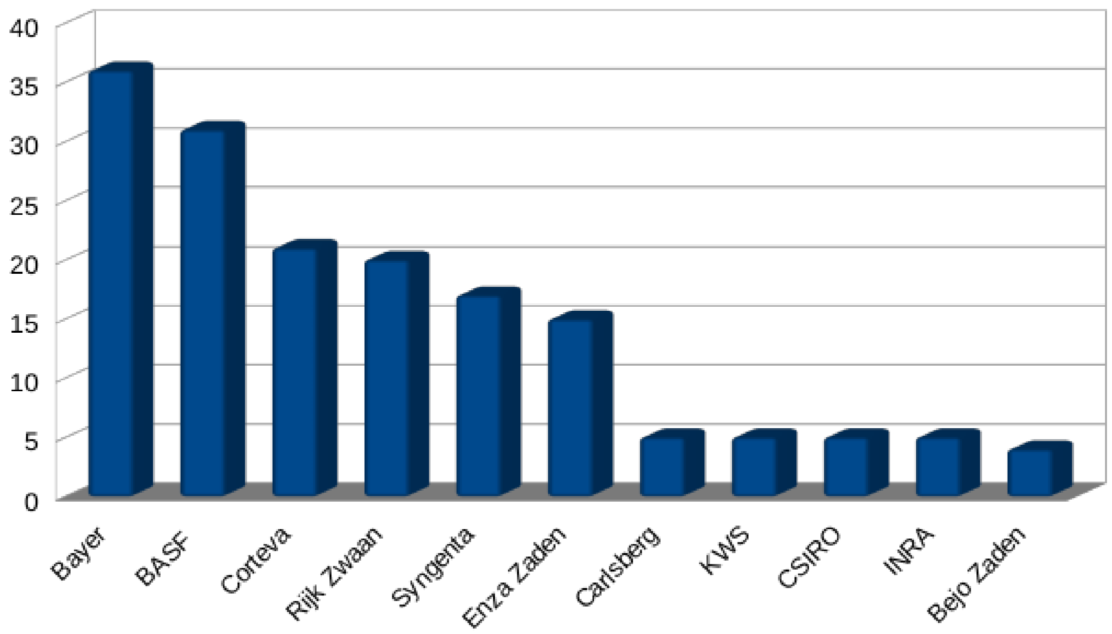


Figure 6: EPO patents granted for conventional plant breeding (international classifications IPC A01H or C12N15/82), between 2012 and 2022, categorized by companies. Source: database of *No Patents on Seeds!*

Maize, brassica and tomatoes (see Figure 7) are amongst the most targeted species. There are some limitations to these findings: the numbers only include the patent applications which explicitly refer to tomatoes (and do not, for example, use the more general term, *Solanaceae*, which also includes the tomato species). Melons, watermelons and sugar melons were put into the same category even though they belong to different species.

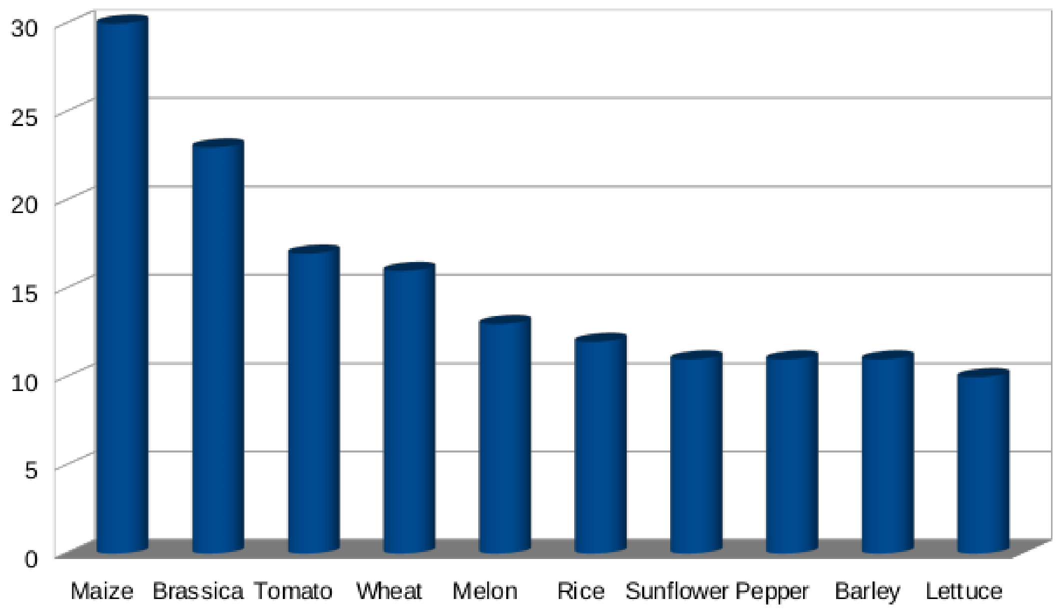


Figure 7: EPO patents granted on conventional plant breeding (international classifications IPC A01H or C12N15/82) between 2012 and 2022, categorized by species. Source: database of *No Patents on Seeds!*

It also should be taken into account that, so far, only a limited number of patents have been granted each year. This is because there were several delays in patent examinations so that the President of the EPO had an opportunity to clarify legal questions in the context of conventional breeding. However, any questions of this kind were declared to have been answered in 2022. Therefore, it can be expected that a massively increased number of patents will be granted.

5. Legal situation

According to Article 53 (b) of the European Patent Convention (EPC) plant and animal varieties as well as conventional breeding are excluded from patentability. It reads: *"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 (...)"*. Until 1998, this prohibition was interpreted in a way that prevented patents on plants or animals from being granted, even if they were genetically engineered (T356/93).

However, in 1998, the EU adopted the Directive 98/44 on the legal protection of biotechnological inventions (EU patent directive). This directive allowed patents on inventions concerning plants and animals to be granted for the first time. While the prohibitions in Article 53 (b) are still included, an exemption to the prohibition was introduced. Article 4 (1) and (2) of the EU patent directive reads:

> "*1. The following shall not be patentable:*
>
> > *(a) Plant and animal varieties;*
> >
> > *(b) Essentially biological processes for the production of plants or animals.*
>
> *2. Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety.*
>
> *3. Paragraph 1(b) shall be without prejudice to the patentability of inventions which concern a microbiological or other technical process or a product obtained by means of such a process."*

Exemptions from the prohibitions need to be put into context in order to clarify their scope. As the title of the Directive 98/44 (Legal Protection of Biotechnological Inventions) and, e. g. the wording of Recitals 52 and 53 of the Directive show, the legislator did not intend to allow the patentability of processes and products obtained from conventional breeding.

At the time when the Directive was being discussed and voted on in the EU Parliament, the European Patent Office (EPO) had already stopped granting patents on genetically engineered plants and animals in accordance with the T356/93 decision published in 1995. This decision was harshly criticized by industry at the time. The subsequent adoption of Directive 98/44 was in part because the EU still wanted to pave the way for plant-related inventions in the context of genetically engineered plants and animals.[12]

The adoption of the EU Directive did indeed lead to a significant shift in current practice at that time. It was only after the Directive was adopted and became an integral part of the new Implementing Regulations of the EPC in 1999 that further patents on plants and animals derived from genetic engineering were granted.

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

On the other hand, it may be concluded all processes in conventional breeding as well as all products (plants, animals, plant varieties, their characteristics, their genetic components, seeds, breeding material) are still fully excluded from patentability under Article 53 (b).

5.1 The definition of 'essentially biological processes'

The history and the context of the technical development (above) shows that the need for EU patent directive 98/44 would never have arisen without the (at that time) new methods of genetic engineering - which for the first time allowed direct and technical insertion of traits into the genome of plants and animals. This is also reflected in decisions taken by the Enlarged Board of Appeal, which is the highest legal decision- making body of the EPO.

In its G2/07 and G1/08 decisions, the Enlarged Board of Appeal at the EPO, emphasizes the fundamental differences between genetic engineering and conventional breeding methods. In order to assess whether a process is eligible for patent protection, the Enlarged Board of Appeal applies the following considerations: "*This is the case, for example, for 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 (cf T 356/93 supra). However, in such cases the claims should not, explicitly or implicitly, include the sexual crossing and selection process.*" (emphasis added)

Consequently, the headnote of decisions G2/07 and G1/08 defines the decisive criteria as a technical step that allows the direct insertion of a trait: "*3. If, however, such a process contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then the process is not excluded from patentability under Article 53(b) EPC.*" (emphasis added)

Accordingly, the only thing needed to overcome the prohibition in Article 53(b) is a technical step within the process that directly and purposefully establishes a desired trait (defined phenotype) in the genome, and thus makes it fundamentally different to conventional breeding methods. A clear distinction between 'essentially biological' processes (conventional breeding) and technical inventions (methods of genetic engineering) is therefore easily made, as shown below:

(1) Essentially biological processes:

Conventional breeding starts with a broad range of genetic diversity, followed by further crossing and selection. If methods such as irradiation are used for random mutagenesis, this does not change the overall process: broadly speaking, physico-chemical mutagenesis just triggers genomic changes in a non-targeted way to enhance genetic diversity in the plant material, which is needed for further steps of crossing and selection. Therefore, to establish a desired trait after random mutagenesis, the process will always, explicitly or implicitly, include sexual crossing and selection processes. Furthermore, the results of these processes are technically neither determined nor predictable, but largely impacted by the biological processes in the cells.[13] In conclusion, even if a step to trigger random mutations is introduced, the overall process still cannot escape the prohibition in Article 53(b). There is

[13] See for example: Monroe G., et al. (2022) Mutation bias reflects natural selection in Arabidopsis thaliana. Nature, https://doi.org/10.1038/s41586-021-04269-6

no doubt that, in light of the G2/07 and G1/08 decisions, such processes must still be considered to be 'essentially biological'.

(2) Technical inventions:

On the other hand, technical genetic engineering methods involve the insertion of additional DNA sequences or the usage of biotechnological mutagens, and therefore allow the direct and targeted change of specific genes in the genome. These techniques not only result in alterations in the genome, but also enable the direct introduction of defined biological characteristics (phenotypes), so-called 'traits', into existing varieties. To achieve these goals, genetic engineering typically uses genetic constructs which, e. g. consist of promotors, start and stop codons and gene sequences optimized for expression in the plant cells. Furthermore, genome engineering techniques can also introduce specific and targeted changes in the genome by using biotechnological mutagens, such as CRISPR/Cas. These techniques can typically eliminate the steps of crossing and selection needed to establish a desired trait. Therefore, these genomic techniques can be considered to fulfill the criteria of a technical invention as established in the G2/07 and G1/08 decisions, while processes using tools such as irradiation cannot escape the prohibitions in Article 53(b).

These findings are illustrated in Figure 8:

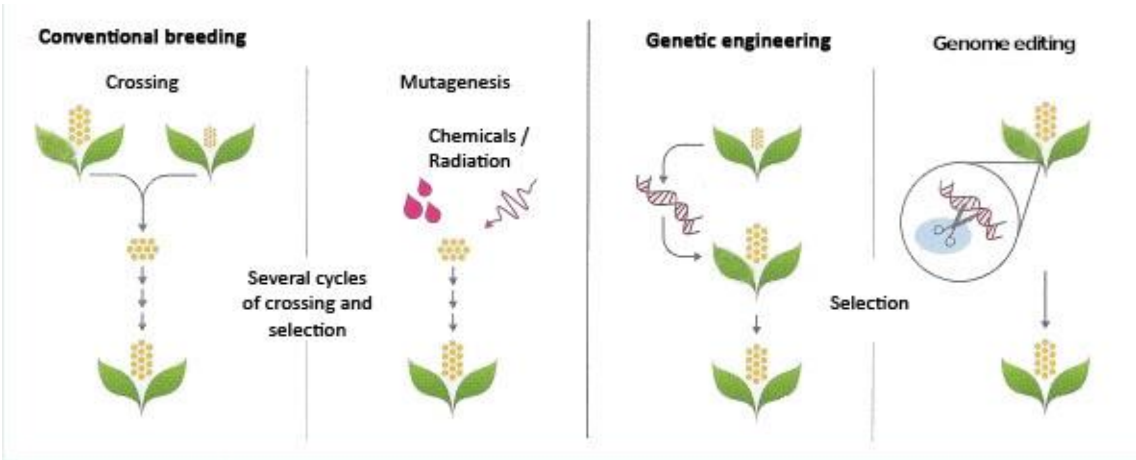


Figure 8: Differences between conventional breeding (including random mutagenesis) and genetic engineering (including genome editing): conventional breeding always uses genetic diversity to perform several cycles of crossing and selection to achieve a desired trait, while genetic engineering can be used to directly insert new characteristics into a plant (adopted from Genomxpress Scholae Nr 5, funded by the German Ministry for Education and Research (BMBF).

In conclusion, in order to correctly apply the EU patent directive and its effects on the interpretation of the EPC, all exemptions to the exceptions to patentability of Article 53(b) have to be contextualized within history and technical developments. The concept of a 'technical invention' has to be defined with reference to the ability to directly insert a desired trait into the genome of a plant or animal with a targeted technical process. This is in line with a historical interpretation of EU Directive 98/44 which was intended to allow patents on transgenic plants and animals.

5.2 The patentability of plant varieties

As aforementioned, Article 4.1 (a) of the EU patent directive 98/44 prohibits patents on plant varieties, while Article 4.2 allows patents on inventions concerning plants or animals if the technical feasibility of the invention is not confined to a particular variety.

Article 4.2 provides the main justification for the European Patent Office (EPO) to currently grant patents on plants and animals derived from genetic engineering. The exemption from the exclusion in Article 53 (b) is also part of the Implementation Regulation of the European Patent Convention, as established in Rule 27 b). This legal approach forms part of the G1/98 decision taken by the Enlarged Board of Appeal. It is regarded as a precedent for the patenting of genetically engineered plants and animals under the EPC – and is a ruling made shortly after the inclusion of EU Directive 98/44 into the Implementation Regulation of the EPC.

However, in the field of conventional breeding, there are several reasons why the exemption (Article 4.2 of 98/44) from prohibition in Article 53(b) cannot be used to allow patents on all plants and animals:

(1) As a general rule, this exemption cannot be applied to conventional breeding since the whole rationale of the EU Directive is based upon "biotechnological inventions", and thus extends to the field of "genetic engineering" (see point above).

(2) If the "technical feasibility" (which should not be confined to a particular plant variety to fall under patent protection) is put in context of the processes for genetic engineering, which enables the technical insertion and transfer of DNA sequences, for example, beyond the boundaries of species, the exemption from the exclusion (Article 4.2, from 98/44) develops a specific meaning. However, in conventional breeding most plant characteristics can be transmitted to another variety within the same species simply by using further breeding, without using a specific technology. As a result, the criterion retained in Article 4.2 (98/44) and applied by the EPO to restrict the exception to patentability, does not have a specific technical meaning in the context of conventional breeding and cannot be used as a legal basis to grant patents.

To summarize, the criterion of "confinement of the technical feasibility of the invention to a particular plant or animal variety" cannot be applied in the field of conventional breeding. If the provisions of Article 4.2 of EU Directive 98/44 were applied to plants derived from conventional breeding in the same way as they are applied to genetically engineered plants, the prohibition of patenting plant varieties would become meaningless.

Therefore, in the case of conventionally-bred plant and animal varieties, the prohibition of Article 53 (b) is not limited by Article 4.2 of the EU patent directive. Consequently, the 'exemption to prohibition' as established in Rule 27 (b) (EPC) cannot be applied in the case of conventionally- bred plants.

This has a substantial impact on the examination of patents in the field of conventional breeding. The definition of plant varieties provided by the EPC. Rule 26 (4) reads: "*'Plant variety' means any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be: (a) defined by the expression of the characteristics that results from a given genotype or combination of genotypes, (b) distinguished from any other plant grouping by the expression of at least one of the said characteristics, and (c) considered as a unit with regard to its suitability for being propagated unchanged.*" It cannot be denied that, e. g., cold-tolerant maize plants such as those claimed in EP

3380618 fulfill this definition. Therefore, the patent that was granted in contradiction to the EPC must be revoked.

5.3 Summary of the legal analysis and further aspects

(1) Within the meaning of Article 53 (b), the processes of 'random mutagenesis' have to be considered as essential biological (conventional breeding): these processes do not allow the direct insertion of an intended trait in a targeted way, it is simply a tool to enhance genetic diversity. The results of these processes are not determined by a technical process, and are substantially impacted by the biological processes in the cells. The resulting genetic changes cannot be considered to be technical inventions within the meaning of Rule 27, EPC.

(2) In the case of conventionally-bred plant and animal varieties, the prohibition of Article 53 (b) is not limited by Article 4.2 in the EU patent directive. Rule 27 (b) cannot be applied in the case of conventionally-bred plants.

(3) In the case of conventionally-bred plants, the crossing or selection processes, either alone or in combination, are excluded from patentability, even if specific tools, such as marker genes, are used to render selection more effective.

(4) There have also been some attempts to exclude plants and animals derived from new genomic techniques if their characteristics may also have occurred naturally (see position of the German Plant Breeders' Association (BDP)[14]). However, according to the EU patent directive, processes using tools such as CRISPR/Cas can be regarded as technical invention. Therefore, the exclusion of resulting plants and animals from patentability may require a change of law and not 'simply' the correct interpretation of existing law as is the case with conventional breeding. The problem: a change in European patent law is a lengthy process that will take several years. Therefore, priority should be given to the correct interpretation of existing patent law in regard to plants and animals derived from conventional breeding, which only requires a decision of the Administrative Council of the EPO - which meets four times each year. In addition, the correct interpretation of existing patent law can also be established in national legislation.

(5) To achieve freedom to operate as guaranteed under PVP-law (called breeders privilege or breeders exemption), it is not sufficient to introduce private initiatives, e. g. a licensing platform like the Agricultural Crop Licensing Platform (ACLP)[15]. Such licenses will require contracts with stewardship agreements, payments and new dependencies. Therefore, these private contracts cannot replace the right of conventional breeders to use existing varieties on the market for further breeding and marketing of their new varieties. Consequently, these platforms cannot solve the problem and cannot be seen as a substitute to replace the correct interpretation of Article 53 (b), EPC.

[14] https://www.bdp-online.de/de/Branche/Patentschutz/BDP_Position_Patentschutz.pdf (German)
[15] https://aclp.eu/